Epidemiology Procedure Manual

Midnight Madness Manual
June 1, 2006

Introduction to the Epidemiology Procedure Manual
June 1, 2006

The original purpose of this manual, also lovingly called the "Midnight Madness Manual," was to provide standardized protocols about public health emergencies for the Section of Epidemiology Infectious Disease Team ("Epi Team") when responding to after-hours calls. The first edition was written in 1995.Since then, this manual has gone through several iterations, and while many in the Division found the disease information and case management forms to be useful, the Manual remained a patchwork of electronic and photocopy documents. This edition is the first fully electronic version, which will allow wider use and more timely updates.
The 2006 update includes new sections on emerging infectious diseases such as avian influenza, as well as updated information on several other diseases. A companion volume—the Bioterrorism and Preparedness Manual—covers biological, chemical, and radiological terrorism agents and emergencies, and will be available soon.

Both the Epidemiology Procedure Manual and the Bioterrorism and Preparedness Manual are being shared with those in the Division of Public Health who conduct infectious disease investigations and emergency preparedness work

Some information in this manual is confidential. Information such as State of Alaska and Municipality of Anchorage personnel contact numbers—especially home phone numbers—is confidential. This type of information should not be shared outside the Division without the named person's consent. Readers should be aware that vital information such as names and numbers may change between updates.

This manual is not designed as an all-inclusive procedure document. It has pertinent information and forms intended to help the user: 1) advise the clinician on diagnosis and treatment, 2) obtain needed laboratory specimens, 3) conduct patient interviews, and 4) provide brief patient educational materials. *Control of Communicable Diseases Manual* by the American Public Health Association is a vital reference.

The manual is bookmarked into sections by disease name. Under each disease section, several supporting files may be found by clicking on their names. Files in each disease section include: information on the disease, investigational procedures and algorithms, laboratory specimen collection, patient interview forms, patient fact sheets, and CDC reporting forms.

Staff using this manual should remember to report any suspected or laboratory confirmed case of reportable disease. Reports may be made via the Rapid Telephone Reporting system (1-800-478-1700 or if in Anchorage, 561-4234), via fax (907-561-4239) or phone (907-269-8000). Diseases designated as public health emergencies should be reported immediately via phone (907-269-8000 during business hours, 1-800-478-0084 after hours).

This manual will be updated on First Class, however the reader should always seek current information on emerging infections directly from the Section of Epidemiology by phone or at www.epi.alaska.gov, or from web sources such as www.cdc.gov.

Section of Epidemiology "Epi Team" members wrote this manual. We would like to especially thank Sharon Tiplady for her stalwart dedication to completing the manual; Kathleen Gibson, Cheryl Patterson, and Christine Brubaker for their collation efforts; and Sections of Nursing and Laboratory personnel who reviewed this update.

Suggestions, corrections, and/or additions should be sent to Sue Anne Jenkerson, Section of Epidemiology, via phone (907-269-8000), fax (907-562-7802) or email (sueanne_jenkerson@health.state.ak.us).

STEPS IN AN EPIDEMIOLOGICAL INVESTIGATION

Step 1. Confirm the existence of an outbreak, gather data

Step 2. Verify the diagnosis

Step 3. Characterize the outbreak by time, place, and person

Step 4. Identify source and mode of transmission

Step 5. Identify the population at risk

Step 6. Institute control measures

Step 7. Evaluate control measures, continue surveillance

Step 8. Report results

1	Contact Information
2	Avian Flu
3	Blood Exposure (Hep B, Hep C, HIV)
4	Botulism
5	Diphtheria
6	Folliculitis
7	GI & Foodborne Illness
8	Haemophilus Influenzae, Invasive
9	Hepatitis A
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12	Meningococcal Disease
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18	SARS
19	Trichinosis
20	Varicella
21	West Nile Virus
22	Laboratory Information & Stool Collection

Contact Information

Section 1. Contact Information

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Section 1 contains private and after-hours contact information for Alaska Public Health agencies and staff who may need to respond to a public health emergency. Division of Public Health staff may access this information in the Division's First Class system, under conference DPH Section Area/DPH Epidemiology/Epi Investigation/Contact Information.

If you do not have access to First Class, and need emergency contact information, you may contact the Section of Epidemiology at 907-269-8000 during office hours or 1-800-478-0084 after hours.

Avian Flu

STATE OF ALASKA
DEPARTMENT OF HEALTH & SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY

3601 C STREET, SUITE 540
P.O. BOX 240249
ANCHORAGE, ALASKA 99524-0249

FRANK H. MURKOWSKI, GOVERNOR

INFECTIOUS DISEASES
AIDS/STD
TUBERCULOSIS
IMMUNIZATION
CHRONIC DISEASES
DIABETES
INJURY CONTROL

(907) 269-8000
(907) 562-7802

Avian Influenza in Humans –Triage and Testing Protocols
Table of Contents

1. **Overview of Avian Influenza in humans**
   (dated June 16, 2006)

2. **Flowchart for managing a suspected human case of H5N1 avian influenza**
   (dated June 16, 2006)

3. **CDC screening form for "Human Influenza A (H5)"**
   (dated February 19, 2004)

4. **CDC instructions for completing "Human Influenza A (H5)" form**
   (4 pages, not dated)

5. **CDC instructions for reporting cases and collecting/shipping specimens**
   (dated April 25, 2005)

6. **APHL information and algorithms for influenza testing**
   (dated April 21, 2006)

7. **Alaska DEC notification protocol for a positive bird**
   (draft in progress, to be included in the future)

8. **Symptom screening form for person in contact with a bird positive for H5N1**
   (dated April 26, 2006)

9. **Instructions for collecting a nasopharyngeal (NP) swab**
   (1 page, schematic)

10. **Storage requirements for viral transport media (VTM)**
    (dated Winter 2000)

Avian Influenza Infection In Humans

Due to rapidly changing status of avian influenza, users should check with Section of Epidemiology and/or websites below for current information and recommendations.

Organism: Primarily avian influenza A H5N1 virus. Other avian influenza strains such as H7N3, H7N7, and H9N2 have also caused disease in humans.

Incubation period: Current data for H5N1 infection indicate an incubation period ranging from 2-8 days and possibly as long as 17 days. World Health Organization (WHO) currently recommends that an incubation period of 10 days be used for field investigations and the monitoring of patient contacts.

Infectious period: **To date: there has been only one probable case of human-to-human transmission of influenza A H5N1.** Viral shedding may occur from 1 day prior to symptom onset to 7 days after resolution of fever, and shedding may be longer in children.

Transmission route: The vast majority of cases have contracted H5N1 from contact with dead or diseased poultry. In one instance (in Azerbaijan), exposure was thought to be during collection of feathers from dead swans. This, if confirmed, would be the first/only instance of transmission from a wild bird to a human. For the person-to-person route, transmission is thought to be by large respiratory droplet, or possibly airborne.

Treatment: Oseltamivir, 75 mg BID x 5 days. Current antiviral treatment options may change; check http://www.cdc.gov/flu/avian/gen-info/avian-flu-humans.htm

Information Needed for the Investigation

Is an investigation indicated?
Check current recommendations at http://www.cdc.gov/flu/avian/index.htm before responding to requests for avian influenza testing.

Testing for avian influenza A (H5N1) virus infection is recommended for:
A patient who has an illness that:

- requires hospitalization or is fatal; AND
- has or had a documented temperature of ≥ 38° (≥ 100.4°F); AND
- has radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness for which an alternate diagnosis has not been established; AND
- has at least one of the following potential exposures within 10 days of symptom onset:

A) History of travel to a country with influenza H5N1 documented in poultry, wild birds, and /or humans†, AND had at least one of the following potential exposures during travel:

- Direct contact with (e.g., touching) sick or dead domestic poultry;
- Direct contact with surfaces contaminated with poultry feces;
- Consumption of raw or incompletely cooked poultry or poultry products;
- Direct contact with sick or dead wild birds suspected or confirmed to have influenza H5N1;
- Close contact (approach within one meter [approx. 3 feet]) of a person who was hospitalized or died due to a severe unexplained respiratory illness;

B) Close Contact (approach within one meter [approx. 3 feet]) of an ill patient who was confirmed or suspected to have H5N1;

C) Worked with live influenza H5N1 virus in a laboratory.

Testing for avian influenza A (H5N1) virus infection can be considered on a case-by-case basis in consultation with local and state health departments, for:

- A patient with mild or atypical disease‡ (hospitalized or ambulatory) who has one of the exposures listed above (criteria A, B, or C); OR
- A patient with severe or fatal respiratory disease whose epidemiological information is uncertain, unavailable, or otherwise suspicious but does not meet the criteria above (examples include: a returned traveler from an influenza H5N1-affected country whose exposures are unclear or suspicious; a person who had contact with sick or well-appearing poultry, etc.).

Note: In addition to the above CDC definitions, we may recommend testing of any of the following individuals in Alaska:

- Individuals who own a poultry flock in which the majority of the flock has a sudden die-off and who subsequently become ill with the above symptoms within 10 days.
- Hunters or subsistence egg gatherers who handle dead birds or eggs and who subsequently become ill with the above symptoms within 10 days.
- FWS or F&G employees or other individuals who obtain wild bird specimens and subsequently become ill with the above symptoms within 10 days.
- Other Alaskans with exposure to ill bird or bird found dead who subsequently become ill with the above symptoms within 10 days.
- Cluster of three or more people within 7-10 days of each other, and within a defined geographical area that meet current case definition.
- Any cluster of deaths from respiratory disease of unexplained cause.

†See references

‡For example, a patient with respiratory illness and fever who does not require hospitalization, or a patient with significant neurologic or gastrointestinal symptoms in the absence of respiratory disease.

Laboratory Specimens

- Obtain respiratory samples:
  - Preferred: oropharyngeal swab and lower respiratory tract specimen (e.g., bronchoalveolar lavage or tracheal aspirates.)
  - Acceptable: Nasal or nasopharyngeal swab.
- Place each sample in a separate vial of viral transport medium (VTM).
- If possible, serial specimens over several days from same patient.
- The samples will be tested by RT-PCR for influenza A, and for H1, H3, and H5 subtype (available at ASVL). Notify ASVL prior to shipment.
- Virus isolation will not be attempted at ASVL. Specimens that are positive for H5 subtype by RT-PCR at ASVL will be sent to CDC for culture and confirmation of molecular results.
- Serologic testing for influenza H5N1-specific antibody, using appropriately timed specimens, can be considered if other influenza H5N1 diagnostic testing methods are unsuccessful (for example, due to delays in respiratory specimen collection.) Paired serum specimens from the same patient are required for influenza H5N1 diagnosis: one sample should be tested within the first week of illness, and a second sample should be tested 2-4 weeks later.

Notes:

- Bronchoalveolar lavage is considered to be a high-risk aerosol-generating procedure. Therefore, infection control precautions should include the use of gloves, gown, goggles or face shield, and a fit-tested respirator with an N-95 (or higher) rated filter. A loose-fitting, powered air-purifying respirator (PAPR) may be used if fit-testing is not possible (e.g., a person has a beard.)
- Swabs used for specimen collection should have a Dacron tip and an aluminum or plastic shaft. Swabs with calcium alginate or cotton tips and wooden shafts are not recommended.
- Specimens should be placed at 4°C (about 40°F) immediately after collection.
- Commercial rapid influenza antigen testing in the evaluation of suspected influenza H5N1 cases should be interpreted with caution. Clinicians should be aware that these tests have relatively low sensitivities, and a negative result would not exclude a diagnosis of influenza H5N1. In addition, a positive result does not distinguish between seasonal and avian influenza A viruses.

Evaluate Public Health Impact

- Obtain a full travel history for the 10 days before the onset of symptoms. Include flight numbers, airports, contact numbers for tour groups, hotel room numbers, and other details (see Influenza A H5 Domestic Case Screening Form later in this section).
- Evaluate family members and close contacts for similar symptoms of illness. Consider hospitalization or voluntary home isolation of symptomatic contacts.
- Obtain a history of animal contact, with special attention to birds known to carry avian influenza (e.g., poultry, domestic ducks, wild birds, pigs).

Contact and Control Measures

- Notify DEC of suspect cases and refer questions about avian influenza in bird and animal populations to the State Veterinarian, Bob Gerlach (907-375-8214-direct office; 907-632-2558-cell; home 907-688-0056).
- Infection control procedures for avian influenza are identical to those recommended for SARS and are described at http://www.cdc.gov/flu/avian/professional/infect-control.htm. **(Note: These guidelines are currently being updated.)**

They include:

- **Standard Precautions**
  - Pay careful attention to hand hygiene before and after all patient contact or contact with items potentially contaminated with respiratory secretions.
- **Contact Precautions**
  - Use gloves and gown for all patient contact.
  - Use dedicated equipment such as stethoscopes, disposable blood pressure cuffs, disposable thermometers, etc.
- **Eye protection** (i.e., goggles or face shields)
  - Wear when within 3 feet of the patient.
- **Airborne Precautions**
  - Place the patient in an airborne isolation room (AIR). Such rooms should have monitored negative air pressure in relation to corridor, with 6 to 12 air changes per hour (ACH), and exhaust air directly outside or have recirculated air filtered by a high efficiency particulate air (HEPA) filter. If an AIR is unavailable, contact the healthcare facility engineer to assist or use portable HEPA filters to augment the number of ACH.
  - Use a fit-tested respirator, at least as protective as a National Institute of Occupational Safety and Health (NIOSH)-approved N-95 filtering face piece (i.e., disposable) respirator, when entering the room.

- Consider post-exposure prophylaxis for contacts: Oseltamivir, 75 mg QD x 10 days.

Reporting Requirements

- Notify Section Chief ASAP.
- Immediate phone report to the CDC on-call epidemiologist at 404-639-3747 or 404-639-3591 (M-F 8:30AM-5:00PM ET) or, all other times, to the Director's Emergency Operations Center (DEOC) at 770-448-7100. CDC will assign a unique case ID number if case meets surveillance criteria.
- FTR: for all avian influenza investigations.

References

For current Avian Influenza information including affected countries:
http://www.cdc.gov/flu/avian/outbreaks/current/htm
http://www.who.int/csr/disease/avian_influenza/en

Avian Influenza Suspect Case Protocol

HOSPITAL

Provider suspects Avian Influenza

- Verify HCW PPE (mask, goggles, gown and gloves)
- Mask patient
- Isolate patient in negative pressure room or single room (if negative pressure room unavailable)
- Notify hospital ICP
- Verify that patient meets case definition

ICP:

- Identify affected hospital personnel
- Begin antiviral prophylaxis in consultation with Section of Epidemiology

- Alaska Section of Epidemiology approves specimen collection

Collect Multiple Specimens

- Rapid flu test (if available)
- Preferred specimens: oropharyngeal swab or lower respiratory tract (e.g., bronchoalveolar lavage or tracheal aspirate) into viral transport medium
- Acceptable: nasal or nasopharyngeal swab
- Acute serum (5 ml) in red top tube

Begin antiviral treatment in consultation with Section of Epidemiology

Submit specimens with Specimen Collection Form to ASVL in Fairbanks via GoldStreak (Section of Epidemiology will help expedite)

EPIDEMIOLOGY

Notify Section of Epidemiology:
1-907-269-8000
OR
1-800-478-0084

- Complete CDC Case Screening Form
- Advise the treating physician on treatment; provide treatment if needed

AND

- Notify Division Director and Section Chief
- Notify CDC DEOC at 1-770-448-7100

AND

Advise ASVL of pending specimens and help expedite

AND

- Interview patient or family member to identify close contacts or others exposed to avian source
- Determine and provide post-exposure prophylaxis as needed.
- Coordinate support for necessary home I & Q

04/06

Human Influenza A (H5) Domestic Case Screening Form

CDC Case ID:

1. Reported By

Date reported to state or local health department: __ __ / __ __ / __ __ __ __ (m m d d y y y y)	State/ local Assigned Case ID:
Last Name:	First Name:

State:	Affiliation:	Email:
Phone 1:	Phone 2:	Fax:

2. Patient Information

City of Residence: County: State:

Age at onset: _____ ☐ Year(s) ☐ Month(s)

Sex: ☐ Male ☐ Female

Race: *(Choose One)*
☐ American Indian/Alaska Native
☐ Asian
☐ Black
☐ Native Hawaiian/Other Pacific Islander
☐ White
☐ Unknown

Ethnicity: ☐ Non Hispanic ☐ Hispanic

3. Optional Patient Information

Last Name: First Name:

4. Signs and Symptoms

A. Date of symptom onset: __ __ / __ __ / __ __ __ __ (m m d d y y y y)

B. What symptoms and signs did the patient have during the course of illness? (check all that apply)

Fever > 38° C (100.4° F)	Feverish (temperature not taken)	Conjunctivitis
Cough	Headache	Shortness of breath
Sore throat	Other (specify): _____	

C. Was a chest X-ray or chest CAT scan performed? ☐ Yes* ☐ No ☐ Unknown

If yes*, did the patient have radiographic evidence of pneumonia or respiratory distress syndrome (RDS)? ☐ Yes* ☐ No ☐ Unknown

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
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Epidemiologic Risk Factors

CDC Case ID:

5. Travel/Exposures

A. In the 10 days prior to illness onset, did the patient travel to any of the countries listed in the table below? If yes*, please fill in arrival and departure dates for all countries that apply. ☐ Yes* ☐ No** ☐ Unknown

**If patient did not travel outside U.S., skip to question 6.

Country	Arrival Date	Departure Date	Country	Arrival Date	Departure Date
☐ Afghanistan			☐ Myanmar (Burma)		
☐ Bangladesh			☐ Nepal		
☐ Brunei			☐ North Korea		
☐ Cambodia			☐ Oman		
☐ China			☐ Pakistan		
☐ Hong Kong			☐ Papua New Guinea		
☐ India			☐ Philippines		
☐ Indonesia			☐ Saudi Arabia		
☐ Iran			☐ Singapore		
☐ Iraq			☐ South Korea		
☐ Israel			☐ Syria		
☐ Japan			☐ Taiwan		
☐ Jordan			☐ Thailand		
☐ Laos			☐ Turkey		
☐ Lebanon			☐ Viet Nam		
☐ Macao			☐ Yemen		
☐ Malaysia					

For the questions 5B to 5E,
In the 10 days prior to illness onset, <u>while in the countries</u> listed above . . . .

B. Did the patient come within 1 meter (3 feet) of any live poultry or domesticated birds (e.g. visited a poultry farm, a household raising poultry, or a bird market)? ☐ Yes* ☐ No ☐ Unknown

If Yes*

C. Did patient touch any recently butchered poultry? ☐ Yes ☐ No ☐ Unknown

D. Did the patient visit or stay in the same household with anyone with pneumonia or severe flu-like illness? ☐ Yes ☐ No ☐ Unknown

E. Did the patient visit or stay in the same household with a suspected human influenza A(H5) case?* ☐ Yes ☐ No ☐ Unknown

F. Did the patient visit or stay in the same household with a known human influenza A(H5) case?* ☐ Yes ☐ No ☐ Unknown

** SEE Influenza A (H5): Interim U.S. Case Definitions*

(continued from previous page)

CDC ID:

6. Exposure for Non Travelers	
For patients whom did not travel outside the U.S., **in the 10 days prior to illness onset**, did the patient visit or stay in the same household with a traveler returning from one of the countries listed above who developed pneumonia or severe flu-like illness?	☐ Yes* ☐ No ☐ Unknown
If yes*, was the contact a confirmed or suspected H5 case patient?	☐ Yes* ☐ No ☐ Unknown
If yes*: CDC ID: _____ STATE ID: _____	

Laboratory Evaluation

7. State and local level influenza test results	
Specimen 1	
☐ NP swab ☐ Broncheoalveolar lavage specimen (BAL) ☐ NP aspirate ☐ OP swab ☐ Other _____	Date Collected: __ __ / __ __ / __ __ __ __ m m d d y y y y
Test Type: ☐ RT-PCR ☐ Direct fluorescent antibody (DFA) ☐ Viral Culture ☐ Rapid Antigen Test* *Name of Rapid Test:	Result: ☐ Influenza A ☐ Influenza B ☐ Influenza (type unk) ☐ Negative ☐ Pending
Specimen 2	
☐ NP swab ☐ Broncheoalveolar lavage specimen (BAL) ☐ NP aspirate ☐ OP swab ☐ Other _____	Date Collected: __ __ / __ __ / __ __ __ __ m m d d y y y y
Test Type: ☐ RT-PCR ☐ Direct fluorescent antibody (DFA) ☐ Viral Culture ☐ Rapid Antigen Test* *Name of Rapid Test:	Result: ☐ Influenza A ☐ Influenza B ☐ Influenza (type unk) ☐ Negative ☐ Pending
Specimen 3	
☐ NP swab ☐ Broncheoalveolar lavage specimen (BAL) ☐ NP aspirate ☐ OP swab ☐ Other _____	Date Collected: __ __ / __ __ / __ __ __ __ m m d d y y y y
Test Type: ☐ RT-PCR ☐ Direct fluorescent antibody (DFA) ☐ Viral Culture ☐ Rapid Antigen Test* *Name of Rapid Test:	Result: ☐ Influenza A ☐ Influenza B ☐ Influenza (type unk) ☐ Negative ☐ Pending

(continued from previous page)

CDC ID:

8. List specimens sent to the CDC

Select a SOURCE* from the following list for each specimen: Serum (acute), serum (convalescent), NP swab, NP aspirate, broncheoalveolar lavage specimen (BAL), OP swab, tracheal aspirate, or tissue

Specimen 1: ☐ Clinical Material ☐ Extracted RNA ☐ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Specimen 2: ☐ Clinical Material ☐ Extracted RNA ☐ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Specimen 3: ☐ Clinical Material ☐ Extracted RNA ☐ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Specimen 4: ☐ Clinical Material ☐ Extracted RNA ☐ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Specimen 5: ☐ Clinical Material ☐ Extracted RNA ☐ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Carrier:	Tracking #:	

9. Case Notes:

(continued from previous page)

CDC ID:

CDC Contact Information (FOR CDC USE ONLY)	
Case status and date status applied: ☐ Clinical Case (lab results pending) __ __ / __ __ / __ __ __ __ (m m d d y y y y) ☐ Influenza A pos. Case (subtype pending) __ __ / __ __ / __ __ __ __ (m m d d y y y y) ☐ Confirmed Case __ __ / __ __ / __ __ __ __ (m m d d y y y y)	☐ Ruled Out/Non-Case: __ __ / __ __ / __ __ __ __ (m m d d y y y y) Reason: ☐ Influenza A neg. (by PCR, viral culture, or influenza A serology) ☐ Non-H5 Influenza Strain ☐ Other etiology* ☐ Did not meet case definition
Date Entered by CDC: __ __ / __ __ / __ __ __ __ (m m d d y y y y)	Contact Date: __ __ / __ __ / __ __ _ __ (m m d d y y y y)
Name of CDC Contact:	

*Alternative Diagnosis			
A. Was an alternative non-influenza respiratory pathogen detected? If yes* specify:	☐ Yes*	☐ No	☐ Unknown
B. Was there a diagnosis other than respiratory infection? If yes* specify:	☐ Yes*	☐ No	☐ Unknown

Influenza A (H5) Domestic Case Screening Form Instructions

Q1. Reported By

Date reported to state or local health department: Date case was first reported to the state or local health department.

State/local Case ID: Case number used by local jurisdiction to identify case.

Last name, First name, State, Affiliation, Email, Phone 1, Phone 2, Fax: Information on how to contact the state or local official responsible for following case.

Q2. Patient Information

HIPPA Note: Please note that CDC is conducting these activities in its capacity as a public health authority, as defined by the Health Insurance Portability and Accountability Act (HIPAA). Health care providers and health departments **may therefore disclose protected health information to CDC** without individual authorization. The information being requested represents the minimum necessary to carry out the public health purposes of this project pursuant to 45 CFR §164.514(d) of the Privacy Rule, and protected health information will not be disseminated. Nevertheless, individual local and state health department privacy policies may vary, and should be followed accordingly.

Age at onset: If patient less than one month old, round age up to one month.

Race: Please choose only one race. For multiracial patients indicate race they most closely identify with.

Ethnicity: Please answer this question **in addition** to the Race question above.

Q3. Optional Patient Information

Last name, First name: **Please see HIPAA note above**. The patient's initials should be listed if state or local policies preclude release of the patient's name.

Q4. Signs and Symptoms – Self-explanatory

Q5. Travel/Exposure

Q5A: The list of affected countries may change. CDC will notify state and local health officials if the list of affected countries changes. In addition, a current list of affected Asian countries can be found at the World Organization for Animal Health website (http://www.oie.int/downld/AVIAN INFLUENZA/A_AI-Asia.htm).

Transit through an airport (i.e., patient did not leave the airport) within an affected country **does not** count as exposure in that country. If patient **did not** travel to any countries affected by

avian influenza outbreaks within 10 days prior to illness onset, skip to Question 6 on Exposure for Non-Travelers.

Q5E: Clinical and epidemiologic criteria for a suspect case in an affected country:

Any person with radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness (regardless of poultry exposure)

OR

Any person with **all** of the following:

1) documented temperature of >100.4°F (>38°C), **and**;
2) cough, sore throat, or shortness of breath; **and;**
3) history of contact with
    a. poultry or domestic birds (e.g., visited a poultry farm, a household raising poultry, or a bird market) **or**
    b. Anyone hospitalized or died of a flu-like illness.

Q6. Exposure for Non-Travelers: See clinical and epidemiologic criteria for influenza A(H5) above

Q7. State and local level influenza testing section – Check off type of specimen, date of specimen collection, type of testing and results for tests conducted at the state and/or local level.

Q8. List Specimens sent to the CDC – Check type(s) of specimen being sent (i.e, clinical material, extracted RNA, or viral isolate).

List specimen source (i.e., Serum (acute), serum (convalescent), nasopharyngeal (NP) swab or aspirate, broncheoalveolar lavage specimen (BAL), oropharyngeal (OP) swab, tracheal aspirate, or tissue (specify source)), and dates collected and sent.

Note: Please list acute and convalescent sera as separate specimens.

Q9. Case Notes: Please include in notes section any pertinent information not covered in the questionnaire.

CDC Contact Information Section – For CDC use only

CDC Case ID: CDC case ID number will be automatically generated when initiating new data entry form. The number system for cases identified in the United States will start with USH5, followed by a dash, followed by the two letter state code for the state in which the case was identified, followed by a 4 digit sequential number starting with 0501 (e.g., the first surveillance case identified in Alabama would have CDC case ID USH5-AL0501).

Clinical case: Indicates the patient meets the influenza A(H5) surveillance clinical criteria (see box below). Include date patient met clinical case definition

Influenza A positive case: Indicates the patient meets the influenza A(H5) surveillance criteria (see box below) and has a positive influenza A test at the state or local level. Include date of positive influenza A test.

Confirmed Case: Indicates the patient meets the influenza A(H5) surveillance criteria and has a positive influenza A(H5) test confirmed by the CDC Influenza Lab (see box below). Include date of positive influenza A(H5) test.

Ruled out/Non-case: Indicates that the patient had a negative PCR or culture for influenza A, had known non-H5 human influenza (i.e., influenza A(H1), influenza A(H3), or influenza B), had an alternative diagnosis other than human influenza, or did not meet influenza A(H5) clinical or epidemiologic criteria for a suspect case. (see box below).

Date Entered by CDC: Date data is entered into CDC database

CDC Contact: Name of CDC personnel responsible for following case

Contact Date: Date case was first reported to the CDC

Influenza A (H5) Surveillance Criteria

1. Patient is hospitalized and has:
    a. radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness for which an alternative diagnosis has not been established **and;**
    b. a history of travel within 10 days of symptom onset to a country with documented H5N1 avian influenza infections in poultry or humans. Ongoing listings of Asian countries affected by avian influenza are available from the World Organization for Animal Health (http://www.oie.int/downld/AVIAN INFLUENZA/A_AI-Asia.htm).

OR

2. Patient is hospitalized or ambulatory and has:
    a. documented temperature of >100.4°F (>38°C), **and**;
    b. cough, sore throat, or shortness of breath; **and either;**
    c. history of contact within 10 days prior to onset of symptoms with:
        i. poultry or domestic birds (e.g., visited a poultry farm, a household raising poultry, or a bird market) in an affected country **or**
        ii. a patient with known or suspected influenza A(H5) infection.

    OR

    d. traveled to an affected country within 10 days prior to onset of symptoms and tests positive for influenza A

Confirmed influenza A(H5) case

Patient is suspect case of influenza A(H5N1) and is laboratory confirmed by CDC as influenza A(H5) positive by:

a. PCR, or
b. viral culture, or
c. influenza A(H5) specific serology

Guidelines for reporting domestic suspect and confirmed human cases of avian influenza A(H5) to CDC and the collection and shipping of specimens for influenza A(H5) testing

Since February 3, 2004, CDC has issued several Health Alert updates requesting that local and state health departments enhance surveillance for human avian influenza A (H5) illnesses. The following document contains more detailed information on reporting and on the collection, shipping and testing of clinical specimens. A case report form and instructions are also attached.

In collaboration with state and local health departments, CDC is collecting information on suspect and confirmed human influenza A(H5) cases in the United States. This effort is intended to enhance current influenza surveillance for early identification of patients with influenza A(H5) infection. CDC requests that state and local health departments obtain specimens for influenza virus testing on patients meeting the influenza A (H5) surveillance criteria below.

Influenza A (H5) Surveillance Criteria

1. Patient is hospitalized and has:
    a. radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness for which an alternative diagnosis has not been established **and;**
    b. a history of travel within 10 days of symptom onset to a country with documented H5N1 avian influenza infections in poultry or humans. Ongoing listings of Asian countries affected by avian influenza are available from the World Organization for Animal Health (http://www.oie.int/downld/AVIAN INFLUENZA/A_AI-Asia.htm).

OR

2. Patient is hospitalized or ambulatory and has:
    a. documented temperature of >100.4°F (>38°C), **and**;
    b. cough, sore throat, or shortness of breath; **and either;**
    c. history of contact within 10 days prior to onset of symptoms with:
        i. poultry or domestic birds (e.g., visited a poultry farm, a household raising poultry, or a bird market) in an affected country **or**
        ii. a patient with known or suspected influenza A(H5) infection.

Patients meeting the influenza A (H5) surveillance criteria may be tested at the state/local level for influenza A or influenza A(H5) if laboratory capacity is available. **See Laboratory Testing Procedures section below for precautions on working with clinical specimens that potentially contain influenza A(H5).**

Specimens from persons meeting the influenza A (H5) surveillance criteria should be sent to the CDC if:

1. specific influenza A(H5) testing done at the state /local laboratory is positive **(this should be done only if the laboratory is able to test for influenza A(H5) by PCR or if they have a BSL 3 with enhancements facility for influenza A(H5) viral culture)**,

OR

2. testing for influenza A is positive by PRC or rapid antigen detection* and the referring jurisdiction is not equipped to test for influenza A(H5),

OR

3. the referring jurisdiction is not equipped to test for influenza A by PCR and is requesting testing at CDC.

State and local health departments **should not** report patients who meet the clinical and epidemiologic criteria but who have an alternative laboratory confirmed diagnosis (e.g. influenza A(H3), influenza A(H1), influenza B, or a non-influenza etiology) or who have tested negative for influenza A by PCR.

*Because the sensitivity of commercially available rapid diagnostic tests for influenza may not always be optimal, CDC also will accept specimens from persons meeting the above clinical criteria even if they test negative by influenza rapid diagnostic testing if PCR assays are not available at the state laboratory.

A **confirmed human influenza A(H5) case** is a case meeting surveillance criteria above that is laboratory confirmed by CDC as influenza A(H5) positive by:

a. PCR, or
b. viral culture, or
c. influenza A(H5) specific serology

HIPAA

CDC is conducting these activities in its capacity as a public health authority, as defined by the Health Insurance Portability and Accountability Act (HIPAA). Health care providers and health departments **may therefore disclose protected health information to CDC** without individual authorization. The information being requested represents the minimum necessary to carry out the public health purposes of this project pursuant to 45 CFR §164.514(d) of the Privacy Rule, and protected health

information will not be disseminated. Nevertheless, individual local and state health department privacy policies may vary, and should be followed accordingly.

Reporting Suspect Cases of Human Influenza A(H5)

A. **Initial Report:** Prior to submitting a case report form, health department officials should first contact the CDC Director's Emergency Operations Center (DEOC) at 770-488-7100. This number is available 24 hours a day, 7 days a week. DEOC staff will notify a member of the human influenza A(H5) surveillance team who will contact the health department and provide a unique CDC case ID number for each case which meets the surveillance criteria.

B. **Written Materials**

1. **Case Report Form:** Following the initial telephone report, health department officials should submit a completed CDC case report form. This form is available through Epi-X, or by contacting CDC DEOC at 770-488-7100.
2. **Sending case report form to CDC:** Materials should be faxed to CDC at 888-232-1322. Please include the CDC case ID number, contact information, and a cover sheet with the header "ATTN: Influenza A(H5N1) case reporting." Rapid return of information is of high priority; complete as much of the case report form as possible and transmit to CDC within 3 to 5 business days of first contact. The remaining information can be sent as soon as it is available. CDC staff will assist local and state health departments in completing the case report forms as needed.

C. **Laboratory Procedures, Specimen Collection and Shipment**

1. **Laboratory precautions for influenza A (H5) testing:** Highly pathogenic avian influenza A(H5N1) is classified as a select agent and **must be** worked with under Biosafety Level (BSL) 3+ laboratory conditions.
   a. **Culture only at BSL 3 with enhancements level facilities.** This includes controlled access double door entry with change room and shower, use of respirators, decontamination of all wastes, and showering out of all personnel. Laboratories working on these viruses must be certified by the U.S. Department of Agriculture. CDC does **not recommend** that virus isolation studies on respiratory specimens from patients who meet the above criteria be conducted unless stringent BSL 3 with enhancements conditions can be met and work is separate from other human influenza A (i.e., H1 or H3) virus work. Therefore, respiratory virus cultures should not be performed in most clinical laboratories and cultures should not be ordered for patients suspected of having influenza A (H5N1) infection.

b. **PCR and rapid antigen detection:** Clinical specimens from suspect influenza A(H5) cases may be tested at the state/local public health laboratory by PCR assays using standard BSL 2 work practices in a Class II biological safety cabinet. In addition, commercial rapid antigen detection testing can be conducted under BSL 2 levels to test for influenza.

2. To assist public health public health laboratories respiratory illness diagnostic efforts, CDC has developed real-time PCR protocols for a number of respiratory pathogens, including influenza A and B viruses, adenovirus, metapneumovirus, Legionella, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*. **These protocols are currently available only to public health laboratories and have been posted at the APHL Members Only (password required) Web site** www.aphl.org/Members_Only/index.cfm, under SARS. These protocols are not available in all public health laboratories, and physicians should consult with their local public health laboratory when ordering these tests.

3. **Sample Collection and Shipping instructions**
   a. **Respiratory specimens:** Aliquots of extracted RNA (for PCR positives) and/or clinical specimen (i.e., nasopharyngeal and oropharyngeal swabs, nasal washings, tracheal aspirates) should be sent through established channels (e.g., via the state laboratory) or directly to CDC for viral characterization.

      Specimens should be frozen at -70° C and shipped on **dry ice** directly to CDC **overnight** to the address in Section 4d.

   b. **Serum specimens:** A serum sample (5-10 cc) should be collected in a serum separator tube, centrifuged, and stored locally at -20° F. A convalescent serum sample should be drawn 2-4 weeks later and both acute and convalescent sera should be sent to the CDC for serologic testing.

   c. **Autopsy Specimens:** CDC can perform immunohistochemical (IHC) staining for influenza A(H5) viruses on autopsy specimens. Viral antigens may be focal and sparsely distributed in patients with influenza, and are most frequently detected in respiratory epithelium of large airways. Larger airways (*particularly primary and segmental bronchi*) have the highest yield for detection of influenza viruses by IHC staining. Collection of the appropriate tissues ensures the best chance of detecting the virus by (IHC) stains. If influenza is suspected, a minimum total of 8 blocks or fixed tissue specimens representing samples from each of the following sites should be obtained and submitted for evaluation:

1. Central (hilar) lung with segmental bronchi
2. Right and left primary bronchi
3. Trachea (proximal and distal)
4. Representative pulmonary parenchyma from right and left lung

In addition, representative tissues from major organs should be submitted for evaluation. In particular, for patients with suspected myocarditis or encephalitis, specimens should include myocardium (right and left ventricle) and CNS (cerebral cortex, basal ganglia, pons, medulla, and cerebellum). Specimens should be included from any other organ showing significant gross or microscopic pathology.

Specimens may be submitted as:

1. Fixed, unprocessed tissue in 10% neutral buffered formalin, or
2. Tissue blocks containing formalin-fixed, paraffin-embedded specimens, or
3. Unstained sections cut at 3 microns placed on charged glass slides (10 slides per specimens)

Specimens should be sent at room temperature (**NOT FROZEN**)

Please include a copy of the autopsy report (preliminary or final if available), and a cover letter outlining a brief clinical history and the full name, title, complete mailing address, phone, and fax numbers of the submitter, in the event that CDC pathologists require further information. Referring pathologists may direct specific questions to CDC pathologists.

4. Shipping Instructions:

a. Specimens should be submitted to CDC by state and local health departments. The Influenza A(H5) Epi/Surveillance Team should be contacted at 770-488-7100 before sending specimens for influenza A(H5) testing.

b. When sending clinical specimens, please include the **specimen inventory sheet (appendix A)**, include the assigned **CDC case ID number,** and indicate **"Human Influenza A(H5) surveillance"** on all materials and specimens sent.

c. Please include the **CDC case ID number** on all materials forwarded to CDC. Protocols for standard interstate shipment of etiologic agents should be followed, and are available at http://www.cdc.gov/od/ohs/biosfty/shipregs.htm.

d. Address for respiratory and serum specimens:

Dr. Alexander Klimov, PhD, ScD, Chief
Strain Surveillance Section
Influenza Branch, CDC
c/o DASH
1600 Clifton Road
Atlanta, GA 30333
Phone: 404-639-3387 or 3591, fax: 404-639-2334, email: AKlimov@cdc.gov

Address for autopsy specimens

Dr. Sherif Zaki, MD, PhD
Infectious Disease Pathology Activity
Division of Viral and Rickettsial Diseases
National Center for Infectious Diseases
Centers for Disease Control and Prevention
Mailstop G-32, Bldg 1, Rm 2301
1600 Clifton Road
Atlanta, GA 30333
Phone: 404-639-3133
fax: 404-639-3043
email: SZaki@cdc.gov

5. ADDITIONAL INFORMATION

Any questions regarding reporting procedures or specimen shipment can be directed to the influenza special investigations team:

Influenza A(H5N1) Epi/Surveillance Team
Division of Viral and Rickettsial Diseases
National Center for Infectious Diseases
Centers for Disease Control and Prevention
Mailstop A-32, Bldg 6, Rm 122
1600 Clifton Road
Atlanta, GA 30333
Phone: 770-488-7100, Fax: 888-232-1322
Email: eocinfluenza@cdc.gov

PHONE NUMBERS

Reporting cases and Notification of specimen shipments	770-488-7100
Fax number for case report forms	888-232-1322
Requests for specimen testing	770-488-7100
Dr. Alexander Klimov, Strain Surveillance	404-639-3387
Dr. Sherif Zaki, Infectious Disease Pathology	404-639-3133

Appendix A

CDC CASE ID:

List specimens sent to the CDC		
Select a SOURCE* from the following list for each specimen: Serum (acute), serum (convalescent), NP swab, NP aspirate, broncheoalveolar lavage specimen (BAL), OP swab, tracheal aspirate, or tissue		
Specimen Type #1: □ Clinical Material □ Extracted RNA □ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y
Specimen Type #2: □ Clinical Material □ Extracted RNA □ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y
Specimen Type #3: □ Clinical Material □ Extracted RNA □ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y
Specimen Type #4: □ Clinical Material □ Extracted RNA □ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y
Specimen Type #5: □ Clinical Material □ Extracted RNA □ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y
Carrier:	Tracking #:	

April 21, 2006

Dear Public Health Laboratory Directors,

We know that many of your laboratories have been called upon to perform some testing for Influenza A H5N1 in recent weeks. With the release of the FDA cleared LRN screening assay for H5, many of you have had questions about how to best conduct testing using the procedures provided by CDC's Influenza branch and the LRN assay.

The CDC's Influenza Branch assays are posted on the APHL members only website. These procedures are provided by CDC to assist you in enhancing influenza surveillance and pandemic preparedness. Use of the Influenza branch assays is not required, laboratories may choose to evaluate and use other commercially available influenza detection assays.

Representatives from most of the state laboratories participated in an APHL/CDC training course when the influenza branch assays were first released, but with the addition of the LRN test and the continuing spread of this virus across the globe, APHL felt it prudent to provide some updated guidance for responding to test requests. The attached algorithms were developed by a working group of APHL members with significant experience in virology at the request of the Infectious Diseases committee. They are intended as guidelines, as we know each jurisdiction may have specific operational requirements that may impact testing. These guidelines are undergoing CDC review, but they are not CDC cleared. We wanted to distribute them to the public health laboratories now because of the increasing likelihood that the virus may appear in the U.S. within wild birds.

There are two algorithms attached:

- Suggested testing for routine influenza surveillance in the current situation of WHO/USA Pandemic Phase 3, which includes recommendations if routine testing suggests that a novel or avian subtype has been detected.
- Testing & interpretation for H5 when a case meets risk assessment requirements or if human H5 cases begin to appear in the US. Note that in the current setting of no H5 in the US, testing for H5 only, without including PCR assay for Influenza A and other subtypes, is not recommended.

An additional algorithm is currently in development with suggestions for modifying testing if a pandemic occurs or other factors influence the need for enhanced surge testing.

The working group strongly recommends that laboratories work with state and local epidemiologists to assess case risk according to the current case definition prior to conducting testing. Due to the potential for false-positives with any method, testing should be limited to patients who meet the case definition or other state determined testing requirements. Also, case risk assessment to limit indiscriminate testing will protect the LRN reagent supply for a true event.

As you know, specimens from patients at risk for novel influenza infection should **NOT** be cultured except under high containment. Due to the risk to the poultry industry from highly pathogenic avian influenza viruses, USDA regulations require laboratories to meet BSL-3 enhanced specifications in order to work with live virus. In addition, it is recommended that cultures for avian or novel influenza virus be kept separate from cultures with seasonal human influenza viruses such as influenza A/H1 or A/H3. (See www.hhs.gov/pandemicflu/plan/sup2.html#app4)

Current assays for H5 infection:

- To improve diagnostic sensitivity, PCR testing for avian influenza should be performed on multiple sample types. Sputum, nasopharyngeal washes/aspirates or bronchial lavages (if performed) are the recommended specimen types. Throat swabs may be used. Most human cases have been lower respiratory tract infections, so collecting only a nasopharyngeal swab or nasal swab is NOT recommended. As noted in the algorithm, **negative** test results may not rule-out avian influenza. If suspicion is high, specimens may be sent to CDC for culture, and PCR testing should be repeated on multiple samples collected over multiple days.
- Both the Influenza Branch H5 primers and probes and the LRN H5 kit detect only the Asian lineage. They do not detect North American H5 viruses. Agriculture laboratories in your jurisdiction may be using a USDA test that detects both lineages.
- Both the Influenza Branch H5 primers and probes and the LRN H5 kit have demonstrated sensitivity for Clade 1 and Clade 2 strains of the Asian HP H5N1 strain currently circulating.
- According to the FDA approved package insert for the LRN H5 assay, this test is for presumptive identification only. Confirmatory testing using multiple tests, including culture, will be needed when the first cases are detected in the US. The attached algorithms include multiple decision points for contacting CDC.
- When performing the H5 tests, you may choose to use either the Influenza Branch procedure or the LRN kit. Choice of tests may depend on your extraction method compatibility with the LRN procedure. Some laboratories have reported different sensitivities with different extraction methods.
- Initial specimen processing including addition of lysis buffer should be performed within a biosafety cabinet in a BSL-2 laboratory. (www.hhs.gov/pandemicflu/plan/sup2.html#app4) If CDC or LRN recommended lysis buffer reagents are used, virus contained in the sample should be inactivated, allowing further processing to be performed outside the BSC. Some lysis buffers such as "RNA-later" do not inactivate the virus.
- The H7 subtyping procedure available on the APHL website is not specifically listed in the algorithm. Currently CDC cannot provide controls for this assay, and there are no human infections of concern, so we recommend limiting its use. If poultry exposure and infection from a novel or avian strain is suspected, laboratories may use this test at your individual discretion. Contact CDC immediately if results are positive.
- As the H5 virus spreads, the sensitivity of the existing procedures may change. CDC is continuing to monitor the performance of the tests as they receive international samples. We will notify you by email if any changes to the primer and probe sequences are made to the procedures posted on the APHL members only website, or if LRN reagents change.

The algorithms and recommendations may also change as we gather new information about how the tests are performing and how the virus is changing. Please send any comments you may have about the algorithms to us for consideration as we continue to refine the guidelines. Once you and your laboratory staff have reviewed the algorithms, please send questions or comments to Rosemary Humes (rosemary.humes@aphl.org) or Patricia Blevins (patricia.blevins@aphl.org).

On behalf of the workgroup who contributed generously to the development of these documents, we hope you find this information helpful. Websites with additional pandemic influenza information are listed below.

Best,

Scott Becker
Executive Director

Rosemary Humes
Director, Infectious Diseases and Preparedness

Additional information to help guide planning and response is available at:

Federal Government Pandemic Flu website:
www.pandemicflu.gov/

HHS Pandemic Plan:
www.hhs.gov/pandemicflu/plan/

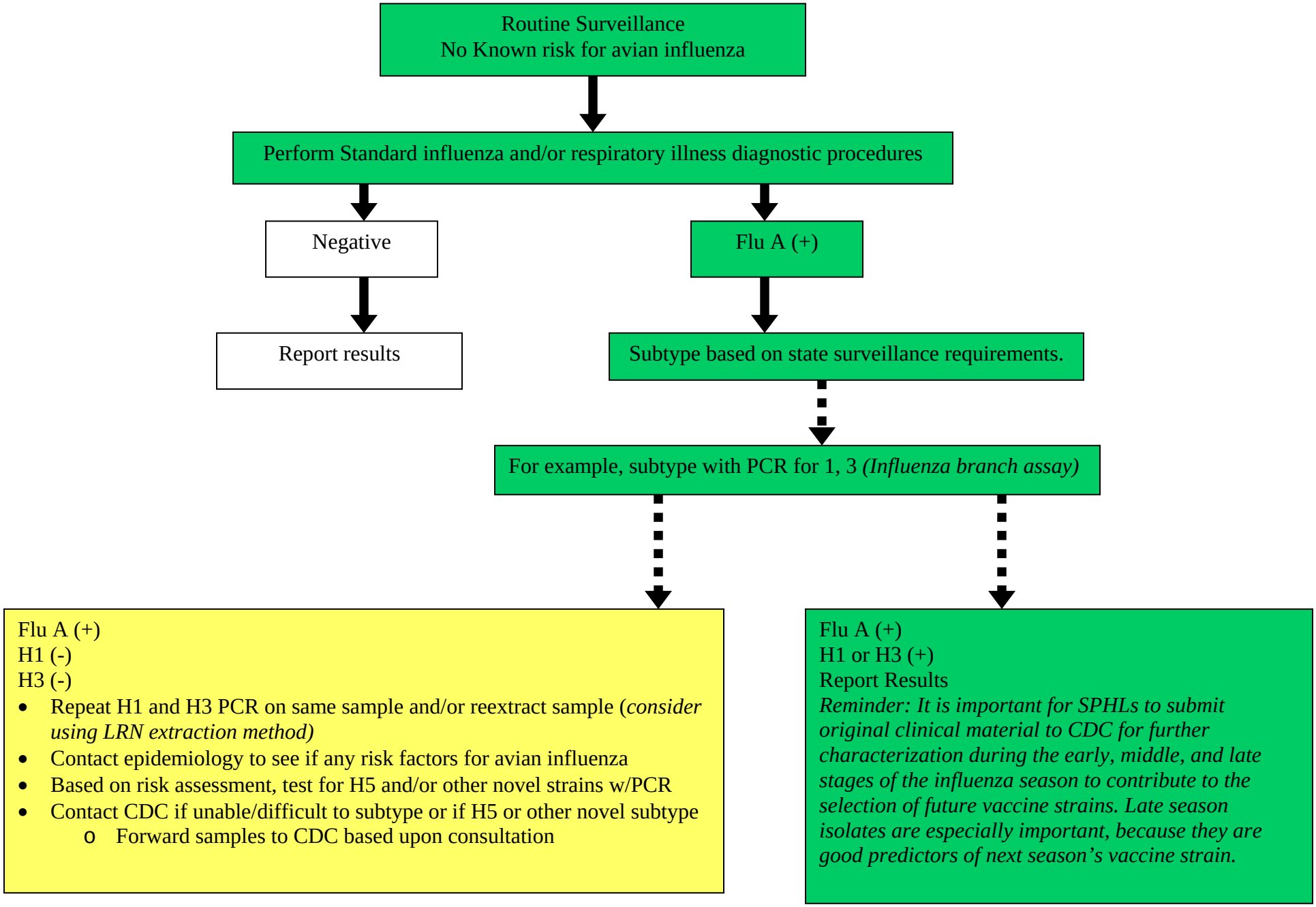
HHS Pandemic Plan- Supplement 2 Laboratory Diagnostics
www.hhs.gov/pandemicflu/plan/sup2.html

> Appendices in this section of the document include Appendix 2. Interim Recommendations: Enhanced U.S. Surveillance and Diagnostic Evaluation to Identify Cases of Human Infection with Avian Influenza A (H5N1) with the current (Oct 2005) case definition: and Appendix 4. Laboratory Biosafety Guidelines for Handling and Processing Specimens or Isolates of Novel Influenza Strains

Influenza branch Influenza detection and subtyping protocols (Note: these cannot be shared outside the public health laboratory community without permission from CDC)
www.aphl.org/member_center/ (member password required)

WHO Pandemic Influenza information:
www.who.int/csr/en/

Routine Influenza Testing Algorithm for SPHLs (WHO/USA Phase 3)



04/20/06 v.3

Influenza A/H5 Testing Algorithm for SPHLs
(Limited H5 activity in the US or known travel/exposure history)

Risk Assessment:
Consultation with epidemiology department
Meets avian influenza/H5 case definition or other state testing requirements

Perform PCR for Flu A/B/1/3/5
Multiple specimen types recommended (e.g. NP, sputum, bronchial lavage if available, and throat)*
DO NOT CULTURE UNTIL H5 OR OTHER NOVEL STRAINS ARE RULED OUT
(Influenza branch assay with/without LRN H5 depending on individual laboratory workflow)

*__Specimen Collection__
Multiple sample types recommended. Some studies demonstrate need for multiple samples collected over several days for optimal H5 detection sensitivity.

Flu A (+)
H5 (+)
H3 (-)
H1 (-)
DO NOT CULTURE
- **Contact CDC** immediately and forward samples for confirmatory testing

Flu A (+)
H5 (-) or Flu B (+)
H1 or H3 (+)
- Report results
- Safe to culture if isolate is needed

Flu A (+)
H5 (-)
H3 (-)
H1 (-)
DO NOT CULTURE
- **Contact CDC** immediately due to potential for novel strain
- Assess need to repeat tests and/or forward samples to CDC

Flu A (+)
H5 (+)
H1 or H3 (+)
DO NOT CULTURE
- **Contact CDC** due to potential for co-infection/cross-contamination
- Assess need to reextract and repeat testing and/or forward samples to CDC

Flu A and B (-)
H5 (-)
H1 and H3 (-)
- Reassess risk and if likelihood of H5 remains high, recollect samples*, **DO NOT CULTURE: Contact CDC**
- If risk is low, proceed with assays and/or culture for other pathogens based on clinical presentation

4/20/2006 v.3

Symptom Screen for Persons Who Handled Birds with Asian H5N1 Influenza

I. Contact information

Person's Name	DOB
Address	Phone Number (include cell)

II. Exposure history

• When was the sample collected:
• Where was the sample collected? (Be as specific as possible).
• Who else was with you collecting the sample?
• Why was the sample collected (circle one): a. Field biology project (live bird) b. Backyard flock surveillance (live bird) c. Subsistence/sport hunter survey (dead bird) d. Found a dead bird e. Other, please specify:_____
• What kind of PPE (e.g., gloves or mask), if any, were you wearing at the time?
• Where is the bird now? (e.g., already consumed or in freezer)
List any other details about the collection circumstances:

III. Symptoms

Since the date that the bird sample was collected, have you had any of the following symptoms?

	YES	**NO**	**DON'T KNOW**	**If Yes, date of symptom onset:**	**If Yes, duration of symptoms:**
• Fever (>100.4ºF or 38ºC)					
• Sore throat					
• Cough					
• Shortness of breath					
• Headache					
• Muscle aches					
• Red eyes					
• Diarrhea					
• Other, please list…					

***********If fever and severe respiratory illness within 10 days of sample collection date, refer to healthcare provider, and obtain in-depth case form.************

Interviewer name:	**Date of interview:**

Draft 4/26/2006

Notes and Other Instructions for Completing Form
"Symptom Screen for Persons Who Handled Birds with Asian H5N1 Influenza"

1. Obtain name of healthcare provider that person intends to visit. Work with hcp to determine if patient does meet case definition and if testing for avian influenza is indicated. If so, complete in-depth case form and follow algorithm for treatment, interviewing contacts, etc.

2. If person is asymptomatic, double check with CDC about indications for antiviral prophylaxis, and/or whether any biologic samples should be collected.

3. If the bird is still available, contact DEC to see if further testing is desired. If not, Epidemiology will likely recommend that the carcass is destroyed.

SOMETHING OF INTEREST

VIRAL TRANSPORT MEDIA (VTM)

Proper Storage Requirements

As the flu season approaches, many submitters are calling the State Virology Laboratory with questions concerning the storage and transport of Viral Transport Media (VTM). We thought it would be beneficial for our present and new submitters to review the requirements for sending viral cultures to the laboratory for identification.

Proper Storage of Viral Transport Media:

- Do NOT store in a frost free freezer. The freeze / thaw cycles will shorten the expiration date of the media. If the only freezer available to you is frost free, you can store the VTM in a styrofoam container with an ice pack to keep the media frozen.
- If the VTM is stored at -20°C, it may be used until the expiration date printed on the vial.
- VTM may be stored up to 30 days at 4°C (refrigerator temperature).
- If the VTM is thawed upon receipt, it can be refrozen once and will be usable up to the expiration date.
- Due to the presence of antibiotics in the VTM, it should not be left at room temperature.
- If the VTM has been allowed to thaw and remain at room temperature, discard any unused media after 7 days.

Transport of Viral Specimens to the Laboratory:

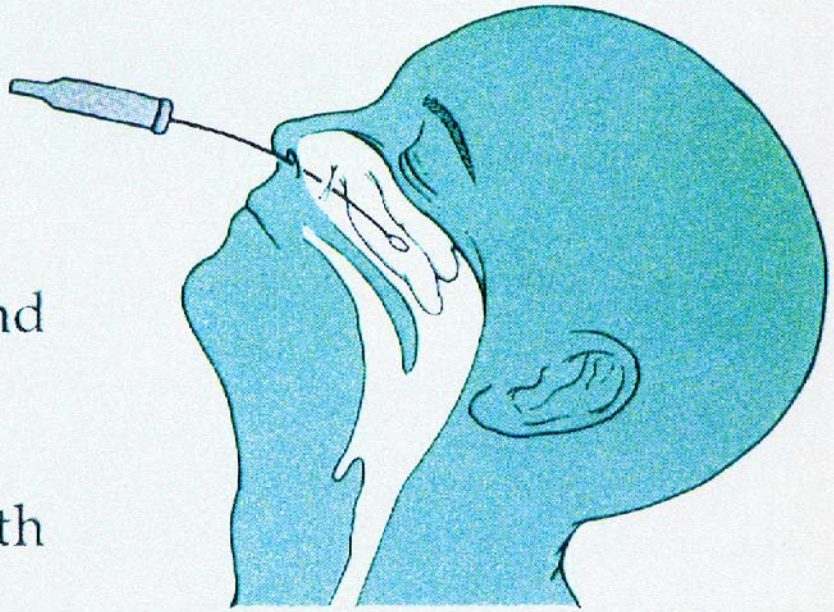
- Culture specimens must be received at the State Virology Laboratory in Fairbanks packed with cold packs within **96 hours** of collection for optimal chance of viral recovery.
- Lipid enveloped viruses; e.g. CMV, HSV, RSV, et., must *NOT* be frozen.
- When specimen submission will be delayed more than 96 hours, specimens must be frozen within 48 hours of collection and shipped frozen.
- The virologists will make every attempt to isolate viruses from less than optimal specimens.
- Be sure to label the vial with the patient's name or identification number. **UNLABELED SPECIMENS ARE UNSATISFACTORY and will not be processed.**
- Do not leave scalpel blades in the VTM; this can be toxic to the specimen.
- Break off the specimen swab below the rim of the vial so the cap can be **tightened securely** to prevent leakage.
- Place paperwork and specimen into separate leakproof bags with absorbent material around the specimen. Specimens which leak may be considered unsatisfactory.

** **NOTE**: Be careful to use **VTM** for viral cultures and **CTM** (Chlamydia Transport Media) for chlamydia cultures. They are NOT interchangeable.

If you have any questions or concerns about the storage, collections, or shipment of viral media and specimens, please contact the State Virology Laboratory in Fairbanks at (907)474-7017 or (888)474-7017.

Mary Westcott
Microbiologist III

Nasopharyngeal Swab Method



Materials: Mini-Tip **Culturette**® Brand Collection and Transport System ***or***

Nasopharyngeal swab with synthetic fiber tip
1-2 ml Viral Transport Medium (VTM)
Specimen container

1. Insert swab into one nostril.
2. Press swab tip on the mucosal surface of the mid-inferior portion of the inferior turbinate (see sketch), and rub the swab tip several times across the mucosal surface to loosen and collect cellular material.
3. Withdraw swab; insert into **Culturette**® or container with VTM.

Blood & Body Fluids Exposure

Blood & Body Fluids Exposure
General Recommendations

Before any exposure happens:

1. Get vaccinated for hepatitis B.
2. Know the protocol for your institution.
3. Know where you would go at your facility, including eye wash area.

After an exposure happens:

1. Immediately wash site with soap and water (eyes with eye wash facility or water).
2. Report exposure to supervisor or employee health nurse according to your institution's protocol.
3. Don't panic. Risk of transmission of HIV or Hepatitis C from needle stick is low.

References:

http://www.hivatwork.org/tools/pdf_laborkit/occupational.pdf

Blood & Body Fluids Exposure: Hepatitis B

The risk of infection varies with:

- The HBsAg and HBeAg status of the source
- The hepatitis B vaccination and vaccine-response status of the exposed person
- The route of exposure (parenteral, sexual, etc.)

Needle stick	Percent Risk of Developing Clinical Hepatitis
HBsAg positive only	1-6
HBsAg and HBeAg positive	22-31

Post-exposure recommendations

Exposure	HBIG Dose	Recommended timing	Vaccine Dose	Recommended timing
Perinatal	0.5 ml IM	Within 12 hours of birth	0.5 ml IM	Within 12 hours of birth
Sexual	0.06ml/kg IM	Single dose within 14 days of last sexual contact	1.0 ml IM	First dose at time of HBIG treatment.

(The first dose of vaccine can be given the same time as the HBIG dose but at a different site.)

Percutaneous or permucosal exposure

Following any such exposure, a blood sample should be obtained from the person who is the source of the exposure and should be tested for HBsAg.
For greatest effectiveness, passive prophylaxis with HBIG, where indicated, should be given as soon as possible after exposure—preferably within 24 hours, if possible, and before 7 days.

Recommended post-exposure prophylaxis for exposure to hepatitis B virus

Exposed person	Source is HbsAg-positive	Source is HbsAg-negative	Source not tested Or unknown
Unvaccinated	HBIG 0.06 ml/kg IM one dose and initiate HB vaccine	Initiate HB vaccine	Initiate HB vaccine
Previously vaccinated			
Known responder	No treatment	No treatment	No treatment
Known Non-responder	HBIG x1 and initiate revaccination or HBIG x 2	No treatment	If known high-risk source, treat as if source were HbsAg-positive.
Response unknown	Test exposed for anti-HBs 1. If inadequate, HBIG x 1 plus HB vaccine booster dose. 2. If adequate, no treatment.	No treatment	Test exposed for anti-HBs 1. If inadequate, administer vaccine booster and recheck titer in 1-2 months 2. If adequate, no treatment

Blood & Body Fluids Exposure: Hepatitis C

Routes of Transmission

- Blood borne (most common route is sharing needles)
- Sexual (very low risk)

Risk of Transmission

- 1.8% (range 0-10%) after a needlestick from an HCV positive source.
- Sexual transmission has occurred, but very infrequently.

Management

- For the source, perform testing for anti-HCV.
- For the person exposed to an HCV positive source:
  - perform baseline testing for anti-HCV and ALT activity; and
  - perform follow-up testing (e.g., at 4–6 months) for anti-HCV and ALT activity (if earlier diagnosis of HCV infection is desired, testing for HCV RNA may be performed at 4–6 weeks).
  - confirm all anti-HCV results reported positive by enzyme immunoassay using supplemental anti-HCV testing (e.g., recombinant immunoblot assay [RIBA™]).
- IG and antiviral agents are not recommended for PEP after exposure to HCV positive blood.
- Limited data indicate that antiviral therapy may be beneficial when started early in the course of HCV infection; refer person to MD.
- HCW may continue regular job duties with no modifications. Person should follow recommended infection control practices, just as all HCP.
- Exposed person should refrain from donating blood, plasma, organs, tissues or semen during follow-up period of 6 months.
- Exposed person does not need to modify sexual practices.
- Exposure to Hepatitis C is not a contraindication to becoming pregnant or breastfeeding.

Prevention

- No vaccine is currently available.
- Do not share needles or other drug injection items.
- Do not share personal care items (razors, toothbrushes).
- HCW should follow barrier precautions and safely handle needles and sharps.
- Consider the risks from tattooing and body piercing, which may cause transmission from dirty instruments.
- HCV positive individuals should not donate blood, organs, or tissue.

Recommendations for Testing for HCV based on risk for HCV Infection

Persons	Risk of Infection	Testing Recommended
Injecting drug users	High	Yes
Recipients of clotting factors made before 1987	High	Yes
Hemodialysis patients	Intermediate	Yes
Recipients of blood and/or solid organs before 1992	Intermediate	Yes
People with undiagnosed liver problems	Intermediate	Yes
Infants born to infected mothers	Intermediate	After 12-18 months old
Healthcare/public safety workers	Low	Only after known exposure
People having sex with multiple partner	Low	No*
People having sex with an infected steady partner	Low	No*

*Anyone wishing to be tested may ask his or her health care provider.

Blood & Body Fluids Exposure: HIV

Most exposures to blood and body fluids do not result in infections. The risk of infection varies with:

- The amount of blood involved in the exposure
- The amount of virus in the person's blood at the time of exposure
- Whether post-exposure treatment was taken
- The immune status of the exposed individual
- Route of exposure (parenteral, sexual, mucosal, etc.)

Risk of Transmission

- The average risk of HIV infection after a needlestick/cut exposure to HIV-infected blood is 0.3% (about 1 in 300). Stated another way, 99.7% of needlestick/cut exposures do not lead to infection.
- The risk of exposure of the eye, nose, or mouth to HIV-positive infected blood is estimated to be, on average, 0.1% (1 in 1,000).
- The risk after exposure of the skin to HIV-infected blood is estimated to be less than 0.1%.
- The risk following one unprotected intercourse with an HIV positive individual is 0.1 %-0.3% (receptive penile and sexual exposure) & 0.1 %-0.2% (receptive vaginal exposure) . There are no published estimates of the risk of transmission from receptive oral exposure, but transmission has been reported.

Management

- Immediate treatment is of utmost importance
- Needle sticks and cuts should be washed with soap and water
- Splashes to the nose, mouth, or skin should be flushed with water
- Eyes should be irrigated with clean water, saline, or sterile irrigants
- **If prophylaxis is chosen, HIV Post-Exposure should optimally be given within 1-2 hours after the exposure.** Although animal studies suggest that treatment is not effective when started more than 24-36 hours after exposure, it is not known if this time frame is the same for humans. Starting treatment after a longer period (e.g., 1-2 weeks) may be considered for the highest risk exposures; even if HIV infection is not prevented, early treatment of initial HIV infection may lessen the severity of symptoms and delay the onset of AIDS.
- Contact the **National Clinician's Post-Exposure Prophylaxis Hotline at 888-448-4911 for risk assessment and current medications to be given for prophylaxis.**
- **If post-exposure treatment is started, obtain a CBC, kidney (BUN/creatinine) and liver function tests just before treatment and 2 weeks after starting treatment.**

Follow-up treatment includes

- Obtain HIV antibody testing as soon as possible after exposure to establish a baseline and then again at 6 weeks, 12 weeks, and 6 months.
- Report any sudden or severe flu-like illness (fever, rash, muscle aches, tiredness, malaise, or swollen glands), especially during the first 6-12 weeks after exposure.
- Refrain from blood, semen, or organ donation and abstain from sexual intercourse (or use a latex condom) for 12 weeks after exposure until the 12-weeks HIV test is completed.
- Women should not breast-feed infants during the follow-up period to prevent exposing their infant to HIV in breast milk.

Botulism - Foodborne

Botulism - Foodborne

Organism: *Clostridium botulinum,* a spore forming obligate anaerobic bacillus that produces a neurotoxin.

Incubation period: 12-36 hours is the usual range. The shortest time is 6 hours and the longest is 10 days. Generally, the shorter the incubation period, the more severe will be the disease.

Infectious period: No person-to-person transmission has ever been documented.

Transmission route: Oral ingestion. Foodborne. In Alaska, all documented cases have been associated with Alaska Native fermented foods.

For a discussion of infant and wound botulism (rare events), see Control of Communicable Diseases Manual.

Treatment: Close observation and monitoring of respiratory Forced Vital Capacity (FVC) should be done. Supportive medical and nursing care with the capability to intubate and place on a ventilator needs to be present. Antitoxin is available for types A, B, and E and should be administered early in the course of the illness after sensitivity testing is completed. Botulinum antitoxin is stored in pharmacies at major hub hospitals (see list attached.) Antitoxin cannot reverse the neurotoxin but can prevent further toxin from attaching to the neurons. Antimicrobial agents, especially aminoglycosides, should be avoided as they could increase the amount of toxin available for absorption.

Information Needed for the Investigation

Verify the Diagnosis

- Is there a history of eating Native fermented foods or home-canned vegetables?
- Are three of the following five symptoms present—nausea or vomiting, dysphagia, diplopia, dilated fixed pupils, or dry mouth or throat?
- Is there evidence of cranial nerve involvement such as fixed dilated pupils, facial paralysis, ptosis, hoarseness or difficulty swallowing?

Determine the Extent of Illness

- Determine if household or other contacts are ill or are at risk for disease (consumption of suspected contaminated food). Contact a local health care provider, public health nurse, patient or family member.

- Try to obtain a 5-day food history from the patient or from someone who knows what he/she may have eaten.
- Identify suspected food sources. While "fermented" foods have traditionally been thought of as the major culprit, it is important to consider all possible food sources. In addition to Alaska Native fermented foods, recent botulism cases in other states have been traced to baked potatoes wrapped in foil, frozen potpies, grilled onions and garlic stored in oil.
- Retrieve and refrigerate suspect foods and their containers. If the food is a commercial product, obtain the brand name, lot number and distributor and notify DEC.

Laboratory Specimens

- From the patient collect 15 ml (2 red top tubes) of blood before administration of the anti-toxin.
- Collect 25-50 gm of stool.
- Collect any emesis or gastric aspirate.
- Collect suspected food samples and bag separately. DEC or OEH can sometimes help with food collection.
- Specimens should be refrigerated, not frozen.
- All specimens and a specimen form for each should be sent to the Alaska State Public Health Laboratory in Anchorage.

Note: Collect 25-50 gm stool from others who ate the suspect food.

Contact and Control Measures

- The goal is to identify other persons at risk and evaluate them for symptoms of botulism. This can be done through the Community Health Aide or the Public Health Nurse. If neither of these individuals is available, an EPI team member should travel to the area.
- Determine the source of infection to prevent other cases. This is done through a 5-day food history, interviews, and epidemiology principles applied as in any foodborne outbreak.
- Determine the need for administration of botulism anti-toxin and if necessary send more out to the regional health care facility.

Reporting Requirements

- FTR: Write up all confirmed and probable cases.
- Write a case summary and file for all suspected negative cases.
- Morbidity Database: Enter all confirmed and probable cases.
- CDC Case Definition is used to define confirmed and probable cases of botulism.

STATE OF ALASKA
DEPARTMENT OF HEALTH & SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY
3601 C STREET, SUITE 540
P.O. BOX 240249
ANCHORAGE, ALASKA 99524-0249
FRANK H. MURKOWSKI, GOVERNOR
INFECTIOUS DISEASES
AIDS/STD
TUBERCULOSIS
IMMUNIZATION
CHRONIC DISEASES
DIABETES
INJURY CONTROL
(907) 269-8000
(907) 562-7802

Botulism Fact Sheet

(Intestinal or Foodborne botulism)

What is botulism?

Botulism is a rare but serious illness that can result in paralysis and death. A nerve toxin that is produced by the bacteria *Clostridium botulinum* causes it. There are three main kinds of botulism. Eating foods that contain the toxin causes foodborne botulism. Consuming the spores of the bacteria, which then grow in the intestines and release toxin, causes infant botulism. Cutaneous or wound botulism occurs among injection drug users.

All forms of botulism can be fatal and are considered medical emergencies. Foodborne botulism is especially dangerous because many people can become ill from eating the same food. Foodborne botulism is the most common form of botulism in Alaska.

What are the symptoms of botulism?

The classic symptoms of botulism include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, and muscle weakness. Infants with botulism appear lethargic, feed poorly, are constipated, and have a weak cry and poor muscle tone.

If untreated, these symptoms may progress to cause paralysis of the arms, legs, trunk, and respiratory muscles.

How soon do symptoms appear?

Symptoms of botulism usually appear 12–36 hours after eating the contaminated food, but can occur as early as 6 hours or as late as 10 days.

What is the treatment for botulism?

Treatment for botulism requires medical and nursing care. If diagnosed early, foodborne botulism can be treated with an antitoxin that blocks the action of toxin circulating in the blood. This can prevent illness from worsening but recovery still takes many weeks. Physicians may try to remove contaminated food still in the gut by inducing vomiting or by using enemas. Difficulty in breathing may require a person to be on a breathing machine (ventilator) for weeks. Currently, antitoxin is not routinely given for treatment of infant botulism.

Untreated botulism may result in death.

How can botulism be prevented?

Botulism can be prevented. Foodborne botulism has come from home-canned foods, chopped garlic in oil, tomatoes, and improperly handled baked potatoes wrapped in aluminum foil. In Alaska, eating contaminated home-canned fish or fermented foods causes most botulism.

Food Safety Tips

1. Wash your hands, your containers and your food before preparing your food.
2. Use proper methods when preparing fermented Native foods. Do not use plastic, glass or sealed plastic bags as these create an environment encouraging the growth of the bacteria. Use salt to preserve dried fish and discourage the growth of *C. botulinum* bacteria.
3. Ferment food at a cold temperature, ideally below 37 degrees Fahrenheit. This discourages the growth of *C. botulinum* bacteria.
4. Consider boiling home-canned food to reduce the risk. Heat destroys botulinum toxin and this can be the best way to reduce the risk of botulism from eating fermented foods.
5. **When in doubt, throw it out.**

Botulism Investigation Flowsheet

Suspected botulism reported:
Acute onset of symmetrical paralysis in a patient whose mental status is generally intact.
Three or more subjective symptoms of botulism
AND one objective neurological finding

History of eating Native fermented OR smoked foods

YES

Collect serum (up to 15 ml) of blood into "tiger" top or red top tube.
Collect serum before administration of antitoxin.
Collect stool, gastric aspirate, and emesis.
Collect suspect foods.
Refrigerate specimens after collection; do not freeze.
Send specimens to ASPHL - Anchorage. Notify ASPHL so they may prepare for specimens' arrival.

Recommend giving Botulism antitoxin per protocol.
Assess and monitor the patient closely for evidence of decreased respiratory function.
Ship or arrange for shipment of botulism antitoxin kits.

Notify the regional nurse manager, OR **PHN** in the region AND **OEH**.

Consider traveling to the location of the Botulism suspect
or where the exposure occurred **if**:
1. there is not an experienced health aide in the village.
2. the suspect food was eaten by many people requested by the health care provider.

NO

NOTE: Sudden appearance of multiple patients with acute onset of illness suggestive of botulism without a history of eating Native foods is characteristic of a Bio-terrorist Event. Notify supervisor immediately.
Notify **CDC** at 770-488-7100
Notify **FBI** at 276-4441 and/or **SECC** at 428-7000 (**SEE Bioterrorism Section)**

Obtain history for potential toxic exposures to organophosphates, belladonna alkaloids, carbon monoxide, aminoglycosides, shellfish.

Consider differential diagnosis of:
Guillain-Barre Syndrome; CVA, brain mass lesion; lung carcinoma (Lamber-Eaton syndrome); toxic exposure
(In Botulism, the LP, MRI, CT and CXR are normal.)

Botulism Investigation Summary

Date_____

Name_____ DOB_____ Sex_____

Address_____ Phone_____

Health Care Provider's Name_____ Phone_____

Date & Time of suspected food consumption _____
Date & Time of onset of symptoms _____

Symptoms
***The presence of three or more of these signs should raise the *suspicion* of botulism**

	Yes	No	Unk		Yes	No	Unk
Nausea or vomiting*	___	___	___	Fatigue	___	___	___
Dysphagia*	___	___	___	Sore throat	___	___	___
Diplopia*	___	___	___	Dizziness	___	___	___
Dilated fixed pupils*	___	___	___	Urinary Retention	___	___	___
Dry throat / mouth*	___	___	___	Muscle Weakness	___	___	___
Abdominal Pain	___	___	___	Upper distal	___	___	___
Dysphonia	___	___	___	Upper proximal	___	___	___
Dyspnea	___	___	___	Lower distal	___	___	___
Blurred Vision	___	___	___	Lower proximal	___	___	___
Photophobia	___	___	___	Where did muscle weakness start			_____
Constipation	___	___	___				
Diarrhea	___	___	___				
Paresthesias	___	___	___				
Convulsions	___	___	___				

Other _____
_____

Physical Exam

	Yes	No	Unk		Yes	No	Unk
Ptosis	___	___	___	Abnormal Sensory	___	___	___
Extraocular Palsy	___	___	___	Specify_____			
Pupils							
Dilated	___	___	___	Ataxia	___	___	___
Constricted	___	___	___	Symmetrical	___	___	___
Mid-position	___	___	___				
Reactive	___	___	___	Nystagmus	___	___	___
Equal	___	___	___				
Facial Paralysis	___	___	___	DTRs			
Symmetric	___	___	___	Normal	___	___	___
Decreased Gag	___	___	___	Hypoactive	___	___	___
Decreased tongue				Hyperactive	___	___	___
protrusion	___	___	___	Symmetric	___	___	___
Weakness or Paralysis							
of extremity	___	___	___	Abnl Mental Status	___	___	___
upper	___	___	___				
lower	___	___	___	Resp. Impairment	___	___	___
Toes (Babinski reflex)	___	___	___	Decreasing FVC	___	___	___
Bradycardia <60	___	___	___	Low Systolic BP <100	___	___	___

Laboratory

Specimens Sent to CDC Lab Yes___ No___

Type of Sample	Date of Sample	Toxin result	Date of results	Culture result	Sample Not obtained
Pretreatment serum					
Gastric Aspirate Vomitus					
Stool					
Food –specify					
Food – specify					

Treatment

Was antitoxin serum administered? Yes___ No___ Unknown___
Number of vials administered _____
Type of antitoxin given AB ___ E ___
Sensitivity testing done? Yes___ No___
Any adverse reaction to the antitoxin? Yes___ No___ Unknown___
If yes, describe adverse reaction _____
_____
_____
_____

Was a ventilator required? Yes___ No___ Unknown___
Comments_____
_____
_____
_____

Outcome

Did the patient live? Yes___ No___ Unknown___

Date patient released from hospital ____/____/____ Not Hospitalized___

Final Diagnosis (circle)
Botulism Dehydration
Stroke Other_____
Guillain-Barre

If botulism, number of cases in the outbreak ____
Number using antitoxin ____

Botulism Specimen Collection

Foodborne Botulism

From the patient(s) collect:

- 15-20 ml of pre-anti-toxin administration serum—NOT whole blood
- 25-50 gm of feces
- 15-20 ml of gastric aspirate or emesis

Obtain the remainder of suspect food in the original container.

From others who ate suspect food:

- 25-50 gm feces

Infant Botulism

- 2 ml of serum—NOT whole blood
- as much feces as possible, up to 25-50 gm.

Wound Botulism

- 15-20 ml of serum
- 25-50 gm of feces
- Tissue, exudates or swab samples from the wound

Packaging and Shipment

- Send by Goldstreak.
- Lab slip required: Miscellaneous Examination

Testing

- Testing will be performed at the State Public Health Laboratory–Anchorage

Botulism - 1996 *(Clostridium botulinum)*

Case Definition

- Foodborne
- Infant
- Wound
- Other

Botulism, Foodborne

Clinical description

Ingestion of botulinum toxin results in an illness of variable severity. Common symptoms are diplopia, blurred vision, and bulbar weakness. Symmetric paralysis may progress rapidly.

Laboratory criteria for diagnosis

- Detection of botulinum toxin in serum, stool, or patient's food, or
- Isolation of *Clostridium botulinum* from stool

Case classification

Probable: a clinically compatible case with an epidemiologic link (e.g., ingestion of a home-canned food within the previous 48 hours)
Confirmed: a clinically compatible case that is laboratory confirmed or that occurs among persons who ate the same food as persons who have laboratory-confirmed botulism

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Botulism, Infant

Clinical description

An illness of infants, characterized by constipation, poor feeding, and “failure to thrive” that may be followed by progressive weakness, impaired respiration, and death

Laboratory criteria for diagnosis

- Detection of botulinum toxin in stool or serum, or
- Isolation of *Clostridium botulinum* from stool

Case classification

Confirmed: a clinically compatible case that is laboratory-confirmed, occurring in a child aged less than 1 year

Botulism, Wound

Clinical description

An illness resulting from toxin produced by *Clostridium botulinum* that has infected a wound. Common symptoms are diplopia, blurred vision, and bulbar weakness. Symmetric paralysis may progress rapidly.

Laboratory criteria for diagnosis

- Detection of botulinum toxin in serum, or
- Isolation of *Clostridium botulinum* from wound

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed in a patient who has no suspected exposure to contaminated food and who has a history of a fresh, contaminated wound during the 2 weeks before onset of symptoms

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Botulism, Other

Clinical description

See Botulism, Foodborne.

Laboratory criteria for diagnosis

- Detection of botulinum toxin in clinical specimen, or
- Isolation of *Clostridium botulinum* from clinical specimen

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed in a patient aged greater than or equal to 1 year who has no history of ingestion of suspect food and has no wounds

BOTULISM ANTITOXIN IN ALASKA

Kit #	Type A&B	Type E	Histatrol	Location	Chief Pharmacist	Contact Phone	Fax	Status
C	03/03/08	5/11/02**	12/31/07	**Alaska Native Medical Center** 4315 Diplomacy Dr. Anchorage, AK 99508	Chief-Gary Givens Alt-John Coleman	(907)729-2130	(907)729-2135	Holding
1	03/03/08	5/11/02**	12/31/07	**Bartlett Memorial Hospital** 5260 Hospital Dr. Juneau, AK 99801	Chief-Kim Poole Alt-Barb Stevenson	(907)586-8412	(907)586-8443	Holding
2	03/03/08	5/11/02**	12/31/07	**Bartlett Memorial Hospital** 5260 Hospital Dr. Juneau, AK 99801	Chief-Kim Poole Alt-Barb Stevenson	(907)586-8412	(907)586-8443	Holding
9	03/03/08	5/11/02**	12/31/07	**Fairbanks Memorial Hospital** 1650 Cowles St. Fairbanks, AK 99701	Chief-John Cotter Alt-Maria Brackney	(907)458-5617	(907)458-5623	Holding
10	03/03/08	5/11/02**	12/31/07	**Fairbanks Memorial Hospital** 1650 Cowles St. Fairbanks, AK 99701	Chief-John Cotter Alt-Maria Brackney	(907)458-5617	(907)458-5623	Holding
G	03/03/08	5/11/02**	12/31/07	**EPI-DEPOT** 9210 Vanguard Dr. Ste 102A Anchorage, AK 99507	Sharon Hamrick	(907)341-2202	(907)341-2228	Holding
H	03/03/08	5/11/02**	12/31/07	**EPI-DEPOT** 9210 Vanguard Dr. Ste 102A Anchorage, AK 99507	Sharon Hamrick	(907)341-2202	(907)341-2228	Holding
I	03/03/08	5/11/02**	12/31/07	**EPI-DEPOT** 9210 Vanguard Dr. Ste 102A Anchorage, AK 99507	Sharon Hamrick	(907)341-2202	(907)341-2228	Holding
J	03/03/08	5/11/02**	12/31/07	**EPI-DEPOT** 9210 Vanguard Dr. Ste 102A Anchorage, AK 99507	Sharon Hamrick	(907)341-2202	(907)341-2228	Holding
K	03/03/08	5/11/02**	12/31/07	**EPI-DEPOT** 9210 Vanguard Dr. Ste 102A Anchorage, AK 99507	Sharon Hamrick	(907)341-2202	(907)341-2228	Holding
L	03/03/08	5/11/02**	12/31/07	**EPI-DEPOT** 9210 Vanguard Dr. Ste 102A Anchorage, AK 99507	Sharon Hamrick	(907)341-2202	(907)341-2228	Holding
N/A	Type E (6 vials expire 11/28/08)			**EPI-DEPOT 9210 Vanguard Dr. Ste 102A Anchorage, AK 99507**	Sharon Hamrick	(907)341-2202	(907)341-2228	Holding
N/A	Type E (1 vial expires 5/11/02**)			**EPI-DEPOT 9210 Vanguard Dr. Ste 102A Anchorage, AK 99507**	Sharon Hamrick	(907)341-2202	(907)341-2228	Holding
**** The CDC has extended the expiration of the Botulism Type E Antitoxin. See letter attached to Vial for further explanation.**								
6	03/03/08	5/11/02**	12/31/07	**Kanakanak Hospital** 6000 Kanakanak Rd. PO Box 130 Dillingham, AK 99576	Chief-Brooks Hurley Alt-Luke Cullins	(907)842-9235	(907)842-9240	Holding

BOTULISM ANTITOXIN IN ALASKA

Kit #	Type A&B	Type E	Histatrol	Location	Chief Pharmacist	Contact Phone	Fax	Status
27	03/03/08	5/11/02**	12/31/07	**Kanakanak Hospital** 6000 Kanakanak Rd. PO Box 130 Dillingham, AK 99576	Chief-Brooks Hurley Alt-Luke Cullins	(907)842-9235	(907)842-9240	Holding
13	03/03/08	5/11/02**	12/31/07	**Ketchikan General Hospital** 3100 Tongass Ave. Ketchikan, AK 99901	Chief-James Buchanan	(907)228-8300 option 4, then option 1	(907)228-8339	Holding
14	03/03/08	5/11/02**	12/31/07	**Ketchikan General Hospital** 3100 Tongass Ave. Ketchikan, AK 99901	Chief-James Buchanan	(907)228-8300 option 4, then option 1	(907)228-8339	Holding
3	03/03/08	5/11/02**	12/31/07	**Maniilaq Medical Center** PO Box 43 Kotzebue, AK 99752	Janet Richardson	(907)442-7182	(907)442-7309	Holding
4	03/03/08	5/11/02**	12/31/07	**Maniilaq Medical Center** PO Box 43 Kotzebue, AK 99752	Janet Richardson	(907)442-7182	(907)442-7309	Holding
23	03/03/08	5/11/02**	12/31/07	**Norton Sound Regional Hospital** 5 Bering St. PO BOX 966 Nome, AK 99762	Chief-Robert Guy Alt-David Herrin	(907)443-3319	(907)443-2847	Holding
24	03/03/08	5/11/02**	12/31/07	**Norton Sound Regional Hospital** 5 Bering St. PO BOX 966 Nome, AK 99762	Chief-Robert Guy Alt-David Herrin	(907)443-3319	(907)443-2847	Holding
D	03/03/08	5/11/02**	01/31/07	**Norton Sound Regional Hospital** 5 Bering St. PO BOX 966 Nome, AK 99762	Chief-Robert Guy Alt-David Herrin	(907)443-3319	(907)443-2847	Holding
E	03/03/08	5/11/02**	12/31/07	**Norton Sound Regional Hospital** 5 Bering St. PO BOX 966 Nome, AK 99762	Chief-Robert Guy Alt-David Herrin	(907)443-3319	(907)443-2847	Holding
F	03/03/08	5/11/02**	12/31/07	**Norton Sound Regional Hospital** 5 Bering St. PO BOX 966 Nome, AK 99762	Chief-Robert Guy Alt-David Herrin	(907)443-3319	(907)443-2847	Holding
11	03/03/08	5/11/02**	12/31/07	**Samuel Simmonds Memorial Hospital** 1296 Agvik St. PO BOX 29 Barrow, AK 99723	Chief-Jerry Steed Alt-Napolean Onyechi	(907)852-4611 option 4, then option1	(907)852-4237	Holding
12	03/03/08	5/11/02**	12/31/07	**Samuel Simmonds Memorial Hospital** 1296 Agvik St. PO BOX 29 Barrow, AK 99723	Chief-Jerry Steed Alt-Napolean Onyechi	(907)852-4611 option 4, then option1	(907)852-4237	Holding

BOTULISM ANTITOXIN IN ALASKA

Kit #	Type A&B	Type E	Histatrol	Location	Chief Pharmacist	Contact Phone	Fax	Status
21	03/03/08	5/11/02**	12/31/07	**SEARHC/Mt Edgecumbe Hospital** 222 Tongass Dr. Sitka, AK 99835	Chief-Traci Gale Alt-Jill Reid	(907)966-8309 Alt# 966-8347	(907)966-8450	Holding
19	03/03/08	5/11/02**	12/31/07	**Y-K Delta Regional Hospital** 700 Chief Eddie Hoffman Hwy. PO BOX 287 Bethel, AK 99559	Chief-Younga Vercelline Alt-Melanie Gibson	(907)543-6382 option 1, then option 6	(907)543-6306	Holding
26	03/03/08	5/11/02**	12/31/07	**Y-K Delta Regional Hospital** 700 Chief Eddie Hoffman Hwy. PO BOX 287 Bethel, AK 99559	Chief-Younga Vercelline Alt-Melanie Gibson	(907)543-6382 option 1, then option 6	(907)543-6306	Holding
B	03/03/08	5/11/02**	12/31/07	**Y-K Delta Regional Hospital** 700 Chief Eddie Hoffman Hwy. PO BOX 287 Bethel, AK 99559	Chief-Younga Vercelline Alt-Melanie Gibson	(907)543-6382 option 1, then option 6	(907)543-6306	Holding
18	03/03/08	5/11/02**	12/31/07	**EPI-DEPOT** 9210 Vanguard Dr. Ste 102A Anchorage, AK 99507	Sharon Hamrick	(907)341-2202	(907)341-2228	Cannibalized 3/20/06
28	03/03/08	5/11/02**	12/31/07	**EPI-DEPOT** 9210 Vanguard Dr. Ste 102A Anchorage, AK 99507	Sharon Hamrick	(907)341-2202	(907)341-2228	Cannibalized 3/20/06
29	03/03/08	5/11/02**	12/31/07	**EPI-DEPOT** 9210 Vanguard Dr. Ste 102A Anchorage, AK 99507	Sharon Hamrick	(907)341-2202	(907)341-2228	Cannibalized 3/20/06
5	03/03/08	5/11/02**	01/31/06	**Kanakanak Hospital** 6000 Kanakanak Rd. PO Box 130 Dillingham, AK 99576	Chief-Brooks Hurley Alt-Luke Cullins	(907)842-9235	(907)842-9240	USED 9/12/05
7	03/03/08	5/11/02**	01/31/06	**SEARHC/Mt Edgecumbe Hospital** 222 Tongass Dr. Sitka, AK 99835	Chief-Traci Gale Alt-Jill Reid	(907)966-8309 Alt# 966-8347	(907)966-8450	OUT OF TEMP replaced with kit #21
8	03/03/08	5/11/02**	01/31/06	**SEARHC/Mt Edgecumbe Hospital** 222 Tongass Dr. Sitka, AK 99835	Chief-Traci Gale Alt-Jill Reid	(907)966-8309 Alt# 966-8347	(907)966-8450	OUT OF TEMP replaced with kit #21
15	03/03/08	5/11/02**	12/31/05	**Y-K Delta Regional Hospital** 700 Chief Eddie Hoffman Hwy. PO BOX 287 Bethel, AK 99559	Chief-Younga Vercelline Alt-Melanie Gibson	(907)543-6382 option 1, then option 6	(907)543-6306	Used 08/21/05
16	03/03/08	5/11/02**	01/31/06	**Y-K Delta Regional Hospital** 700 Chief Eddie Hoffman Hwy. PO BOX 287 Bethel, AK 99559	Chief-Younga Vercelline Alt-Melanie Gibson	(907)543-6382 option 1, then option 6	(907)543-6306	Used 08/21/05

BOTULISM ANTITOXIN IN ALASKA

Kit #	Type A&B	Type E	Histatrol	Location	Chief Pharmacist	Contact Phone	Fax	Status
17	03/03/08	5/11/02**	01/31/06	**Y-K Delta Regional Hospital** 700 Chief Eddie Hoffman Hwy. PO BOX 287 Bethel, AK 99559	Chief-Younga Vercelline Alt-Melanie Gibson	(907)543-6382 option 1, then option 6	(907)543-6306	Used 08/22/05
20	03/03/08	5/11/02**	12/31/05	**Norton Sound Regional Hospital** 5 Bering St. PO BOX 966 Nome, AK 99762	Chief-Robert Guy Alt-David Herrin	(907)443-3319	(907)443-2847	Unaccounted for as of 3/7/06 (Holding)
22	03/03/08	5/11/02**	12/31/05	**Norton Sound Regional Hospital** 5 Bering St. PO BOX 966 Nome, AK 99762	Chief-Robert Guy Alt-David Herrin	(907)443-3319	(907)443-2847	Used 3/1/06
25	03/03/08	5/11/02**	01/01/07	**Y-K Delta Regional Hospital** 700 Chief Eddie Hoffman Hwy. PO BOX 287 Bethel, AK 99559	Chief-Younga Vercelline Alt-Melanie Gibson	(907)543-6382 option 1, then option 6	(907)543-6306	Used 08/22/05
A	03/03/08	5/11/02**	10/31/07	**Alaska Native Medical Center** 4315 Diplomacy Dr. Anchorage, AK 99508	Chief-Gary Givens Alt-John Coleman	(907)729-2130	(907)729-2135	Damaged in Transit

**** The CDC has extended the expiration of the Botulism Type E Antitoxin. See letter attached to Vial for further explanation.**

Botulism Kit Packing List

(Revised April 2006)

1. New Botulism Treatment Instructions (Effective April 5, 2006) with
   Attachment A for Treating Physician:
   - Patient Consent Form/Parental Permission Form
   - Suspected Botulism Clinical Outcome Report
   - Botulism Antitoxin Questionnaire
   - FDA Form 1572 "Statement of Investigator"

2. Botulism Treatment Packet (Prepared by the US Centers for Disease Control and Prevention)

3. "Guide to Skin Testing For Sensitivity to Botulinum Antitoxin" (blue paper)

4. "Protocol for Use of Botulinum Antitoxin (Equine) Type E" (green paper)

5. Botulism Antitoxin Administration Flow Chart

6. One vial of Botulism Antitoxin Types A and B (licensed) with package insert

7. One vial of Botulism Antitoxin Type E (investigational)

8. One vial of Histatrol® (Positive Skin Test Control – Histamine)

9. One Allergy Syringe Testing Tray 27g x 3/8 inch (25 needles/tray)

10. One ruler

Questions??
Report all suspected cases of botulism immediately to:

Section of Epidemiology
907-269-8000 during business hours
1-800-478-0084 after hours

New Botulism Treatment Instructions

Effective April 2006

Botulism is both a medical and public health emergency. As soon as the patient(s) is stable, any suspected case of botulism should be immediately reported to the **Alaska Division of Public Health, Section of Epidemiology**: call 1-907-269-8000 during business hours or 1-800-478-0084 after hours.

Two vials of botulism antitoxin are now required to treat suspected cases of botulism: one vial of Botulism Antitoxin Bivalent Types A and B (hereafter referred to as Type AB) and one vial of Botulism Antitoxin Type E. **Type E antitoxin is currently available only as an investigational drug.** Therefore, you must follow the specific instructions below. You may refer to the documentation supplied by the **US Centers for Disease Control and Prevention (CDC)** for more details. However, the instructions below were designed to resolve conflicting information found in the CDC materials and package inserts.

Overview of treatment plan

1. Obtain patient consent to participate in investigational new drug trial.
2. Obtain blood specimen for botulism testing.
3. Order pregnancy testing (if patient is a woman of childbearing age).
4. Collect stool and vomitus for botulism testing.
5. Save suspected food.
6. Conduct sensitivity testing. (Note: Use the CDC document "Guide to Skin Testing for Sensitivity to Botulinum Antitoxin," **printed on blue paper**. Disregard sensitivity testing instructions in the document entitled "Protocol for Botulinum Antitoxin Type E," **printed on green paper**. Sensitivity testing is for use of equine products, not for use of a particular type of botulinum antitoxin. The document entitled "Protocol for Botulinum Antitoxin Type E" is included because it contains the Type E antitoxin desensitization protocol, should it be needed.)
7. *If sensitivity testing is negative*, administer botulism antitoxin **intravenously**. Give one vial of Type E antitoxin followed by one vial of Type AB antitoxin.
8. *If sensitivity testing is positive*, administer botulism antitoxin using **desensitization protocol**. First give Type E antitoxin; follow with Type AB antitoxin.

Detailed, step-by-step instructions

Warning: Make sure you read and understand these instructions, including those for botulism antitoxin sensitivity testing, before proceeding.

1. Type E botulism antitoxin is an investigational drug. **Before administering Type E antitoxin, patients must provide informed consent.** A blank consent form is included in **Attachment A for Treating Physician**. After the patient understands the information on the consent form, have him/her sign it in the appropriate space on the back. If the patient is too ill to give informed consent, next of kin (if available) should sign. If next-of-kin are not available, the treating physician can proceed – be sure to complete the relevant portions on the back of the consent form.

2. Draw 20 cc of whole blood in red top tubes. Ask your laboratory to separate the serum, discard the cells, and refrigerate the serum. Your laboratory should hold the serum pending instructions from the Section of Epidemiology.
3. If the patient is a woman of childbearing age, obtain blood or urine for a pregnancy test. **Pregnancy is not a contraindication for administration of antitoxin–antitoxin does not need to be held pending results of the pregnancy test.** Pregnancy testing is required only as part of the drug protocol, not to determine if antitoxin should be withheld.
4. Whenever possible, obtain stool, vomitus, and gastric contents for botulism testing. Send these clinical specimens to your laboratory and ask them to be held pending instructions from the Section of Epidemiology.
5. Save any suspect food items brought to the hospital by the patient or family member(s). Food should be refrigerated, sent to your laboratory, and held pending instructions from the Section of Epidemiology.
6. Sensitivity testing must be performed before administration of either Type E or Type AB antitoxin can proceed.

   If the sensitivity test is negative, **1 vial of Type E antitoxin** should be administered intravenously. Dilute the Type E vial in 100 ml of sterile normal saline. The solution should be brought to room temperature and then administered slowly IV over at least 30 minutes. Epinephrine solution (1:1000) and other appropriate agents should be available for immediate use if an anaphylactic reaction occurs.

   Stop the infusion if the patient develops signs or symptoms of hypersensitivity (wheezing, respiratory distress, generalized urticaria, edema, cyanosis, hypotension, etc.). At this point, you should determine if the Type AB antitoxin should either be administered by the desensitization protocol (see H, below) or not administered at all.

   If the patient tolerates the Type E infusion, administer **1 vial of Type AB antitoxin**. Dilute the Type AB vial in 100 ml of sterile normal saline. The solution should be brought to room temperature and then administered slowly IV over at least 30 minutes. Epinephrine solution (1:1000) and other appropriate agents should be available for immediate use if an anaphylactic reaction occurs.

   > Note: The Type AB antitoxin should **not** be administered using the same bag or IV lines as was used for the Type E antitoxin: **you must change the IV bag and lines before starting the Type AB infusion**.

7. If a patient has a positive reaction to the sensitivity test, antitoxin should be administered according to the desensitization protocols in the package inserts for Type AB and Type E antitoxin. (The Type E package insert is titled “Protocol for Botulinum Antitoxin Type E” and is included in the materials supplied by the CDC. As an investigational drug, the Type E vial is boxed without a package insert). First administer Type E antitoxin using the Type E desensitization protocol. If this is successful, follow with Type AB antitoxin using the desensitization procedure in the Type AB antitoxin package insert.

Detailed information from CDC and the manufacturer are included. Some of the information included in these materials is outdated and contradictory. Disregard all references to:

- Intramuscular administration of antitoxin
- Administration of antitoxin in a 1:10 dilution
- Use of antitoxin for asymptomatic persons (prophylaxis)
- Use of partial vials of antitoxin
- Use of multiple vials of Type E or Type AB antitoxin
- Concurrent use of Types AB and Type E antitoxin
- Sensitivity testing as described in the "Protocol for Botulinum Antitoxin Type E"

For further clarification regarding the administration of botulism antitoxin, call the Section of Epidemiology at any time, 24 hours a day.

Attachment A for Treating Physician:

Patient Consent Form/Parental Permission Form
Suspected Botulism Clinical Outcome Report
Botulism Antitoxin Questionnaire
FDA Form 1572 "Statement of Investigator"

Enclosed:

Botulism Treatment Packet (prepared by the US Centers for Disease Control and Prevention)
"Protocol for Botulinum Antitoxin Type E" **on green paper**
Guide to Skin Testing for Sensitivity to Botulinum Antitoxin" (prepared by the US Centers for Disease Control and Prevention) **on blue paper**

ATTACHMENT A: FOR TREATING PHYSICIAN

Botulism Antitoxin (Equine) Type E

PATIENT CONSENT FORM/PARENTAL PERMISSION FORM

Flesch-Kincaid Grade Level: 7.5

The Centers for Disease Control and Prevention (CDC) and your State Health Department are able to offer Botulism Antitoxin Type E (BAT-E) for emergency treatment of botulism. Your doctor thinks that you/your child may have botulism caused by type E toxin. The only drug currently available for type E botulism is a research product (investigational new drug, IND). It has not been approved by the Food and Drug Administration (FDA) for use in the United States. Your doctor thinks it is the best treatment you can get.

BACKGROUND
Botulism is an illness caused by a toxin that is made by a group of bacteria. The toxin can result in serious paralysis (loss of motion) or death because the toxin interferes with the normal sending of nerve signals. Signs of botulism can begin as early as three hours or as late as several days after being exposed to the toxin. Signs include blurred vision, weakness, problems with swallowing and talking, dizziness, nausea, vomiting, constipation and stomach cramps. If the drug is given soon after the signs begin, the signs will be less severe. The time it takes to recover will be less.

BENEFIT OF TREATMENT
The benefit is that you/your child will receive a drug that is likely to reduce signs of botulism. Also you/your child may have a higher risk of dying without this treatment. Without drug treatment, the paralysis may last longer and affect more parts of the body. This may require a longer time to recover in a hospital.

METHODS
Your doctor will do a skin test to see if you/your child are allergic to horse (equine) products. If this test shows that you/your child may have an allergic response, then your doctor may give you the drug in very small doses. This will lower the risk for a reaction to the product. Your doctor may also give you other medicines to lower the risk. First the skin test will be done. Then you/your child will be given the drug by a needle placed directly into your vein. You/your child will be asked to have blood tests before and 24 hours after treatment and at/after hospital discharge. These blood tests will measure the amount of toxin or antitoxin in your blood. They are used to help prove that you have botulism and to follow your progress. The largest amount of blood drawn at any time will not be more than 2 tablespoons for adults and children over 1 year of age, or 1 teaspoon for infants less than 1 year old.

RISK
The risk of getting any drug by vein includes brief pain from the needle, minor bleeding, and a skin bruise around the site. There may also be soreness and swelling at the site. It is also possible to get an infection where the needle entered the skin.

The risk of having blood drawn for tests is brief pain from the needle, minor bleeding, and a skin bruise.

A small amount (5% or less of the total population) of persons are allergic or sensitive to horse products. A reaction to this type of product would include fever, chills, and an unpleasant sensation. In such a case, standard medical methods would be used to treat these reactions. Rarely a severe reaction (less than 1%) can occur. This causes a rapid drop in blood pressure and difficulty in breathing. This may require emergency treatment and a machine to assist breathing. Skin testing shortly before giving the drug can identify allergic persons. Steps can then be taken to lower the risk.

A small number of (less than 5%) persons who get horse serum, may develop fever, hives, and a rash a 7 to 14 days after treatment. This is also known as serum sickness. It can be treated with standard drugs. These symptoms can last for several weeks. One out of ten persons with serum sickness may also get pains in the joints or back. This can be with or without joint swelling. These signs will go away after a few weeks.

PREGNANCY

There are no known extra risks of drug treatment for the pregnant woman or fetus. Botulism is a severe life-threatening illness. The benefit of treatment for the mother and the fetus is felt to be much greater than the risk of problems from the product itself. Pregnancy test (blood or urine test) in all women of child-bearing age will be done.

MEDICAL RECORDS/CONFIDENTIALITY

People from the local health department, the CDC, and the FDA may read your medical records about this illness. They may collect data from these records. All data about you/your child will be kept private to the extent allowed by law. You/your child will not be named if results of this study are published.

STATEMENT OF VOLUNTARY PARTICIPATION

Treatment with the IND drug is for you alone to decide. You may refuse or stop treatment at any time. You/your child will not lose the ability to receive medical care. There is no plan for payment of medical costs resulting from problems which are the result of you/your child receiving this drug. You/your child are not giving up any legal rights that otherwise would be available to you/your child. You are entitled to receive a copy of this document.

CDC is providing the drug at no cost. CDC has set aside no funds to pay for lab tests.

If you have any questions or concerns about your rights as a participant or you think you may have been harmed in this research study, please contact the office of CDC's Deputy Associate Director for Science at no cost to you by calling 1-800-584-8814. Please leave a brief message including your name, phone number, and mention that you are calling in reference to CDC protocol # 8771. Someone will return your call as soon as possible.

CONSENT

Signing this consent form means that you have read the document or had it read to you. It means that you agree to receive or have your child receive a research drug. Signing this consent form means you agree to let the local/state health department, CDC, and the FDA see your medical records.

I have read and understand the above. I have had my questions answered. I agree to be part of the study.

Signature of patient or guardian_____

Date _____

Type/Print name of
patient_____

IF PATIENT IS INCAPABLE OF PROVIDING INFORMED CONSENT

If the patient is too ill to give informed consent; and if next of kin cannot be found after a solid try to locate them; and if the illness is life threatening, a physician has made the decision to begin this treatment:

Signature of physician: _____

Date: _____

Time of day: _____ AM/PM (circle one)

Type/print name of physician: _____

Efforts to reach the next of kin have included the following (describe):

There may be blood left over from your sample after the tests. This blood will be stored at CDC for future research if you agree. You may choose not to have your sample stored for future research and still be part of this study. Also, you may agree to have your sample stored and later decide that you want to withdraw it from storage. If so, you should call the study person

listed in this consent form and tell him/her to discard your sample. The sample will be discarded as you instruct. But any data from testing your sample until that point will remain part of the research

We ask you to agree to freeze part of your blood and other fluid samples at CDC. We will use these samples for botulism research in the future. We are not sure what studies might be done. But if any test results seem to have meaning for your health, we will inform you or your doctor, as you direct. Some tests we do may be experimental and have no clear meaning to your health. In those cases, we will not report any results to you or your doctor. We will not test your samples for HIV or other STDs. Also, we do not plan to do any genetic testing on your samples.

If results of the future testing are medically important to me or my child CDC will make every attempt to locate me.

☐ I agree to allow storage and future research of my/my child's sample.

☐ I do not agree to allow storage of my/my child's sample.

Signature of patient or guardian

_____

Date_____

Form 2 (version 03/27/2001)

Suspected Botulism Clinical Outcome Report

PLEASE PLACE ON FRONT OF PATIENT CHART:

To be filled out and faxed/mailed to CDC at The time Patient is Discharged from hospital.

Send to: **Centers for Disease Control and Prevention**
Foodborne and Diarrheal Disease Branch
Mail Stop A 38
1600 Clifton Rd.
Atlanta, GA 30033
Phone: 404-639-2206

OR **Fax to: 404-639-2205**

THANK YOU.

Person filling out Form: _____ Date: _____/_____/_____ ***(mm/dd/yyyy)***
Patient=s Name: _____
Hospital: _____ State: _____
Attending Physician: _____ Phone: _____ Fax: _____

Clinical Outcome ***(Please circle the appropriate answer)***

1. Was the diagnosis of botulism confirmed? YES NO DK
   If no:
   A. What was the final diagnosis? _____
2. Did patient require mechanical ventilation? YES NO DK
   If yes:
   A. How many days was patient on a ventilator? _____ days
3. Did the patient require a tracheostomy? YES NO DK
   If yes:
   A. When was the tracheostomy done? ____/____ /_____ ***(mm/dd/yyyy)***
4. Did the patient develop pneumonia? YES NO DK
5. How many days was patient hospitalized? _____ days
6. How many days was patient in intensive care? _____ days
7. Describe the clinical course of paralysis after administration of the antitoxin
   _____
   _____
8. Was there residual paralysis? YES NO DK
9. Did the patient survive? YES NO DK
   If yes:
   A. Was patient discharged from hospital to ***(circle appropriate answer)***:
      Home Nursing home Rehabilitation facility Other
      Specify other _____
   B. Did the patient have residual disability on discharge? YES NO DK
      Explain _____
   If no:
   A. What was the cause of death? _____

Thank you. Please return to CDC at the contact information above.

BOTULISM ANTITOXIN QUESTIONNAIRE

Revised 1/97

The Foodborne and Diarrheal Diseases Branch of the Centers for Disease Control and Prevention is the national center for consultation of suspected botulism and is responsible for providing botulism antitoxin for therapy. If you have given botulism antitoxin to a patient, we need your assistance. Please complete and return this form for each patient receiving antitoxin.

Patient's name _____/_____ age____ (years) sex ___
last first

Person filling out this form_____ Date_____

Attending physician _____

BOTULISM ANTITOXIN

SENSITIVITY TESTING

Was sensitivity testing done prior to antitoxin administration? yes___ no___

If yes, at what site (ie. Skin)_____
what route(ie. subcutaneously)?_____
what dosage and diluent?_____
result_____

ANTITOXIN ADMINISTRATION

Antitoxin given by intravenous (IV) injection:

date	time	number of vials given	lot no.
_____		_____	_____
_____		_____	_____

Antitoxin given by intramuscular (IM) injection:

date	time	number of vials given	lot no.
_____		_____	_____
_____		_____	_____

ANTITOXIN REACTIONS (excluding reactions during sensitivity testing)
Please circle "yes" or "no" to each of the following reactions. For each "yes" answer, please indicate how soon reaction began after the start of the antitoxin treatment, and how long the reaction lasted.

		If yes, how soon after?	lasting how long?
Fever:	yes no	_____	_____
Chills:	yes no	_____	_____
Rash:	yes no	_____	_____

If rash, describe_____

		If yes, how soon after?	lasting how long?
Urticaria:	yes no	_____	_____

If urticaria, describe_____

		If yes, how soon after?	lasting how long?
Swelling/edema:	yes no	_____	_____

If swelling/edema, describe location_____

		If yes, how soon after?	lasting how long?
Other hypersensitivity:	yes no	_____	_____

If other, describe_____

		If yes, how soon after?	lasting how long?
Anaphylaxis:	yes no	_____	_____

If anaphylaxis, describe_____

		If yes, how soon after?	lasting how long?
Serum sickness:	yes no	_____	_____

If serum sickness, describe_____

		If yes, how soon after?	lasting how long?
Other reactions:	yes no	_____	_____

If other reaction, describe_____

If the patient received any treatment for a reaction, or antitoxin administration was stopped, please describe _____

CLINICAL HISTORY

Please indicate which symptoms and signs were noted in the patient before the antitoxin was administered. (We recognize that signs and symptoms sometime progress after administration of antitoxin, but we do not want these later findings recorded here.)

SYMPTOMS	yes	no	don't know
Abdominal pain	___	___	____
Nausea	___	___	____
Vomiting	___	___	____
Diarrhea	___	___	____
Blurred vision	___	___	____
Diplopia	___	___	____
Dizziness	___	___	____
Slurred speech	___	___	____
"Thick tongue"	___	___	____
Change in sound of voice	___	___	____
Hoarseness	___	___	____
Dry mouth	___	___	____
Difficulty swallowing	___	___	____
Shortness of breath	___	___	____
Subjective weakness	___	___	____
Fatigue	___	___	____
Paresthesia	___	___	____

site_____

SIGNS	yes	no	don't know	check if bilateral
Altered Mental State	___	___	____	
Extraocular palsy	___	___	____	____
Ptosis	___	___	____	____
Pupils dilated	___	___	____	____
Pupils constricted	___	___	____	____
Pupils fixed	___	___	____	____
Pupils reactive	___	___	____	____
Facial paralysis	___	___	____	____
Palatal weakness	___	___	____	
Impaired gag reflex	___	___	____	
Wound	___	___	____	

If yes, describe_____

Please indicate if weakness or paralysis was noted in the patient before the antitoxin was administered.

Weakness or paralysis of:	check if yes	no	don't know	bilateral
Upper extremities	___	___	____	____
upper distal	___	___	____	____
upper proximal	___	___	____	____
Lower extremities	___	___	____	____
lower distal	___	___	____	____
lower proximal	___	___	____	____

Describe weakness/paralysis:

ascending (beginning in lower extremities, progressing to upper extremities, then cranial nerves)

yes___ no___ don't know____

descending (beginning with cranial nerves, progressing to upper extremities, then (in some cases) to lower extremities)

yes___ no___ don't know____

comments_____

LABORATORY RESULTS

Please list the laboratory results which were available before the patient received antitoxin.

Were lumbar puncture results available? yes___ no___

RBC_____ WBC_____ Protein_____ Glucose_____

Were Tensilon (edrophonium chloride) test results available? yes___ no___

Results_____

Were electromyography (EMG) results available? yes___ no___

Which muscle groups were used_____

Results_____

Was rapid repetitive stimulation performed: yes___ no___

At what hertz_____ Results_____

Please FAX form to: Foodborne and Diarrheal Diseases Branch at (404) 639-2205

or mail form to: Foodborne and Diarrheal Diseases Branch
Mailstop C09, Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, Georgia 30333

THANK YOU FOR YOUR ASSISTANCE

The following label will be attached to each vial of Botulinum Antitoxin Type E provided to CDC for distribution under this IND:

Distributed by:
Centers for Disease Control & Prevention
Drug Service D-09
Atlanta, GA 30333 (404)639-3670
Caution: New Drug Limited by Federal
Law to Investigational use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR

(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)
(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014.
Expiration Date: September 30, 2002.
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

(Treating physician)

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFIES THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS ATTACHED.

☒ CURRICULUM VITAE ☐ OTHER STATEMENT OF QUALIFICATIONS

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED.

N/A

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY.

N/A

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES).

CDC IRB
1600 Clifton Rd.
Atlanta, GA 30333

6. NAMES OF THE SUBINVESTIGATORS *(e.g., research fellows, residents, associates)* WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATION(S).

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR.

Botulinum Antitoxin Type E
BB-IND 8771

Created by: PSC Media Arts Branch (301) 443-2454 EF

8. ATTACH THE FOLLOWING CLINICAL PROTOCOL INFORMATION:

☐ FOR PHASE 1 INVESTIGATIONS, A GENERAL OUTLINE OF THE PLANNED INVESTIGATION INCLUDING THE ESTIMATED DURATION OF THE STUDY AND THE MAXIMUM NUMBER OF SUBJECTS THAT WILL BE INVOLVED.

☐ FOR PHASE 2 OR 3 INVESTIGATIONS, AN OUTLINE OF THE STUDY PROTOCOL INCLUDING AN APPROXIMATION OF THE NUMBER OF SUBJECTS TO BE TREATED WITH THE DRUG AND THE NUMBER TO BE EMPLOYED AS CONTROLS, IF ANY; THE CLINICAL USES TO BE INVESTIGATED; CHARACTERISTICS OF SUBJECTS BY AGE, SEX, AND CONDITION; THE KIND OF CLINICAL OBSERVATIONS AND LABORATORY TESTS TO BE CONDUCTED; THE ESTIMATED DURATION OF THE STUDY; AND COPIES OR A DESCRIPTION OF CASE REPORT FORMS TO BE USED.

9. COMMITMENTS:

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64.

I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR:

1. Complete all sections. Attach a separate page if additional space is needed.
2. Attach curriculum vitae or other statement of qualifications as described in Section 2.
3. Attach protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND ATTACHMENTS TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND).

10. SIGNATURE OF INVESTIGATOR	11. DATE

(**WARNING:** A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

Public reporting burden for this collection of information is estimated to average 100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CBER (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
CDER (HFD-94)
12229 Wilkins Avenue
Rockville, MD 20852

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please **DO NOT RETURN** this application to this address.

BOTULISM TREATMENT PACKET

Guide to Skin Testing For Sensitivity to Botulinum Antitoxin

Rationale for Guide:

You have received,

1.) 1 vial of Botulinum Antitoxin Types A & B, with package insert (and possibly a second vial of Botulinum Antitoxin Type E). This vial contains the amount needed for all skin tests and therapeutic administration.

2.) 1 vial of Histatrol (histamine phosphate 2.75 mg/mL for percutaneous testing) with package insert.

Botulinum antitoxin is a horse serum product. Because a small (< 1%) proportion of patients are allergic to horse products, it is recommended that patients be tested for this allergy by skin test before the therapeutic horse serum is administered. This additional 5-page, step-by step illustrated instructional insert is intended to help guide proper execution of the skin testing procedure and interpretation of results. **These instructions supercede all instructions in the Botulinum Antitoxin package insert and the Histatrol® package insert**. This guide includes an overview of the skin testing procedure (pp.1-2), detailed skin testing instructions (p. 3), photographs illustrating positive and negative skin tests (p. 4), and a flow chart of the procedure (p. 5).

Definition of Terms:

Negative Control: Control illustrating non-reaction
Positive Control: Control illustrating a positive (acute allergic) reaction
Botulinum Antitoxin: Equine origin antibody preparation for treatment of botulism
Histatrol (histamine phosphate): a reagent that produces acute allergic reaction on skin testing; serves as a positive control illustrating what an allergic reaction would look like when testing for sensitivity to botulinum antitoxin.
Normal Saline: Reagent that produces no allergic reaction on skin testing; serves as a negative control illustrating what a skin test with no reaction would look like when testing for sensitivity to botulinum antitoxin. (Normal saline is not included in package.)

Overview of Skin Testing Procedures:

Epinephrine Hydrochloride Solution (1:1000) and other appropriate agents must be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs. In addition, the patient should be placed in a comfortable position during the tests and the test areas should be cleaned with alcohol before testing.

You will perform skin tests using the left arm for the controls (saline and histamine phosphate) and the right arm for the test (Botulinum Antitoxin types A&B):

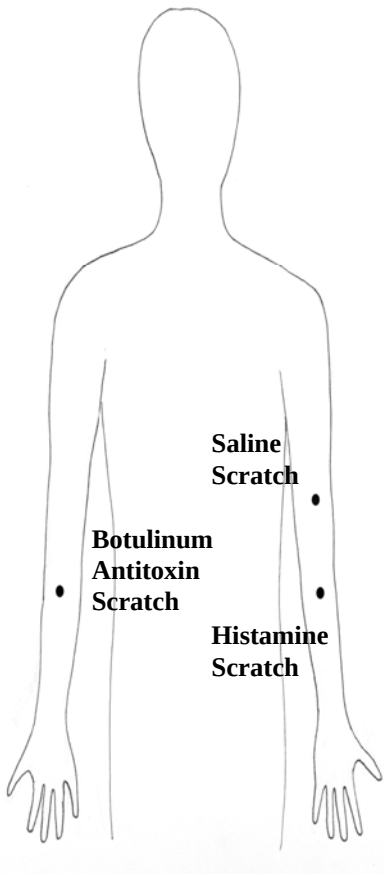
1. Normal saline as the negative control (left arm)
2. Histamine phosphate 2.75mg/mL as the positive control (left arm)
3. Botulinum Antitoxin Types A & B at 1:100 dilution (right arm)
   (prepared by diluting 0.1 mL antitoxin serum in 10mL normal saline)

Tests are performed by making a small scratch in the skin and placing a small drop of the solution to be tested on the site of the scratch.

Interpretation of Results:

Photographs are provided in this guide (p. 4) to assist with interpretation of the results.

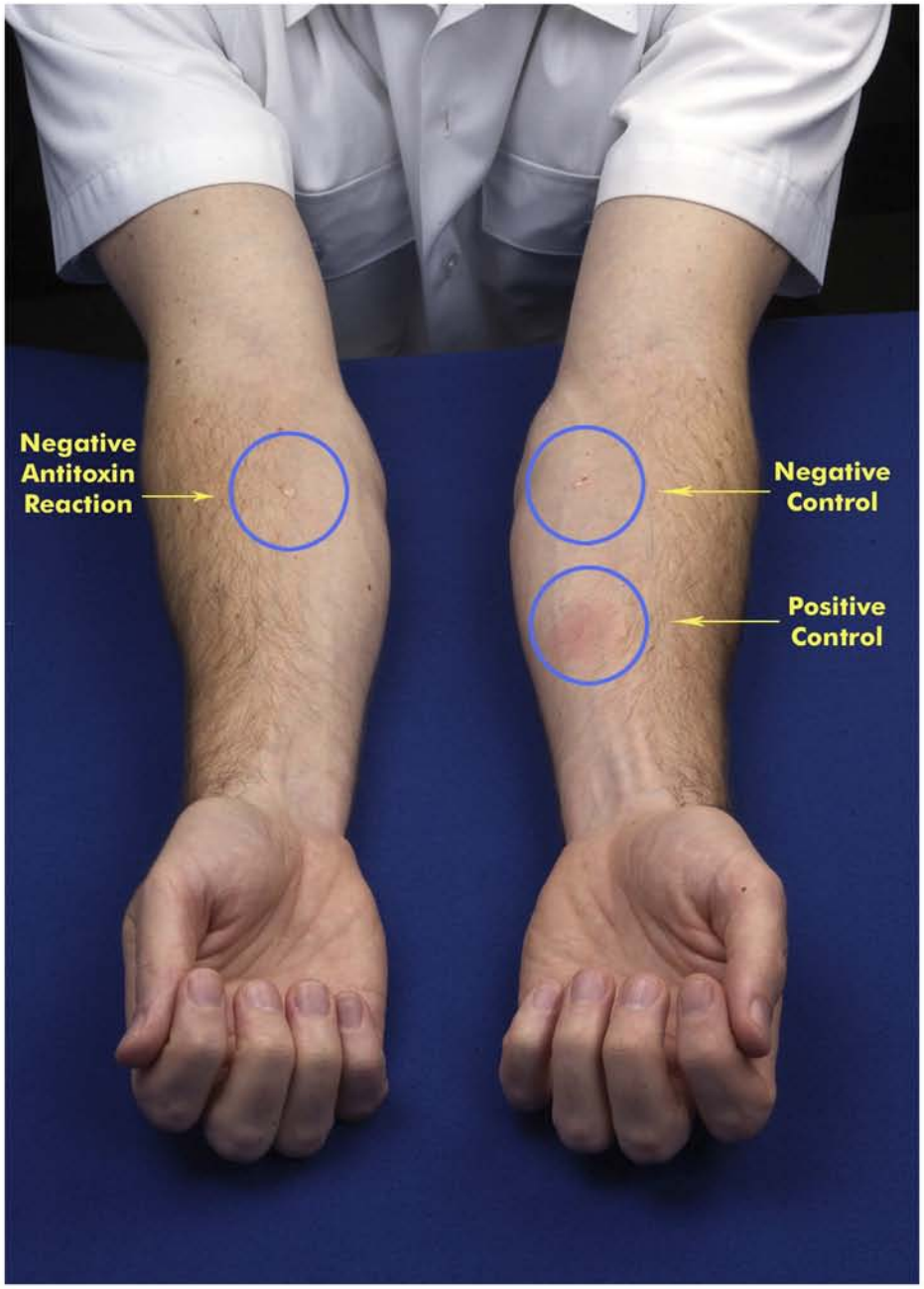
- If the test arm (right arm) reaction looks like the negative control (normal saline), then the patient has no allergic reaction to the Botulinum Antitoxin and may be treated.
- If the test arm (right arm) reaction looks like the positive control (Histamine Phosphate), then the patient is allergic and must undergo desensitization before treatment. (See package insert for desensitization protocol.)

STEP	PROCEDURE	ILLUSTRATION
1.	**SCRATCH TEST:**	
A.	**Negative Skin Test Control—Saline Solution (left arm)** a. Carefully scratch the skin approximately 2mm-4mm in length with a sterile needle (27 gauge) without drawing blood. b. Place a small drop of normal saline on the site of the scratch. c. Read the test at 15 minutes; no reaction should occur	
B.	**Positive Skin Test Control- Histamine (Histatrol) (left arm)** a. Choose a site on the arm at least 5 cm from any other test site. Carefully scratch the skin approximately 2mm-4mm with a sterile needle (27 gauge) without drawing blood. b. Using dropper from Histatrol vial (Histamine Phosphate 2.75 mg/mL for percutaneous testing), place a small drop of Histatrol on the site of the scratch. c. Read the test at 15 minutes; if a large wheal reaction occurs before that time, the test site should be wiped free of histamine	
C.	**Botulinum Antitoxin Types A & B Testing (right arm)** a. Dilute 0.1 mL antitoxin serum in 10 mL normal saline to make a 1:100 dilution of botulinum antitoxin serum. b. Choose a site on the arm at least 5 cm from any other test site. Carefully scratch the skin approximately 2mm-4mm in length with a sterile needle (27 gauge) without drawing blood. c. Place a small drop of a 1:100 dilution of the botulinum antitoxin serum in normal saline on the site of the scratch. d. Read the test at 15 minutes; no reaction should occur. A reaction indicates the patient is allergic and requires desensitization.	

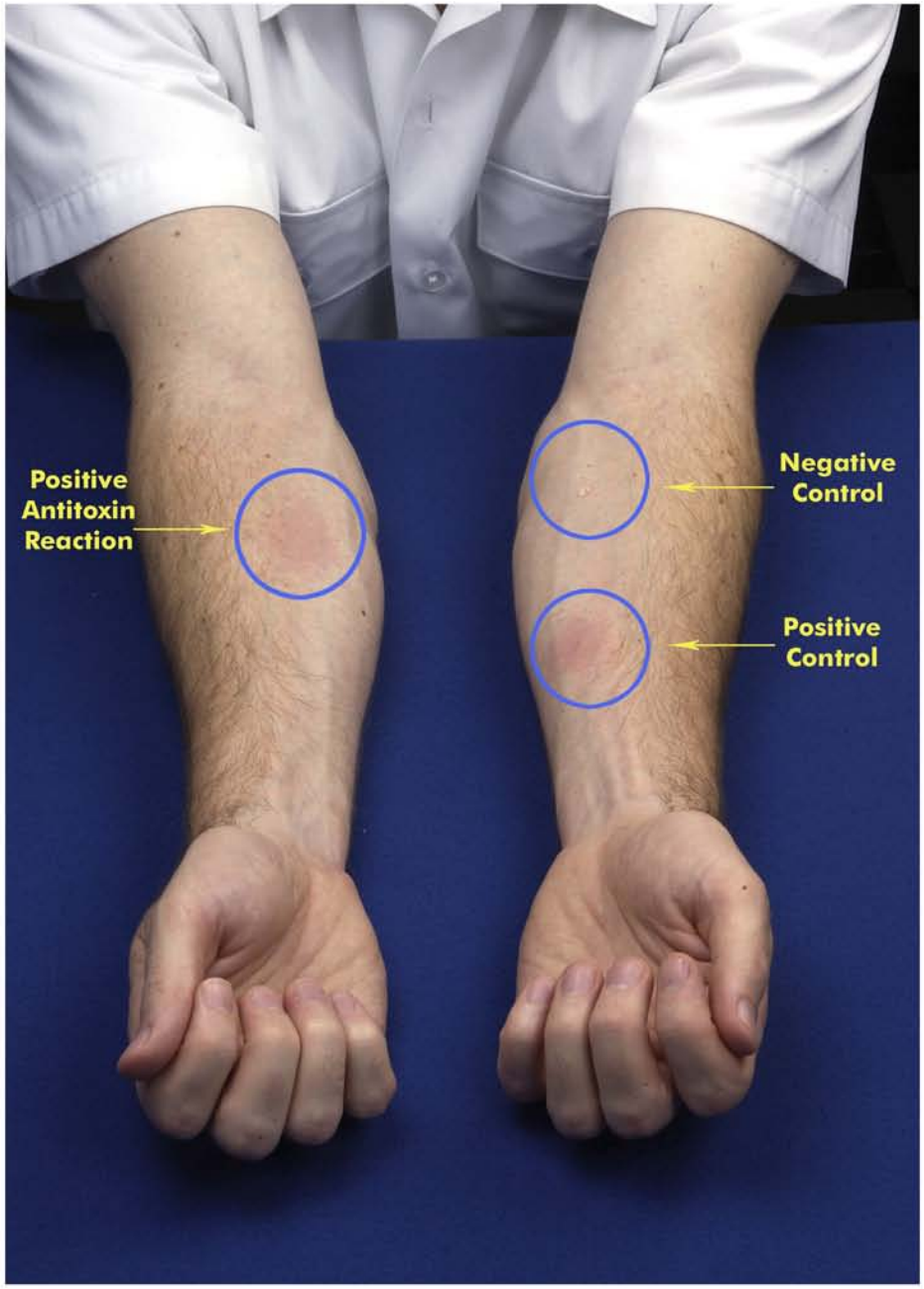
EXPLANATION OF RESULTS

If the patient has a **negative** skin test (Botulinum Antitoxin test site on right arm looks like the Saline Solution test site on left arm), botulinum antitoxin can be administered to the patient.

If the patient has a **positive** skin test (Botulinum Antitoxin test site on right arm looks like the Histamine (HISTATROL) test site on left arm), **patient requires desensitization before administering dose of antitoxin**. If patient experiences a systemic reaction (e.g., hypotension, respiratory distress, generalized rash) administer epinephrine as necessary. See package insert for desensitization protocol.



Negative Skin Test



Positive Skin Test

Flow Chart Insert for Botulinum Antitoxin Types A & B Administration

Perform scratch test as described in text:

A. Saline Solution - left arm
B. Histamine - left arm
C. Botulinum Antitoxin - right arm

Result

Scratch Test:
A. Saline Solution (left arm) = negative
B. Histamine (left arm) = positive
C. Botulinum Antitoxin (right arm) = **positive**

YES → **Positive Scratch Test** → Patient requires **desensitization before administering** therapeutic dose of antitoxin intravenously. If patient experiences a systemic reaction, treat as necessary.

Scratch Test:
C. Saline Solution (left arm) = negative
D. Histamine (left arm) = positive
E. Botulinum Antitoxin (right arm) = **negative**

YES → **Negative Scratch Test** → Administer therapeutic dose of botulinum antitoxin intravenously.

Scratch Test:
A. Saline Solution (left arm) = positive

OR

B. Histamine (left arm) = negative

YES → **Indeterminate Scratch Test** → Consider repeating procedure. Consult CDC Foodborne and Diarrheal Diseases Branch on call epidemiologist.

Use of Botulinum Antitoxin (Equine) Type E For The Treatment Of Persons Thought To Be Suffering From Type E Botulism And For The Prophylaxis Of Type E Botulism.

A Manufacturer Sponsored Treatment Investigational New Drug (IND) Proposal

Table of Contents:

1. Introduction.....Pages 2 - 3

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3. Informed Consent Form.....Pages 12 -15

4. Botulism Antitoxin Questionnaire.....Pages 16 -19

5. Copy of Attached Label to BAT-E.....Page 20

INTRODUCTION/BACKGROUND

This Treatment Investigational New Drug (IND) Application was filed by Pasteur Merieux Connaught, now Aventis Pasteur, and approved by the FDA in order to provide Botulism Antitoxin (Equine) Type E for treatment of persons thought to be suffering from type E botulism. The company originally manufactured a licensed Botulism Antitoxin Trivalent (Equine) Types A, B and E (BAT-ABE) for distribution and use in the United States until 1999. Due to potency problems with the E component, Aventis was unable to blend the three antitoxin serotypes for a final product that would meet the concentration as stated in their original BLA. Consequently, Aventis had to supply two separate products for distribution in the United States: a licensed Botulism Antitoxin Bivalent (Equine) Types A and B (BAT AB) and a Treatment IND Botulism Antitoxin (Equine) Type E (BAT E or Type E antitoxin).

In early 2003, CDC purchased the balance of the Aventis Pasteur Botulism Antitoxin Type AB and Type E for storage in the Strategic National Stockpile (SNS). There are two lots of type BAT E: 120-12 and 121-12. Aventis has stated that they will no longer manufacture botulism antitoxin , but will conduct routine potency testing on Lot 120-12 and Lot 121-12 to allow for continued use of lots 120-12 and 121-12 Type E antitoxin when potency falls below the currently labeled 5000 IU per vial. When the potency falls below the labeled 5000 IU per vial, number of vials to be administered will be increased according to the potency test results.

There are no specific indications that are to be investigated under this Amendment to the Treatment IND. The protocol enclosed with this Amendment to the Treatment IND lists no research questions to be answered or data analyses to be conducted. Nevertheless, should it become necessary for BAT E to be used under this Treatment IND, data on the clinical course and outcome of the patient will be obtained from the treating physician as described in the enclosed protocol. These patient reports will be forwarded to Aventis Pasteur and the FDA as part of the annual report for this Treatment IND.

The intended use of the drug:

Botulism Antitoxin (Equine), Type E specifically neutralizes the toxins produced by *Clostridium botulinum* type E and is indicated for the treatment of persons thought to be suffering from type E botulism and for the prophylaxis of type E botulism.

Rationale for use of the drug:

Type E antitoxin is required for treatment primarily of native populations in the northwest United States and in Alaska. Without this treatment, persons suffering from Type E botulism have a high risk of death. To the best of our knowledge, there is no other supply of Type E antitoxin available in North America for use in humans.

Criteria for patient selection:

Persons exhibiting signs and symptoms of Type E botulism or persons suspected of consuming food contaminated with *Clostridium botulinum* Type E or Type E toxin**.**

Method of administration of drug and dosage:

See package insert (information attached below and entire package insert attached with each vial of BAT E), section 'DOSAGE AND ADMINISTRATION.'

Description of clinical procedures, laboratory tests, or other measures to monitor the effects of the drug and to minimize risk:

See package insert (information attached below and entire package insert attached with each vial of BAT E), sections 'CLINICAL PHARMACOLOGY,' 'WARNING,' 'PRECAUTIONS,' 'ADVERSE REACTIONS,' and 'DOSAGE AND ADMINISTRATION,'

Information brochure for supplying to each treating physician:

The following information (attached below) is contained in the package insert attached to each vial of BAT E.

Additional technical information that is relevant to safety and effectiveness of the drug for the intended treatment purpose:

Lots 120-12 and 121-12 have been satisfactorily tested to meet all the requirements for Type E antitoxin in Aventis Pasteur's current license.

BOTULISM ANTITOXIN (EQUINE) Type E

For Prevention or Treatment of Botulism, Type E.[1]

DESCRIPTION
Botulism Antitoxin (Equine), Type E as supplied by Aventis Pasteur is a processed and concentrated liquid preparation of horse (equine) globulins modified by enzymatic digestion. It is clear and straw-coloured in appearance.

Each vial was formulated to contain Botulism antitoxin:
Type E 5000 International Units (I.U.) and phenol 0.4% w/v as a preservative.

Routine potency assays will continue to be performed by Aventis Pasteur Limited to determine how many I.U. each vial contains. If potency assays demonstrate botulism antitoxin value of less than 5,000 IU/vial, two vials of Botulism Antitoxin Type E will be administered.

Trace amounts of equine blood substance A and residual porcine pepsin may be present.

CLINICAL PHARMACOLOGY

Experimental evidence concerning the amount of circulating antitoxin needed to counteract botulinum toxin poisoning by antitoxin therapy is not fully documented. The outcome of treatment depends, as it does in other comparable conditions, largely on the time interval elapsing after onset of symptoms before the peak of absorbed antitoxin is reached. This principle has been illustrated in animal experiments.[1]

Clinical trials of type E botulism antitoxin in Canada and in Japan showed that dosages of not more than 5000 I.U. of type E antitoxin, administered (as a rule) intravenously, proved remarkably efficacious.[2,3] Since the mouse-protective value of one I.U. of types A and B antitoxin is several times that of one I.U. of type E antitoxin, the relative proportions of types A and B present in Botulism Antitoxin Types A and B (Equine) are believed to be adequate to establish a level of neutralizing capacity in the blood stream, against the homologous toxins, of several times the level shown to be clinically efficacious for type E antitoxin. One or more vials of Botulism Antitoxin (Equine), Type E may be necessary to provide adequate circulating antibody of each type, depending upon the severity of the toxemia and body weight of individual being treated.

Serum levels of equine-botulism antitoxin to types A, B, and E were measured in four type-A botulism patients who received trivalent botulism antitoxin. High circulating levels capable of neutralizing 1×10^8, 9×10^7, and 6×10^6 50% mouse lethal doses of types A, B, and E, respectively were detected. Peak serum levels of antitoxin were 10 – 1,000 times higher than amounts needed to neutralize the toxin measured in the serum of these and other patients with botulism.[4]

Patients who received antitoxin in the first 24 hours after onset of signs and symptoms had a lower fatality rate (10 percent) than those who received antitoxin more than 24 hours after onset (15 percent fatality) or those who did not receive antitoxin at all (46 percent fatality). Patients who received antitoxin in the first 24 hours after onset had fewer days in the hospital, fewer

days on a ventilator, and fewer days to sustained improvement than patients who received late antitoxin.[5]

INDICATIONS

Botulism Antitoxin (Equine), Type E specifically neutralises the toxins produced by *Clostridium botulinum* type E and is indicated for the treatment of persons thought to be suffering from type E botulism and for the prophylaxis of type E botulism.[6]

A blood sample of serum (from 20 mL of blood) should be collected before administration of antitoxin to aid in diagnosis.[7]

Botulism Antitoxin (Equine), Type E may be administered consecutively with Botulism Antitoxin Bivalent (Equine), Types A and B if the type of Botulism is not known and is suspected to be A, B or E.

WARNINGS

Precautionary Measures in the Administration of any Serum or Antitoxin
Before administering Botulism Antitoxin (Equine), Type E to a patient, physicians should ascertain whether the patient has a history of asthma, hay fever, or urticaria, whether the patient suffers distress when in proximity to horses, as well as history of previous injections of equine serum. Patients with such a history may develop serious anaphylactic reactions upon the administration of serum of equine origin either subcutaneously, intramuscularly or intravenously. Those who have previously received serum of equine origin are at increased risk of developing allergic reactions and serum sickness after administration of sera from the same animal species.[8] (See section Tests for Sensitivity to Serum or Antitoxin)

Intramuscular injections should be given with care in persons suffering from coagulation disorders or on anticoagulant therapy because of the risk of haemorrhage.[6]

PRECAUTIONS

General
The possibility of allergic reactions in individuals sensitive to components of Botulism Antitoxin (Equine), Type E should be evaluated. Epinephrine Hydrochloride Solution (1:1000) and other appropriate agents should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs. Health care providers should be familiar with current recommendations for the management of anaphylaxis, including proper airway management.[6]

Skin tests for sensitivity should be done before any injection of antitoxin, regardless of whether or not the patient has had the serum previously.[8] (see Tests for Sensitivity to Serum or Antitoxin)

Caution
A separate sterile needle and syringe, or a sterile disposable unit, must be used for each individual patient to prevent the transmission of infectious agents.

There have been case reports of transmission of HIV and hepatitis by failure to scrupulously observe sterile technique. In particular, the same needle and/or syringe must never be used to re-enter a multi-dose vial to withdraw antitoxin even when it is to be used for inoculation of the same patient. This may lead to contamination of the vial contents and infection of patients who subsequently receive antitoxin from the vial.[9]

Needles should not be recapped and should be disposed of properly.

Equine antitoxin rarely has been used in infant botulism because of the risk of inducing lifelong hypersensitivity to equine antigens and lack of evidence of its benefit.[8]

ADVERSE REACTIONS

Approximately 20% of treated persons experience some degree of hypersensitivity reaction.[8]

1. Anaphylactic reactions have been reported following administration of equine sera.

2. Acute febrile reactions.

3. Serum Sickness: Manifestations consist of fever, urticaria, or maculopapular rash (90% of cases); arthritis or arthralgia; and lymphadenopathy which usually begin 7 to 10 days after the primary exposure. Local edema can occur at the serum injection site a few days before the systemic signs and symptoms appear. Angioedema, glomerulonephritis, Guillain-Barré syndrome, peripheral neuritis and myocarditis also can occur. However, serum sickness may be mild and resolve spontaneously within a few days to 2 weeks. Black and Gunn found that the incidence of serum sickness in patients treated with botulism antitoxin equine was highest for persons who received more than four vials (30,000 I.U. Type A, 22,000 I.U. Type B, 34,000 I.U. Type E).[10]

Persons who have previously received equine serum injections are at an increased risk after re-administration; manifestations in these patients occur shortly (from hours to 2 or 3 days) after administration.

In populations at risk for repeated exposures to botulism toxin because of particular food habits, the repeated use of prophylactic antitoxin can lead to an increased incidence of severe reactions. Caution should therefore be exercised in the use of botulism antitoxin in such circumstances.[6]

Physicians, nurses, and pharmacists should report any adverse occurrences temporally related to the administration of the product in accordance with local requirements and to the Medical Director, Aventis Pasteur Limited, 1755 Steeles Avenue West, Toronto, Ontario, Canada, M2R 3T4.

DOSAGE AND ADMINISTRATION

Tests For Sensitivity To Serum Or Antitoxin
Skin tests for sensitivity should be done before any injection of antitoxin, regardless of whether or not the patient has had the serum previously.[8] Sensitivity to any particular serum or antitoxin

may be gauged by several methods, including the following:[8]

Whereas intradermal skin tests have resulted in fatalities, the scratch test is usually safe. Therefore, scratch tests always should precede the intradermal tests. Nevertheless, any sensitivity test or injection of a serum always should be performed by trained personnel familiar with the treatment of acute anaphylaxis; necessary medications and equipment should be readily available.[8]

1. Scratch, prick, or puncture test. Apply one drop of a 1:100 dilution of the serum in preservative-free normal saline to the site of a superficial scratch, prick, or puncture on the volar aspect of the forearm. Positive (histamine) and negative (physiologic saline) control tests for the scratch test also should be applied. A positive test is a wheal with surrounding erythema at least 3 mm larger than the negative control test, read at 15 to 20 minutes. The histamine control must be positive for valid interpretation. If the scratch test is negative, an intradermal (ID) test is performed.[8]

2. Intradermal (ID) test. A dose of 0.02 mL of 1:1000 saline-diluted serum (enough to raise a small intradermal wheal) is administered. Positive and negative control tests as described for the scratch test also should be applied. If the test is negative, it should be repeated using a 1:100 dilution. In persons with negative history for both animal allergy and prior exposure to animal serum, the 1:100 dilution may be used initially if a scratch, prick, or puncture test with the serum is negative. Interpretation is the same as for the scratch test.[8]

Although a positive (histamine) control is recommended for accurate interpretation of sensitivity tests, sensitivity testing and treatment with Botulism Antitoxin type E (Equine) should not be deferred because of lack of availability of histamine control.

Positive tests not due to an irritant reaction indicate sensitivity, but a negative skin test is not an absolute guarantee of lack of sensitivity. Therefore, animal sera should be administered with caution even in persons whose tests are negative. Immediate hypersensitivity testing is performed to identify IgE-mediated disease and does not predict other immune reactions such as serum sickness.[8]

If the intradermal test is positive or if the history for systemic anaphylaxis after previous administration of serum is highly suggestive in a person for whom the need for the serum is unquestioned, desensitization can be undertaken (see Desensitization to Sera).

Treatment of Botulism Type E

The best results in the treatment of botulism are likely to be obtained where very large doses of antitoxin are given early in the disease. The object is to provide an excess of circulating antitoxin as early as possible.

a) Intravenous injection (IV). In order to ensure the quickest possible neutralization of all toxin in the tissue and fluids, it is advisable to give immediately 5000 I.U. of Type E antitoxin intravenously diluted in 0.9% saline for intravenous infusion at a 1:10 dilution. If potency results are less than 5000 I.U. per vial, more than one vial may be needed. The preparation should be at ambient temperature before being administered. This may be accomplished with safety simply by holding the vial in one's hand for a minimum of 2 minutes. It should be

given by slow intravenous infusion.

b)Intramuscular injection (IM). Intramuscular injection to provide a reservoir of antitoxin from which it may be absorbed will not be recommended in this Treatment IND. Please note that this is different from the package insert.

Prevention of Botulism Type E

The recommended prophylactic dose for an individual who has eaten food suspected of being infected with *C. botulinum* is 1000-5000 I.U. of Type E given intramuscularly depending on the amount of food eaten. This may be followed in 12 to 24 hours by the injection of the contents of a second vial if any signs or symptoms of botulism appear.[6]

In populations at risk for repeated exposures to botulism toxin because of particular food habits, the repeated use of prophylactic antitoxin can lead to an increased incidence of severe reactions. Caution should therefore be exercised in the use of botulism antitoxin in such circumstances. [6]

Parenteral biological products should be inspected visually for extraneous particulate matter and/or discolouration before administration. If these conditions exist, the product should not be administered.

When administering a dose from a rubber-stoppered vial, do not remove either the rubber stopper or the metal seal holding it in place. Aseptic technique must be used for withdrawal of each dose. (see PRECAUTIONS)

This product contains dry natural rubbers as follows: The stopper to the vial contains dry natural rubber.

Administration of Antitoxin to Sensitive Persons

Whenever there is a history of allergy, sensitivity to horse serum or manifestations of sensitivity when in proximity to horses, or if the reaction to the skin test is positive, great care must be exercised in the administration of serum (or antitoxin).

No one method can be advised for the administration of serum or antitoxin for sensitive persons as each presents an individual problem. Desensitization of the patient may be carried out by serial injections of diluted antitoxin as indicated below at intervals of 15 minutes, provided no reactions occur. The desensitization procedure should be performed by trained personnel familiar with the treatment of anaphylaxis and with appropriate drugs and equipment available.[6,8] Some physicians advocate concurrent use during the procedure of an oral or parenteral antihistamine, with or without IV hydrocortisone or methylprednisolone. If signs of anaphylaxis occur, aqueous epinephrine should be administered immediately. Administration of antitoxin under the protection of a desensitization procedure must be continuous because after administration is interrupted, protection from desensitization is lost.

"Desensitization" to Serum - Intravenous Route[8]

Dose Number*	Dilution of Serum in Normal Saline	Amount of Injection (mL)

1	1:1,000	0.1
2	1:1,000	0.3
3	1:1,000	0.6
4	1:100	0.1
5	1:100	0.3
6	1:100	0.6
7	1:10	0.1
8	1:10	0.3
9	1:10	0.6
10	Undiluted	0.1
11	Undiluted	0.3
12	Undiluted	0.6
13	Undiluted	1.0

*Administer consistently at 15-minute intervals.

NOTE: Following the administration of serum (or antitoxin), and particularly in those cases showing a positive skin test, the patient should be kept under close observation for one to two hours and under reasonably close surveillance for a period of twenty-four hours.

Concurrent Administration of Botulism Antitoxin (Equine), Type E

Botulism Antitoxin (Equine), Type E may be administered consecutively with Botulism Antitoxin Bivalent (Equine), Types A and B if the type of Botulism is not known and is suspected to be A, B or E. Each product should be administered separately and should not be mixed in the same syringe or administration set.

STORAGE

Botulism Antitoxin (Equine) Type E should be stored between 2º and 8ºC (35º and 46ºF). DO NOT FREEZE. Product which has been exposed to freezing should not be used.

HOW SUPPLIED

Botulism Antitoxin (Equine) Type E is supplied in vials, each vial was formulated to contain Type E - 5000 International Units

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9. Plott RT, et al. Iatrogenic contamination of multidose vials in simulated use. Arch Dermatol 1990;126:1441-1444.

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Product Information as of May 2005.

Manufactured by:
CSL Limited
45 Poplar Road
Parkville, Victoria 3052
Australia

Distributed by:
Aventis Pasteur Limited
Toronto, Ontario, Canada R1-0301 GENERAL

Botulism Antitoxin (Equine) Type E

PATIENT CONSENT FORM/PARENTAL PERMISSION FORM

Flesch-Kincaid Grade Level: 7.5

The Centers for Disease Control and Prevention (CDC) and your State Health Department are able to offer Botulism Antitoxin Type E (BAT-E) for emergency treatment of botulism. Your doctor thinks that you/your child may have botulism caused by type E toxin. The only drug currently available for type E botulism is a research product (investigational new drug, IND). It has not been approved by the Food and Drug Administration (FDA) for use in the United States. Your doctor thinks it is the best treatment you can get.

BACKGROUND
Botulism is an illness caused by a toxin that is made by a group of bacteria. The toxin can result in serious paralysis (loss of motion) or death because the toxin interferes with the normal sending of nerve signals. Signs of botulism can begin as early as three hours or as late as several days after being exposed to the toxin. Signs include blurred vision, weakness, problems with swallowing and talking, dizziness, nausea, vomiting, constipation and stomach cramps. If the drug is given soon after the signs begin, the signs will be less severe. The time it takes to recover will be less.

BENEFIT OF TREATMENT
The benefit is that you/your child will receive a drug that is likely to reduce signs of botulism. Also you/your child may have a higher risk of dying without this treatment. Without drug treatment, the paralysis may last longer and affect more parts of the body. This may require a longer time to recover in a hospital.

METHODS
Your doctor will do a skin test to see if you/your child are allergic to horse (equine) products. If this test shows that you/your child may have an allergic response, then your doctor may give you the drug in very small doses. This will lower the risk for a reaction to the product. Your doctor may also give you other medicines to lower the risk. First the skin test will be done. Then you/your child will be given the drug by a needle placed directly into your vein. You/your child will be asked to have blood tests before and 24 hours after treatment and at/after hospital discharge. These blood tests will measure the amount of toxin or antitoxin in your blood. They are used to help prove that you have botulism and to follow your progress. The largest amount of blood drawn at any time will not be more than 2 tablespoons for adults and children over 1 year of age, or 1 teaspoon for infants less than 1 year old.

RISK
The risk of getting any drug by vein includes brief pain from the needle, minor bleeding, and a skin bruise around the site. There may also be soreness and swelling at the site. It is also possible to get an infection where the needle entered the skin.

The risk of having blood drawn for tests is brief pain from the needle, minor bleeding, and a skin bruise.

A small amount (5% or less of the total population) of persons are allergic or sensitive to horse products. A reaction to this type of product would include fever, chills, and an unpleasant sensation. In such a case, standard medical methods would be used to treat these reactions. Rarely a severe reaction (less than 1%) can occur. This causes a rapid drop in blood pressure and difficulty in breathing. This may require emergency treatment and a machine to assist breathing. Skin testing shortly before giving the drug can identify allergic persons. Steps can then be taken to lower the risk.

A small number of (less than 5%) persons who get horse serum, may develop fever, hives, and a rash a 7 to 14 days after treatment. This is also known as serum sickness. It can be treated with standard drugs. These symptoms can last for several weeks. One out of ten persons with serum sickness may also get pains in the joints or back. This can be with or without joint swelling. These signs will go away after a few weeks.

PREGNANCY

There are no known extra risks of drug treatment for the pregnant woman or fetus. Botulism is a severe life-threatening illness. The benefit of treatment for the mother and the fetus is felt to be much greater than the risk of problems from the product itself. Pregnancy test (blood or urine test) in all women of child-bearing age will be done.

MEDICAL RECORDS/CONFIDENTIALITY

People from the local health department, the CDC, and the FDA may read your medical records about this illness. They may collect data from these records. All data about you/your child will be kept private to the extent allowed by law. You/your child will not be named if results of this study are published.

STATEMENT OF VOLUNTARY PARTICIPATION

Treatment with the IND drug is for you alone to decide. You may refuse or stop treatment at any time. You/your child will not lose the ability to receive medical care. There is no plan for payment of medical costs resulting from problems which are the result of you/your child receiving this drug. You/your child are not giving up any legal rights that otherwise would be available to you/your child. You are entitled to receive a copy of this document.

CDC is providing the drug at no cost. CDC has set aside no funds to pay for lab tests.

If you have any questions or concerns about your rights as a participant or you think you may have been harmed in this research study, please contact the office of CDC's Deputy Associate Director for Science at no cost to you by calling 1-800-584-8814. Please leave a brief message including your name, phone number, and mention that you are calling in reference to CDC protocol # 8771. Someone will return your call as soon as possible.

CONSENT

Signing this consent form means that you have read the document or had it read to you. It means that you agree to receive or have your child receive a research drug. Signing this consent form means you agree to let the local/state health department, CDC, and the FDA see your medical records.

I have read and understand the above. I have had my questions answered. I agree to be part of the study.

Signature of patient or guardian_____

Date _____

Type/Print name of
patient_____

IF PATIENT IS INCAPABLE OF PROVIDING INFORMED CONSENT

If the patient is too ill to give informed consent; and if next of kin cannot be found after a solid try to locate them; and if the illness is life threatening, a physician has made the decision to begin this treatment:

Signature of physician: _____

Date: _____

Time of day: _____ AM/PM (circle one)

Type/print name of physician: _____

Efforts to reach the next of kin have included the following (describe):

There may be blood left over from your sample after the tests. This blood will be stored at CDC for future research if you agree. You may choose not to have your sample stored for future research and still be part of this study. Also, you may agree to have your sample stored and later decide that you want to withdraw it from storage. If so, you should call the study person

listed in this consent form and tell him/her to discard your sample. The sample will be discarded as you instruct. But any data from testing your sample until that point will remain part of the research

We ask you to agree to freeze part of your blood and other fluid samples at CDC. We will use these samples for botulism research in the future. We are not sure what studies might be done. But if any test results seem to have meaning for your health, we will inform you or your doctor, as you direct. Some tests we do may be experimental and have no clear meaning to your health. In those cases, we will not report any results to you or your doctor. We will not test your samples for HIV or other STDs. Also, we do not plan to do any genetic testing on your samples.

If results of the future testing are medically important to me or my child CDC will make every attempt to locate me.

☐ I agree to allow storage and future research of my/my child's sample.

☐ I do not agree to allow storage of my/my child's sample.

Signature of patient or guardian

_____

Date_____

BOTULISM ANTITOXIN QUESTIONNAIRE

Revised 1/97

The Foodborne and Diarrheal Diseases Branch of the Centers for Disease Control and Prevention is the national center for consultation of suspected botulism and is responsible for providing botulism antitoxin for therapy. If you have given botulism antitoxin to a patient, we need your assistance. Please complete and return this form for each patient receiving antitoxin.

Patient's name _____/_____ age____ (years) sex ___
last first

Person filling out this form_____ Date_____

Attending physician _____

BOTULISM ANTITOXIN

SENSITIVITY TESTING

Was sensitivity testing done prior to antitoxin administration? yes___ no___

If yes, at what site (ie. Skin)_____
what route(ie. subcutaneously)?_____
what dosage and diluent?_____
result_____

ANTITOXIN ADMINISTRATION

Antitoxin given by intravenous (IV) injection:

date	time	number of vials given	lot no.
_____		_____	_____
_____		_____	_____

Antitoxin given by intramuscular (IM) injection:

date	time	number of vials given	lot no.
_____		_____	_____
_____		_____	_____

ANTITOXIN REACTIONS (excluding reactions during sensitivity testing)
Please circle "yes" or "no" to each of the following reactions. For each "yes" answer, please indicate how soon reaction began after the start of the antitoxin treatment, and how long the reaction lasted.

		If yes, how soon after?	lasting how long?
Fever:	yes no	_____	_____
Chills:	yes no	_____	_____
Rash:	yes no	_____	_____

If rash, describe_____

		If yes, how soon after?	lasting how long?
Urticaria:	yes no	_____	_____

If urticaria, describe_____

		If yes, how soon after?	lasting how long?
Swelling/edema:	yes no	_____	_____

If swelling/edema, describe location_____

		If yes, how soon after?	lasting how long?
Other hypersensitivity:	yes no	_____	_____

If other, describe_____

		If yes, how soon after?	lasting how long?
Anaphylaxis:	yes no	_____	_____

If anaphylaxis, describe_____

		If yes, how soon after?	lasting how long?
Serum sickness:	yes no	_____	_____

If serum sickness, describe_____

		If yes, how soon after?	lasting how long?
Other reactions:	yes no	_____	_____

If other reaction, describe_____

If the patient received any treatment for a reaction, or antitoxin administration was stopped, please describe _____

CLINICAL HISTORY

Please indicate which symptoms and signs were noted in the patient before the antitoxin was administered. (We recognize that signs and symptoms sometime progress after administration of antitoxin, but we do not want these later findings recorded here.)

SYMPTOMS	yes	no	don't know
Abdominal pain	___	___	____
Nausea	___	___	____
Vomiting	___	___	____
Diarrhea	___	___	____
Blurred vision	___	___	____
Diplopia	___	___	____
Dizziness	___	___	____
Slurred speech	___	___	____
"Thick tongue"	___	___	____
Change in sound of voice	___	___	____
Hoarseness	___	___	____
Dry mouth	___	___	____
Difficulty swallowing	___	___	____
Shortness of breath	___	___	____
Subjective weakness	___	___	____
Fatigue	___	___	____
Paresthesia	___	___	____

site_____

SIGNS	yes	no	don't know	check if bilateral
Altered Mental State	___	___	____	
Extraocular palsy	___	___	____	____
Ptosis	___	___	____	____
Pupils dilated	___	___	____	____
Pupils constricted	___	___	____	____
Pupils fixed	___	___	____	____
Pupils reactive	___	___	____	____
Facial paralysis	___	___	____	____
Palatal weakness	___	___	____	
Impaired gag reflex	___	___	____	
Wound	___	___	____	

If yes, describe_____

Please indicate if weakness or paralysis was noted in the patient before the antitoxin was administered.

Weakness or paralysis of:	check if yes	no	don't know	bilateral
Upper extremities	___	___	____	____
upper distal	___	___	____	____
upper proximal	___	___	____	____
Lower extremities	___	___	____	____
lower distal	___	___	____	____
lower proximal	___	___	____	____

Describe weakness/paralysis:

ascending (beginning in lower extremities, progressing to upper extremities, then cranial nerves)

yes___ no___ don't know____

descending (beginning with cranial nerves, progressing to upper extremities, then (in some cases) to lower extremities)

yes___ no___ don't know____

comments_____

LABORATORY RESULTS

Please list the laboratory results which were available before the patient received antitoxin.

Were lumbar puncture results available? yes___ no___

RBC_____ WBC_____ Protein_____ Glucose_____

Were Tensilon (edrophonium chloride) test results available? yes___ no___

Results_____

Were electromyography (EMG) results available? yes___ no___

Which muscle groups were used_____

Results_____

Was rapid repetitive stimulation performed: yes___ no___

At what hertz_____ Results_____

Please FAX form to: Foodborne and Diarrheal Diseases Branch at (404) 639-2205

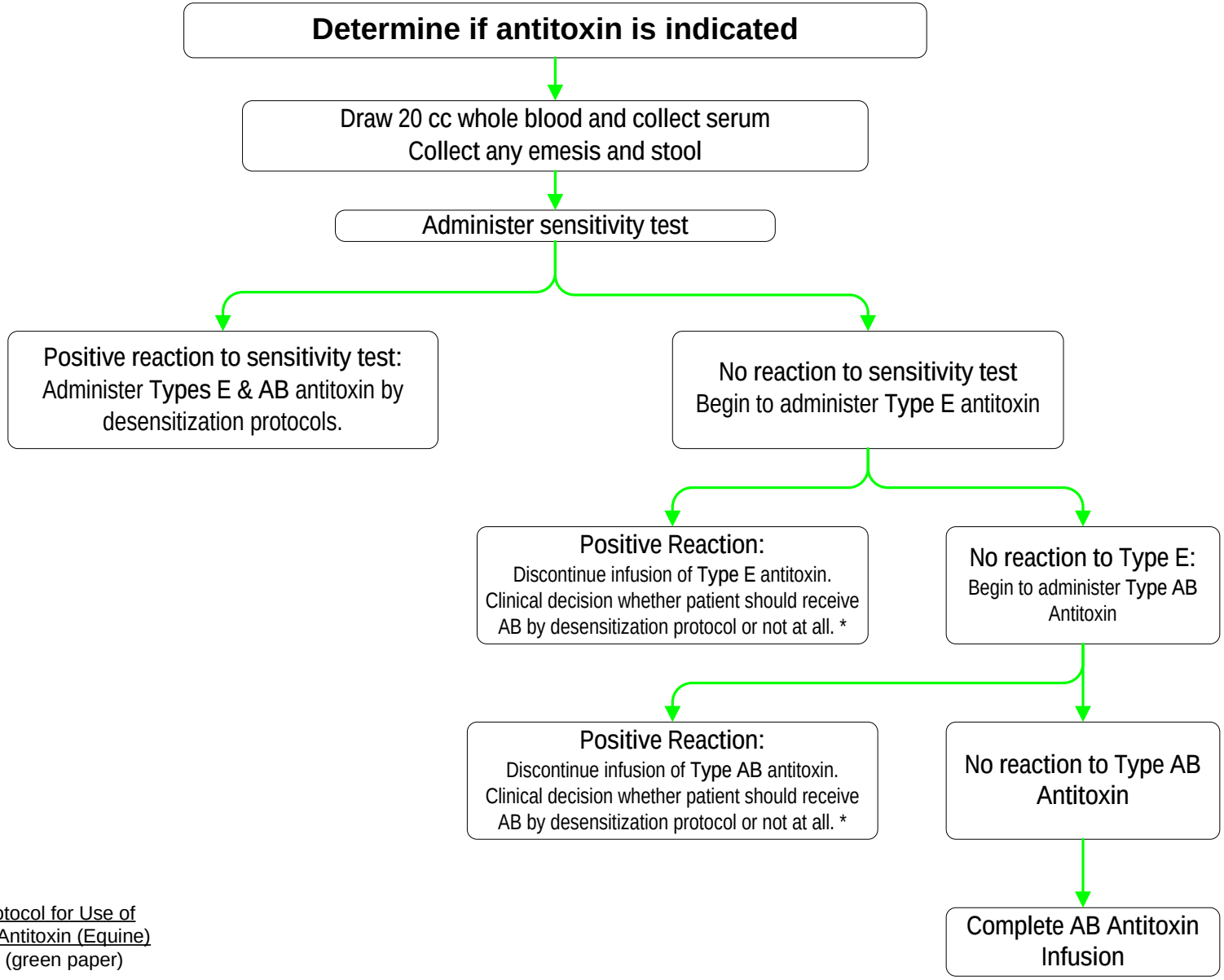
or mail form to: Foodborne and Diarrheal Diseases Branch
Mailstop C09, Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, Georgia 30333

THANK YOU FOR YOUR ASSISTANCE

The following label will be attached to each vial of Botulinum Antitoxin Type E provided to CDC for distribution under this IND:

Distributed by:
Centers for Disease Control & Prevention
Drug Service D-09
Atlanta, GA 30333 (404)639-3670
Caution: New Drug Limited by Federal
Law to Investigational use

Botulism Antitoxin Administration



*See "Protocol for Use of Botulinum Antitoxin (Equine) Type E" (green paper)

Revised 04/06

Botulism, Intestinal (Infant)

Organism: *Clostridium botulimum* and other clostridial species; *C. baratti*, *C. butyricum*. Usually toxin type A or B in U.S.

Incubation period: Unknown since precise time of ingestion can often not be determined.

Infectious period: None. No secondary cases ever documented despite excretion from infant.

Treatment:

- Primarily supportive; mechanical ventilation can be lifesaving. Antimicrobials, particularly aminoglycosides, have been reported to increase the incidence of respiratory paralysis. However, complications, such as respiratory infections, may require antimicrobial therapy. Antitoxin, such as is used in cases of foodborne botulism, has **not** been shown to affect the outcome of infant botulism.

- Treatment with human-derived Botulism Immune Globulin Intravenous (BIG-IV) might reduce the length of time needed for recovery. BIG-IV can be obtained from the California Department of Health Services, Infant Botulism Treatment and Prevention Program (IBTPP, main number is 510-540-2646; see also www.infantbotulism.com).

- Use of BIG-IV, FDA-approved Investigational New Drug, requires informed parental consent and coordination with the treating hospital's institutional review board. BIG-IV should be requested from the IBTPP pediatrician on-call (**510-231-7600 24/7**#) without awaiting laboratory confirmation. BIG-IV has been shown to be most effective if given within 7 days of hospital admission. FDA approval of BIG-IV was based upon studies that its use produced a statistically signification reduction in the durations of hospital stay, mechanical ventilation, and tube feeding.

Information Needed for the Investigation

Infant botulism is the most commonly reported form of botulism in the United States. In Alaska three infants have been diagnosed with this disease; none of these cases have occurred in Alaska Natives. In a study conducted outside of Alaska, affected infants had higher birth weights, their mothers tended to be Caucasian, and they were more commonly breast-fed.

In contrast to foodborne botulism where the toxin is ingested, infant botulism results from ingestion of *C. botulinum* spores with subsequent intestinal colonization and toxin production. Most infants affected by botulism are between 3 and 20 weeks of age. The first symptom is often constipation, followed in several days by progressive muscular weakness, poor suck, weak cry, and difficulty swallowing. Respiratory arrest occurs in half of affected infants. Numerous examples exist of infants presenting with apnea, or becoming apneic, during a diagnostic procedure. Examination may show a decreased gag reflex; cranial nerve involvement including ptosis, ophthalmoplegia, and facial nerve palsy; mydriasis; and areflexia and generalized hypotonia. Patients are usually afebrile and have normal cerebrospinal fluid. Electromyography may be helpful in differentiating botulism from other causes of neuromuscular disease.

Verify the Diagnosis

- Demonstration of botulinum toxin in stool and positive stool culture; unusual to find toxin in serum.

Laboratory Specimens

- Collect bulk stool; send to ASPHL for culture.
- Environmental and food specimens usually not helpful; consult with California Department of Health Services prior to any collection efforts.

Contact and Control Measures

- Not applicable.

Prevention

- Approximately 20% of infant botulism cases reported to the CDC have been associated with the ingestion of honey. The sources for the other cases are unknown, but hypotheses include soil, household dust, and other foods. Honey should not be fed to infants less than 1 year of age. No other specific prevention measures exist.

Reporting Requirements

- FTR: write up all *suspect* or *confirmed* cases
- Morbidity Database: enter all *confirmed* cases
- CDC Case definition is used to define *confirmed* cases

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
Centers for Disease Control
Center for Infectious Diseases
Atlanta, Georgia 30333

GUIDE TO INVESTIGATION OF INFANT BOTULISM

A. EPIDEMIOLOGIC (OBTAIN PRINCIPALLY FROM PARENT(S)

PERSONAL DATA

Name (Last) (First)

Date of Birth Mo. (1-2) Day (3-4) Yr. (5-6)

SEX (7)
1 ☐ Male
2 ☐ Female

RACE/ETHNICITY (8)
1 ☐ White, not Hispanic
2 ☐ Black, not Hispanic
3 ☐ Hispanic
4 ☐ Asian or Pacific Islander
5 ☐ American Indian or Alaska native
6 ☐ Unknown

ADDRESS (No. and Street) | City | County | State (9-10) | Phone

MOTHER'S AGE (11-12) | OCCUPATION (13) | FATHER'S AGE (14-15) | OCCUPATION (16)

EDUCATION (17)
1 ☐ Some grade school
2 ☐ Grade school graduate
3 ☐ Some high school
4 ☐ High School graduate
5 ☐ Jr. College/Trade school graduate
6 ☐ College graduate
7 ☐ Higher

EDUCATION (18)
1 ☐ Some grade school
2 ☐ Grade school graduate
3 ☐ Some high school
4 ☐ High school graduate
5 ☐ Jr. College/Trade school graduate
6 ☐ College graduate
7 ☐ Higher

MATERNAL AND PERINATAL HISTORY

NO. OF PREGNANCIES (19) (including case) _____

NO. OF LIVE BIRTHS (20) _____

TYPE OF DELIVERY:
(21) 1 ☐ VAGINAL 2 ☐ C-SECTION
Complications: (22) 1 ☐ Yes 2 ☐ No 9 ☐ Unknown

If yes, describe (23) _____

Was infant premature? (24) 1 ☐ Yes 2 ☐ No 9 ☐ Unk

If yes, gestational age (25-26) _____ Weeks

What was infant's birth weight: _____ lb (27-28) _____ oz. (29-30) _____ (Gms) (31-34)

DIETARY HISTORY (BEFORE ONSET OF PRESENT ILLNESS)

PRESENT ILLNESS – INFANT BOTULISM
DEFINED AS ONSET OF CONSTIPATION OR IF NO CONSTIPATION WHEN MOTHER SAYS CHILD BECAME ILL

BEFORE ONSET OF PRESENT ILLNESS

Was infant ever breast fed? (35) 1 ☐ Yes 2 ☐ No If yes, for how many weeks _____ (36-37)

Was infant ever formula fed? (38) 1 ☐ Yes 2 ☐ No

Was infant primarily (more than 50%) (39) 1 ☐ Breast fed 2 ☐ Formula fed 3 ☐ Both approximately equally

Did infant ever eat or taste (before onset of illness):

FOOD/LIQUID		NEVER 1	ONCE OR A FEW TIMES 2	MANY TIMES 3	DAILY OR MOST DAYS 4	PRINCIPAL TYPE OR BRAND
Formula	(40)	☐	☐	☐	☐	_____ (41)
Cow's Milk (Past.)	(42)	☐	☐	☐	☐	
Unpasteurized (raw milk)	(43)	☐	☐	☐	☐	
Fruit juices	(44)	☐	☐	☐	☐	
Cereal	(45)	☐	☐	☐	☐	
Bread	(46)	☐	☐	☐	☐	
Syrup/water	(47)	☐	☐	☐	☐	_____ (48)
Honey/water	(49)	☐	☐	☐	☐	_____ (50)
Sugar/water	(51)	☐	☐	☐	☐	
Tea/water	(52)	☐	☐	☐	☐	
Fruits, cooked	(53)	☐	☐	☐	☐	
Fruits, raw	(54)	☐	☐	☐	☐	
Vegetables, cooked	(55)	☐	☐	☐	☐	
Vegetables, raw	(56)	☐	☐	☐	☐	
Home-canned foods	(57)	☐	☐	☐	☐	
Baby Foods (Jars)	(58)	☐	☐	☐	☐	
Other _____	(59)	☐	☐	☐	☐	

DIETARY HISTORY

Dietary History (Cont'd.)

Did infant use a pacifer? (60) 1 ☐ Often 2 ☐ Sometime 3 ☐ Rarely 4 ☐ No

If yes, was it ever dipped in: (61) 1 ☐ Syrup 2 ☐ Honey 3 ☐ Other _____ 4 ☐ Nothing

INFANT'S MEDICAL HISTORY (PRIOR TO ONSET OF INFANT BOTULISM)

Were infant's usual bowel movements: (62) 1 ☐ Two or more per day 2 ☐ One per day 3 ☐ Every other day 4 ☐ Less than every other day

Illness prior to onset of present illness (infant botulism)

		Yes 1	No 2	Unk 9	Age in weeks	
Fever (>101°F)	(63)	☐	☐	☐	_____ (64-65)	
Cold(s)	(66)	☐	☐	☐	_____ (67-68)	_____ wks. (69-70)
Constipation (Mother's opinion)	(71)	☐	☐	☐	_____ (72-73)	
Diarrhea (Mother's opinion)	(74)	☐	☐	☐	_____ (75-76)	
Other	(77)	_____				

Did infant receive antibiotics prior to onset of present illness (Infant botulism)? (78) 1 ☐ Yes 2 ☐ No 9 ☐ Unk.

If yes, give

AGE (IN WEEKS)	REASON	DRUG	ROUTE (Oral, Parenteral or Both)	DURATION (Days)
_____ (79-80)	_____ (81)	_____ (82)	_____ (83)	_____ (84-85)
_____ (86-87)	_____ (88)	_____ (89)	_____ (90)	_____ (91-92)
_____ (93-94)	_____ (95)	_____ (96)	_____ (97)	_____ (98-99)

ENVIRONMENTAL HISTORY (PRIOR TO ONSET OF INFANT BOTULISM)

Was there any construction, excessive dust, or environmental change around home from birth of infant until onset of present illness (Infant botulism)? (100)

1 ☐ Yes 2 ☐ No 9 ☐ Unk.

If yes, describe (101) _____

Was parent(s) involved in gardening or yard work from birth of infant until onset of present illness? (102) 1 ☐ Yes 2 ☐ No 9 ☐ Unk.

If yes, describe (103) _____

Did infant remain away from home for more than 1 week prior to onset of present illness? (104) 1 ☐ Yes 2 ☐ No 9 ☐ Unk.

If yes, describe (105) _____

SYMPTOMS OF PRESENT ILLNESS (INFANT BOTULISM)

a) Mother first noted infant was ill on ☐☐ (106-107) ☐☐ (108-109) ☐☐ (110-111) Mo. Day Yr., at _____ (112-113) weeks of age.

(114) First symptom _____

(115) Second symptom _____

b) The initial visit to a physician was on ☐☐ (116-117) ☐☐ (118-119) ☐☐ (120-121) Mo. Day Yr., at _____ (122-123) weeks of age?

c) Infant was hospitalized on ☐☐ (124-125) ☐☐ (126-127) ☐☐ (128-129) Mo. Day Yr., at _____ (130-131) weeks of age?

d) Symptoms noted before patient hospitalized:

		Yes 1	No 2	Unk. 9	Mo.	Day	Yr.	Weeks old
Constipation	(132)	☐	☐	☐	☐☐ (133-134)	☐☐ (135-136)	☐☐ (137-138)	_____ (139-140)
Poor feeding	(141)	☐	☐	☐				

(Symptoms cont'd on next page)

SYMPTOMS OF PRESENT ILLNESS (INFANT BOTULISM)

d) Symptoms noted before patient hospitalized: (Cont'd)

		Yes 1	No 2	Unk 9
Altered cry	(142)	☐	☐	☐
Irritable	(143)	☐	☐	☐
Poor Head Control	(144)	☐	☐	☐
General Weakness	(145)	☐	☐	☐
Difficulty Breathing	(146)	☐	☐	☐
Fever	(147)	☐	☐	☐
Other	(148)_____	☐	☐	☐

If infant had constipation, how many bowel movements were occurring? (149)

1 ☐ Two or more per day 2 ☐ One per day 3 ☐ One every other day 4 ☐ Two-three times per week

5 ☐ One per week 6 ☐ Less than one per week 7 ☐ Other _____

Interviewee(s) (150) 1 ☐ Mother 2 ☐ Father 3 ☐ Both 4 ☐ Other _____

Interviewer: (Name) _____ Title (151) _____

(Agency) (152) _____ (Phone) _____

Are there problems with this case history form (153) 1 ☐ Yes 2 ☐ No

If yes, describe _____

HOSPITAL DATA

B. HOSPITALIZATION DATA (OBTAIN PRINCIPALLY FROM MEDICAL RECORD OR PHYSICIAN)

Hospital where diagnosis established Medical Record No. _____

Name (154) Address Phone

Primary Physician(s) Phone

	Mo.	Day	Yr.
Date of first hospital admission	(155-156)	(157-158)	(159-160)
Date of last hospital discharge	(161-162)	(163-164)	(165-166)

Total days _____ hospitalization
(167-168)

PHYSICAL FINDINGS

Symptoms and Physical Findings observed at any time during illness:

		Yes 1	No 2	Unk. 9
Loss of facial expression	(169)	☐	☐	☐
Ptosis	(170)	☐	☐	☐
Extraocular muscle palsies	(171)	☐	☐	☐
Pupils dilated	(172)	☐	☐	☐
constricted	(173)	☐	☐	☐
sluggish pupil reactivity	(174)	☐	☐	☐
Trouble swallowing	(175)	☐	☐	☐
Constipation	(176)	☐	☐	☐
Diarrhea	(177)	☐	☐	☐
Altered cry	(178)	☐	☐	☐
Weak sucking	(179)	☐	☐	☐
Muscle weakness				
Poor head control	(180)	☐	☐	☐
Upper extremeties	(181)	☐	☐	☐
Lower extremeties	(182)	☐	☐	☐
"Floppy"	(183)	☐	☐	☐
Knee Deep Tendon Reflex				
Absent	(184)	☐	☐	☐
Depressed	(185)	☐	☐	☐
Somnolent	(186)	☐	☐	☐
Irritable	(187)	☐	☐	☐
Fever	(188)	☐	☐	☐
Dehydration	(189)	☐	☐	☐
Respiratory difficulty	(190)	☐	☐	☐
Respiratory arrest	(191)	☐	☐	☐
Pneumonia	(192)	☐	☐	☐
Other _____	(193)	☐	☐	☐

TREATMENT

		1	2	9	
Respiratory Assistance Needed	(194)	☐	☐	☐	_____ (195-196) No. of Days
Oxygen only	(197)	☐	☐	☐	
Intubation	(198)	☐	☐	☐	
Tracheostomy	(199)	☐	☐	☐	
Ventilator	(200)	☐	☐	☐	
Infant feeding					
Feeding tube	(201)	☐	☐	☐	_____ (202-203) No. of Days

TREATMENT

Treatment (Cont'd.)
Antibiotics Given:

Drug	Oral or Parenteral	Dose (Gms/day)	Duration (days)	Date started Mo.	Day
(204)	(205)	(206-208)	(209-210)	(211-214)	
(215)	(216)	(217-219)	(220-221)	(222-225)	
(226)	(227)	(228-230)	(231-232)	(233-236)	
(237)	(238)	(239-241)	(242-243)	(244-247)	

Was antitoxin given? (248) 1 ☐ Yes 2 ☐ No

If yes, give route of administration (249) 1 ☐ I.V. 2 ☐ I.M. 3 ☐ Both 9 ☐ Unk.

If yes, how many C.C. Total (Connaught Adult 10cc/vial, Connaught Ped. 2cc/vial

_____ Total cc (250-51)

Other specific therapeutic medication given: (252) _____

DIAGNOSTIC TESTS

Was a spinal tap done? (253) 1 ☐ Yes 2 ☐ No 9 ☐ Unk. Date Mo. ☐☐ Day ☐☐ Yr. ☐☐ (254-259)

Was spinal tap reported as normal? (260) 1 ☐ Yes 2 ☐ No 9 ☐ Unk.

Spinal fluid protein _____ mgm% (261-263)

Total number of white cells _____ (264-266)

Was a Tensilon test done? (267) 1 ☐ Yes 2 ☐ No 9 ☐ Unk. Date Mo. ☐☐ Day ☐☐ Yr. ☐☐ (268-273)

If yes, results (274) 1 ☐ Pos. 2 ☐ Neg. 3 ☐ Equivocal 9 ☐ Unk.

Was an EMG (electromyography) done? (275) 1 ☐ Yes 2 ☐ No 9 ☐ Unk. Date Mo. ☐☐ Day ☐☐ Yr. ☐☐ (276-281)

If yes, was it interpreted as compatible or diagnostic of botulism? (282)

1 ☐ Yes 2 ☐ No 3 ☐ Not sure 9 ☐ Unk.

If EMG done, was BSAP noted? (283) 1 ☐ Yes 2 ☐ No 9 ☐ Unk.

Source of hospitalization data: (284)

1 ☐ Physician 2 ☐ Medical Record 3 ☐ Both 4 ☐ Other _____

Hospitalization section completed by:

Name _____ Title (285) _____

Agency (286) _____ Phone No. _____ Date _____

C. SPECIMEN TESTING FOR *C. BOTULINUM* (OBTAIN FROM MEDICAL RECORDS, STATE LABORATORY, OR CDC BOTULISM LABORATORY)

Serum sample for toxin: (287) 1 ☐ Type A 2 ☐ Type B 3 ☐ Type E 4 ☐ Neg 5 ☐ Not tested 6 ☐ Toxic but not typed

Stool sample: (288) 1 ☐ Type A 2 ☐ Type B 3 ☐ Type E 4 ☐ Neg 5 ☐ Not tested

STOOL SPECIMEN(S)

Date Mo. Day Yr.	Infant's Age (Wks)	Direct Toxin Assay			Enrichment Culture			Organism Isolated	
		Type Specific Toxic 1	Non-Specific Toxic 2	Non Toxic 3	Type Specific Toxic 1	Non-Specific Toxic 2	Non Toxic 3	Yes 1	No 2
☐☐ ☐☐ ☐☐ (289-294)	____ (295-296)	☐	☐	☐ (297)	☐	☐	☐ (298)	☐	☐ (299)
☐☐ ☐☐ ☐☐ (300-305)	____ (306-307)	☐	☐	☐ (308)	☐	☐	☐ (309)	☐	☐ (310)
☐☐ ☐☐ ☐☐ (311-316)	____ (317-318)	☐	☐	☐ (319)	☐	☐	☐ (320)	☐	☐ (321)
☐☐ ☐☐ ☐☐ (322-327)	____ (328-329)	☐	☐	☐ (330)	☐	☐	☐ (331)	☐	☐ (332)

Date Mo. ☐☐ Day ☐☐ Yr. ☐☐ (333-338) of first negative follow-up specimen.

Were food, medications, or environmental samples tested? (339) 1 ☐ Yes 2 ☐ No 9 ☐ Unk.

If yes, list: (340) _____

Samples positive for: (341) 1 ☐ Performed toxin 2 ☐ *C. botulinum* 3 ☐ Both 4 ☐ Neither

If any positive for toxin or organisms, please describe: (342) _____

Specimen testing section completed by:

Name _____ Title _____ (343)

Agency _____ (344) Phone No. _____ Date _____

Patient outcome (345) 1 ☐ Improving 2 ☐ Recovered 3 ☐ Death

If patient died, date Mo. ☐☐ Day ☐☐ Yr. ☐☐ (346-351)

Form Reviewed and Submitted by:

Name _____ Title _____ (352)

Agency _____ (353) Phone No. _____ Date _____

Diphtheria

Diphtheria

Organism: *Corynebacterium diphtheriae,* a gram-positive pleomorphic bacillus. Clinical presentation usually includes nasopharyngitis or obstructive laryngotracheitis, low-grade fever, and a gradual onset over 1-2 days.

Incubation: Usually 2-5 days, occasionally longer.

Infectious period: Usually 2 weeks or less, rarely up to 4 weeks. Effective antibiotic therapy promptly terminates shedding; usually within 4 days. A rare chronic carrier may shed the organisms 6 months or more. Humans are the only known reservoir.

Transmission route: Transmission is usually by airborne respiratory droplets and direct contact with either respiratory secretions or exudates from infected skin lesions. Fomites can play a role in transmission and epidemics have been caused by contaminated milk.

Treatment: If diphtheria is strongly suspected based on clinical findings (see under **Verify the Diagnosis** below), begin immediate treatment with:

- **Diphtheria antitoxin (DAT).** After completion of tests to rule hypersensitivity, a single dose of 20,000-100,000 units IM, depending on area of involvement and severity of disease. In severe infections, may need to give both IM and IV.
- **Antibiotic.**
  Children: Procaine penicillin G, 25,000-50,000 units /kg/d in 2 divided doses IM, until patient can swallow.
  Adults: Procaine penicillin G, 1.2 million units /kg/d in 2 divided doses IM, until patient can swallow.

  –OR–

  Parenteral Erythromycin (40-50 mg/kg/d with a maximum of 2g|d, until patient can swallow.

  –THEN–

  When patient can swallow comfortably:
  - erythromycin* PO in 4 divided doses.

  –OR–

  - penicillin V PO (125-250 mg 4 times daily)

  (*Note: Azithromycin and Clarithromycin should be effective for erythromycin susceptible strains.)

Maintain strict isolation for patient until at least 2 cultures—collected at least 24 hours after antibiotic treatment has ended—are negative.

Information Needed for the Investigation

Verify the Diagnosis

- What are the patient's clinical symptoms? The health care provider **must act on a presumptive diagnosis** based upon (1) mildly painful tonsillitis or pharyngitis with an adherent membrane (asymmetrical grayish white) of the tonsil; (2) adenopathy and cervical swelling; (3) hoarseness and stridor; (4) palatal paralysis; (5) serosanguineous nasal discharge; and (6) temperature <103 F. Moderate elevation of WBC and proteinuria are common, but nonspecific.
- What laboratory tests were conducted and what are the results?
- Diphtheria Anti-toxin is available from the Vaccine Depot.

Determine the Extent of Illness

- Determine if household or other contacts are ill or are at risk for disease.
- Daycare involvement? Travel recently?
- Notify an Epi supervisor immediately of all presumptive diphtheria cases.

Laboratory Specimens

- Culture of the lesion is done to confirm the diagnosis, preferably from material beneath the lesion. Special media is required (Loffler's). In remote areas, collect on a bacteriostatic transport system such as Ames swab transport system. Although Ames media has a low yield, it is better than nothing.
- Obtain Loffler's media from the AK State Public Health Laboratory. If after hours, call the microbiologist on call at 269-5520 or pager 269-2035
- Obtain sera for a diphtheria antibody titer prior to administering antitoxin. In the event that prior antibiotic therapy may have impeded a positive culture in a suspect diphtheria case, a low non-protective diphtheria antibody titer in sera may aid in a presumptive diagnosis. (Pink Book, 8th Ed., January 2004, p.58.)

Contact and Control Measures

- Immediate action on all highly suspect cases (including cutaneous) is warranted until it is shown not to be toxigenic *C. diphtheriae.*
- Obtain appropriate culture and preliminary clinical and epidemiological information including vaccine history.
- Determine the source of infection.
- Identify close contacts, especially household members and other persons directly exposed to oral secretions of the patient. Culture all close contacts, regardless of their immunization status. Ideally, culture should be from both throat and nasal swabs. After culture, all contacts should receive antibiotic prophylaxis.
- Treatment for household contacts: a single dose of benzathine penicillin G, (600,000 units IM for persons less than 6 years of age and 1.2 million units IM for persons 6 years of age or older), or a 7-10 day course of erythromycin (40mg/kg/d PO for children and 1g/d PO for adults) regardless of immunization status.
- Inadequately immunized contact should receive boosters or an accelerated vaccine administration schedule. See the Red Book for current guidelines.
- Unimmunized contacts should start a series of DTaP/DT/Td vaccine and be monitored closely for symptoms for 7 days.

Reporting Requirements

- FTR: write up all confirmed, presumptive, and probable cases.
- Morbidity Database: enter all confirmed and probable cases.
- CDC Case Definition is used for case definition.

Diphtheria *(Corynebacterium diphtheriae)*

1995 Case Definition

Clinical description

An upper respiratory tract illness characterized by sore throat, low-grade fever, and an adherent membrane of the tonsil(s), pharynx, and/or nose

Laboratory criteria for diagnosis

- Isolation of *Corynebacterium diphtheriae* from a clinical specimen, or
- Histopathologic diagnosis of diphtheria

Case classification

Probable: a clinically compatible case that is not laboratory confirmed and is not epidemiologically linked to a laboratory-confirmed case
Confirmed: a clinically compatible case that is either laboratory confirmed or epidemiologically linked to a laboratory-confirmed case

Comment

Cutaneous diphtheria should not be reported. Respiratory disease caused by nontoxigenic *C. diphtheriae* should be reported as diphtheria. All diphtheria isolates, regardless of association with disease, should be sent to the Diphtheria Laboratory, National Center for Infectious Diseases, CDC.

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
OFFICE OF SURVEILLANCE

RECORD OF INVESTIGATION OF DIPHTHERIA

CHECK PRELIMINARY DIAGNOSIS ☐ CLINICAL CASE ☐ CARRIER ☐ SUSPECT			DATE		
PATIENT'S NAME			AGE	SEX	RACE
STREET ADDRESS OR RFD		CITY OR TOWN	COUNTY		
PREVIOUS ADDRESS (IF SIGNIFICANT)			DATE MOVED		
PLACE EMPLOYED OR SCHOOL ATTENDED		OCCUPATION			
DATE OF ONSET	DATE REPORTED	HOW DID YOU FIRST LEARN OF THIS CASE?			DATE
PATIENT HOSPITALIZED? ☐ YES ☐ NO	DATE	ATTENDING PHYSICIAN			
NAME OF HOSPITAL		HOSPITAL PHYSICIAN			

CHIEF CLINICAL SYMPTOMS WITH DATES

TREATMENT (TYPE, AMOUNT, DATES)

BACTERIOLOGICAL RESULTS OF NOSE AND THROAT CULTURES FROM PATIENT

DATE COLLECTED	RESULTS		DATE COLLECTED	RESULTS		NAME OF LABORATORY
	CULTURE	VIRULENCE		CULTURE	VIRULENCE	
RELEASE SPECIMENS						

DIPHTHERIA IMMUNIZATION? INOCULATIONS AND DATES		DATE OF BOOSTER
SEVERITY OF DISEASE	WAS ANTITOXIN GIVEN PATIENT?	DATE

(CONTINUED ON REVERSE SIDE)

Are there other associated cases? ☐ Yes ☐ No

If yes, how many, and how associated? _____

_____

_____

_____

Household Sanitation: ☐ Good ☐ Fair ☐ Poor

Milk Supply _____

Other Milk Products _____

Other Pertinent Epidemiological Data: _____

_____

_____

_____

CONTACTS (Household and Other)

NAME AND ADDRESS	AGE	SEX	RELATION TO PATIENT	SIMILAR ILLNESS? ONSET DATE	BACTERIOLOGICAL EXAMINATION		
					DATE	CULTURE	VIRULENCE TEST

NARRATIVE AND FOLLOW-UP NOTES

_____

_____

_____

PROBABLE SOURCE

☐ RECOVERED ☐ DIED	DATE OF DEATH	CAUSE OF DEATH
INVESTIGATED BY		FINAL DIAGNOSIS
NAME OF AGENCY		DATE

AN EQUAL OPPORTUNITY/AFFIRMATIVE ACTION EMPLOYER
services provided on a nondiscriminatory basis

CDC Diphtheria Worksheet

Appendix 3

PATIENT INFORMATION

Date of Request (Month / Day / Year)

Name (Last, First)

Birth Date (Month / Day / Year)

Age (Unk = 999)

Age Type
0 = 0-120 years
1 = 0-11 months
2 = 0-52 weeks
3 = 0-28 days
9 = Age unknown

Sex
M = Male
F = Female
U = Unknown

Pregnant?
Y = Yes
N = No
U = Unknown

Race
N = Native Amer./Alaskan Native
A = Asian/Pacific Islander
B = African American
W = White
O = Other
U = Unknown

Ethnicity
H = Hispanic
N = Not Hispanic
U = Unknown

Address (Street and No.)

County

State

Zip

Phone

Date Symptom onset (Month / Day / Year)

Date First Diagnosis (Month / Day / Year)

Date Hospitalized (Month / Day / Year)

History of immunization against diphtheria

Childhood primary series
Y = Yes
N = No
U = Unknown

If < 18 years old, number of doses

Boosters as adult
Y = Yes
N = No
U = Unknown

Date of last dose (Month / Day / Year) Or U = Unk

Description of Clinical Picture

Outcome
N = Recovered, No Residua
R = Recovered, Residua
D = Died
U = Unknown

CLINICAL INFORMATION

Enter Y = Yes, N = No, or U = Unknown in the boxes below unless otherwise indicated

Symptoms

- Fever
- Sore throat
- Difficulty swallowing
- Change in voice
- Shortness of breath
- Weakness
- Fatigue
- Other

Fever

If Yes, Temp _____ ° F / C

Membrane present?

If Yes, Sites
- Tonsils
- Soft Palate
- Hard Palate
- Larynx
- Nares
- Nasopharynx
- Conjunctiva
- Skin

Signs

Soft tissue swelling (Around membrane)

Neck edema?

If Yes,
B = Bilateral
L = Left side only
R = Right side only

If Yes, Extent
S = Submandibular only
M = Midway to clavicle
C = To clavicle
B = Below clavicle

- Stridor
- Wheezing
- Palatal weakness
- Tachycardia
- EKG abnormalities

Complications

- Complications
- Airway obstruction
  - Date of onset (Month / Day / Year)
- Intubation required
- Myocarditis
  - Date of onset (Month / Day / Year)
- (Poly)neuritis
  - Date of onset (Month / Day / Year)
- Other
  - Describe:

LABORATORY

Specimen for diphtheria culture obtained
Y = Yes
N = No
U = Unknown

If Yes, date specimen obtained (Month / Day / Year) Or U = Unk

Culture result
P = Positive
N = Negative
U = Unknown

Specify lab performing culture:

If culture positive, biotype
M = Mitis
G = Gravis
I = Intermedious
B = Belfanti

If culture positive, results of toxigenicity testing
X = Not done
P = Positive
N = Negative
U = Unknown

Specimen sent to CDC Diphtheria Lab for confirmation/molecular typing
Y = Yes
N = No
W = Will be Sent

Type of specimen (Check all that apply)
- Clinical swab
- Piece of membrane
- *C. diphtheria* isolate

Serum Specimen for Diphtheria Antitoxin Antibodies Obtained?
Y = Yes
N = No
U = Unknown

PCR Result
P = Positive
N = Negative
U = Unknown
X = Not Done

ANTIBIOTICS

Treated with Antibiotics?
Y = Yes
N = No
U = Unknown

As an Outpatient
If Yes, Date Initiated (Month / Day / Year)

Antibiotic See Codes Below

Duration of Therapy Days

Antibiotic Therapy in Hospital?
Y = Yes
N = No

As an Inpatient
If Yes, Date Initiated (Month / Day / Year)

Antibiotic See Codes Below

Duration of Therapy Days

Were Antibiotics Given in the 24 Hours Before Culture?
Y = Yes
N = No
U = Unknown

Antibiotic Codes

1 = Erythromycin (incl. Pediazole, ilosone)
2 = Penicillin (Bicillin, Pfizerpen-AS, Wycillin)
3 = Amoxicillin/ Ampicillin/Augentin/Ceclor/Cefixime
4 = Clarithromycin/azithromycin
5 = Cotrimoxazole (bactrim/septra)
6 = Tetracycline/Doxycycline
7 = Other
9 = Unknown

EXPOSURE

Country of Residence
☐ U = US
O = Other

If Other, Country Name:

Date of U.S. Arrival
Month Day Year OR ☐ U = Unknown

History of International Travel? (2 Weeks Prior to Onset)
☐ Y = Yes
N = No
U = Unknown

Country(s) Visited	From Month	From Day	From Year	To Month	To Day	To Year

History of Interstate Travel? (2 Weeks Prior to Onset)
☐ Y = Yes
N = No
U = Unknown

State(s) Visited	From Month	From Day	From Year	To Month	To Day	To Year

Known Exposure to Diphtheria Case or Carrier?
☐ Y = Yes
N = No
U = Unknown

Known Exposure to International Travelers?
☐ Y = Yes
N = No
U = Unknown

Known Exposure to Immigrants?
☐ Y = Yes
N = No
U = Unknown

REPORTING INFO

Has this Suspected Case been Reported to the State or Local Health Department?
☐ Y = Yes
N = No
U = Unknown

Date Reported to State or Local Health Department
Month Day Year

Person Informed: Phone: Fax:

Reporting Physician: Phone: Fax:

REQUESTING PHYSICIAN

Name

Institution

Street

City State Zip code

Phone: Fax:

Name of Investigator under the IND
(If different from requesting physician)
Phone: Fax:

SHIP DRUG TO:

Name

Attn:

Institution

Street

City State Zip code

Phone: Fax:

DOSE

Amount of DAT Administered: ☐☐☐,☐☐☐ IU DAT

DISPOS.

Final Diagnosis:

How was the final diagnosis confirmed?

Final Case Disposition
☐ C = Confirmed
P = Probable
N = Not a Case

Information for Close Contacts*
Diphtheria

*Close Contact = Household members and others with a history of direct contact with a case-patient, and medical staff exposed to oral or respiratory secretions of a case-patient

CONTACT INFORMATION

Name _____ Age _____ Relation to Case _____

Vaccinated? ☐ Y = Yes N = No U = Unknown
If Vaccinated, Number lifetime of Doses ☐ U = Unknown L = < 3 Doses U = Unknown
If Vaccinated, Last Dose ☐ L = =5 Years Ago G = > 5 Years Ago
Nasopharyngeal Culture Obtained? ☐ Y = Yes N = No U = Unknown
Oropharyngeal (Throat) Culture Obtained? ☐ Y = Yes N = No U = Unknown
Date of Culture ☐☐ Month ☐☐ Day ☐☐ Year
Results ☐ P = Positive N = Negative U = Unknown
Antibiotic Prophylaxis ☐ See Codes Below

Name _____ Age _____ Relation to Case _____

Vaccinated? ☐ Y = Yes N = No U = Unknown
If Vaccinated, Number lifetime of Doses ☐ U = Unknown L = < 3 Doses U = Unknown
If Vaccinated, Last Dose ☐ L = =5 Years Ago G = > 5 Years Ago
Nasopharyngeal Culture Obtained? ☐ Y = Yes N = No U = Unknown
Oropharyngeal (Throat) Culture Obtained? ☐ Y = Yes N = No U = Unknown
Date of Culture ☐☐ Month ☐☐ Day ☐☐ Year
Results ☐ P = Positive N = Negative U = Unknown
Antibiotic Prophylaxis ☐ See Codes Below

Name _____ Age _____ Relation to Case _____

Vaccinated? ☐ Y = Yes N = No U = Unknown
If Vaccinated, Number lifetime of Doses ☐ U = Unknown L = < 3 Doses U = Unknown
If Vaccinated, Last Dose ☐ L = =5 Years Ago G = > 5 Years Ago
Nasopharyngeal Culture Obtained? ☐ Y = Yes N = No U = Unknown
Oropharyngeal (Throat) Culture Obtained? ☐ Y = Yes N = No U = Unknown
Date of Culture ☐☐ Month ☐☐ Day ☐☐ Year
Results ☐ P = Positive N = Negative U = Unknown
Antibiotic Prophylaxis ☐ See Codes Below

Name _____ Age _____ Relation to Case _____

Vaccinated? ☐ Y = Yes N = No U = Unknown
If Vaccinated, Number lifetime of Doses ☐ U = Unknown L = < 3 Doses U = Unknown
If Vaccinated, Last Dose ☐ L = =5 Years Ago G = > 5 Years Ago
Nasopharyngeal Culture Obtained? ☐ Y = Yes N = No U = Unknown
Oropharyngeal (Throat) Culture Obtained? ☐ Y = Yes N = No U = Unknown
Date of Culture ☐☐ Month ☐☐ Day ☐☐ Year
Results ☐ P = Positive N = Negative U = Unknown
Antibiotic Prophylaxis ☐ See Codes Below

Name _____ Age _____ Relation to Case _____

Vaccinated? ☐ Y = Yes N = No U = Unknown
If Vaccinated, Number lifetime of Doses ☐ U = Unknown L = < 3 Doses U = Unknown
If Vaccinated, Last Dose ☐ L = =5 Years Ago G = > 5 Years Ago
Nasopharyngeal Culture Obtained? ☐ Y = Yes N = No U = Unknown
Oropharyngeal (Throat) Culture Obtained? ☐ Y = Yes N = No U = Unknown
Date of Culture ☐☐ Month ☐☐ Day ☐☐ Year
Results ☐ P = Positive N = Negative U = Unknown
Antibiotic Prophylaxis ☐ See Codes Below

Name _____ Age _____ Relation to Case _____

Vaccinated? ☐ Y = Yes N = No U = Unknown
If Vaccinated, Number lifetime of Doses ☐ U = Unknown L = < 3 Doses U = Unknown
If Vaccinated, Last Dose ☐ L = =5 Years Ago G = > 5 Years Ago
Nasopharyngeal Culture Obtained? ☐ Y = Yes N = No U = Unknown
Oropharyngeal (Throat) Culture Obtained? ☐ Y = Yes N = No U = Unknown
Date of Culture ☐☐ Month ☐☐ Day ☐☐ Year
Results ☐ P = Positive N = Negative U = Unknown
Antibiotic Prophylaxis ☐ See Codes Below

Name _____ Age _____ Relation to Case _____

Vaccinated? ☐ Y = Yes N = No U = Unknown
If Vaccinated, Number lifetime of Doses ☐ U = Unknown L = < 3 Doses U = Unknown
If Vaccinated, Last Dose ☐ L = =5 Years Ago G = > 5 Years Ago
Nasopharyngeal Culture Obtained? ☐ Y = Yes N = No U = Unknown
Oropharyngeal (Throat) Culture Obtained? ☐ Y = Yes N = No U = Unknown
Date of Culture ☐☐ Month ☐☐ Day ☐☐ Year
Results ☐ P = Positive N = Negative U = Unknown
Antibiotic Prophylaxis ☐ See Codes Below

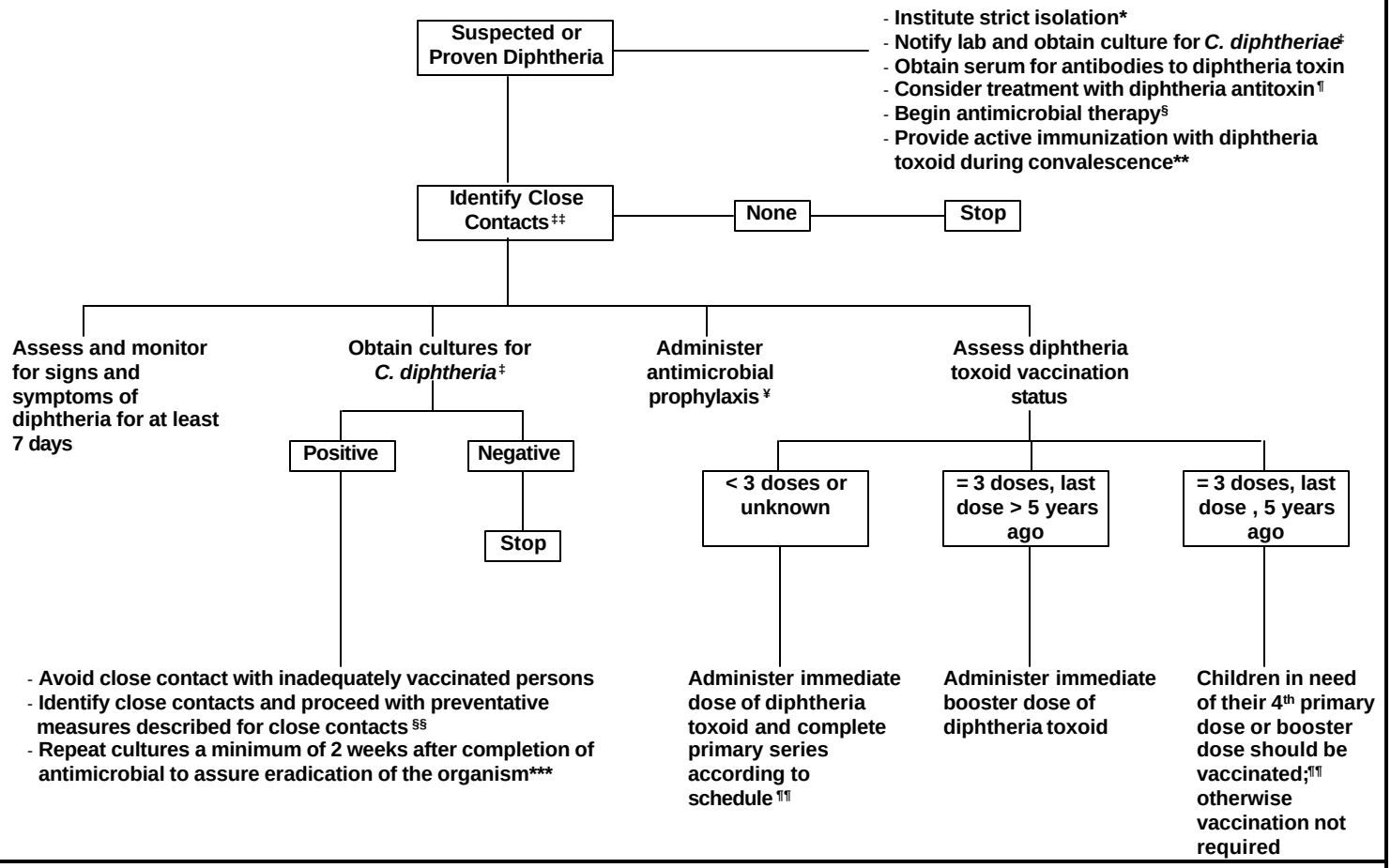
Name _____ Age _____ Relation to Case _____

Vaccinated? ☐ Y = Yes N = No U = Unknown
If Vaccinated, Number lifetime of Doses ☐ U = Unknown L = < 3 Doses U = Unknown
If Vaccinated, Last Dose ☐ L = =5 Years Ago G = > 5 Years Ago
Nasopharyngeal Culture Obtained? ☐ Y = Yes N = No U = Unknown
Oropharyngeal (Throat) Culture Obtained? ☐ Y = Yes N = No U = Unknown
Date of Culture ☐☐ Month ☐☐ Day ☐☐ Year
Results ☐ P = Positive N = Negative U = Unknown
Antibiotic Prophylaxis ☐ See Codes Below

Antibiotic Codes

1 = Erythromycin (inc. Pediazole, ilosone)
2 = Penicillin (Bicillin, Pfizerpen-AS, Wycillin)
3 = Amoxicillin/Ampicillin/Augmentin/Ceclor/Cefixime
4 = Clarithromycin/azithromycin
5 = Cotrimoxazole (bactrim/septra)
6 = Tetracycline/Doxycycline
7 = Other

CONTACT INFORMATION



* Maintain isolation until elimination of the organism is demonstrated by negative cultures of two samples obtained at least 24 hours apart after completion of antimicrobial therapy.

‡ Both nasal and pharyngeal swabs should be obtained for culture.

¶ If equine diphtheria antitoxin is needed, contact your State Health Department. Before administration, patients should be tested for sensitivity to horse serum and, if necessary, desensitized. The recommended dosage and route of administration depend on the extent and duration of disease. Detailed recommendations can be obtained from the package insert and other publications.

§ Antimicrobial therapy is not a substitute for antitoxin treatment. Intramuscular procaine penicillin G (25,000–50,000 unites/[kg/d] for children and 1.2 million units/d for adults, in two divided doses) or parenteral erythromycin in four divided doses or oral penicillin V (125–250 mg four times daily) may be substituted for a recommended total treatment period of 14 days.

** Vaccination is required because clinical diphtheria does not necessarily confer immunity.

‡‡ Close contacts include household members and other persons with a history of direct contact with a case-patient (e.g. caretakers, relatives, or friends who regularly visit the home) as well as medical staff exposed to oral or respiratory secretions of a case-patient.

¥ A single dose of intramuscular benzathine penicillin G (600,000 units for persons < 6 years of age and 1.2 million units for persons = 6 years of age: or a 7- to 10-day course of oral erythromycin (40 mg/[kg/d]) for children and 1 g/d for adults) has been recommended.

§§ Preventative measures may be extended to close contacts of carriers but should be considered a lower priority than control measures for contacts of each case.

***Persons who continue to harbor the organism after treatment with either penicillin or erythromycin should receive an additional 10-day course of oral erythromycin and should submit samples for follow-up cultures.

¶¶ Refer to published recommendations for the schedule for routine administration of DTP.

Farizo KM, Strebel PM, Chen RT, et al. Fatal respiratory disease due to *Corynebacterium diphtheriae*: Case report and review of guidelines for management, investigation, and control. *Clin Infect Dis* 1993;16:59-68.

Folliculitis

Folliculitis

Illness: Folliculitis is an inflammation of the hair follicles caused by infection or physical or chemical irritation. The most common form of superficial folliculitis is idiopathic. More serious forms of folliculitis involve the deep portion of the hair follicle and, usually, are more symptomatic and may cause scarring.

Infectious agent: *Pseudomonas aeruginosa* (other possibilities include: *Staphylococcus aureus*, *Klebsiella* spp., *Enterobacter* spp., *Proteus* spp, others)

Incubation period: 12-36 hours

Duration of illness: 3-7 days

Symptoms: Maculopapular rash (numerous red bumps that look like pimples), soreness in the armpits or breasts, headache, earache, sore nose, itchy skin, or fatigue. Fever and lymph node enlargement denote systemic infection, a rare complication.

Infectious period: No person-to-person transmission.

Transmission route: Swimming in poorly maintained hot tubs or pools, or contaminated lakes.

Treatment: Symptomatic.
Systemic illness may require antibiotic therapy (rare).

Information Needed for the Investigation

Verify the Diagnosis

- Is there a recent history of swimming in a hot tub, pool, or spa?
- Obtain culture of skin lesions.
- Environmental swabs.

Environmental Investigation

- Notify DEC.
- Obtain disinfection records for public pools/spas.
- Bather load history.
- If large outbreak, may request DEC to obtain environmental specimens.

Reporting Requirements

- FTR: Write up all outbreaks >5 persons.
- Fill out CDC waterborne outbreak form.
- Morbidity Database: None.

Folliculitis Questionnaire

Name: _____ DOB: ___ /___ /_____Date: ___ /___ /_____

Address: _____ Phone Number: _____
_____

Have you noticed any rash, bumps or sores on your skin during the week of_____? Y N
Where was the rash located: _____
Describe what it looked like: _____
How big was it? _____
When did you first notice the rash? _____

Did you visit a clinic? Y N Phone #: _____
Was a culture taken? Y N Result: _____
Did you take any medicine? Y N Name: _____

Did you have any of the following symptoms?

Fever	Y	N	Itchy skin	Y	N	Nausea	Y	N
Vomiting	Y	N	Muscle aches	Y	N	Earache	Y	N
Chills	Y	N	Soreness or swelling of armpits			Y	N	
Fatigue	Y	N	Frequent or painful urination			Y	N	
For females only:			Painful swelling of breasts			Y	N	
			Painful swelling of nipples			Y	N	

What dates did you stay at the (HOTEL)? _____

Did you swim in the pool or hot tub at the (HOTEL)? Y N

If NO, stop here. If YES, continue.

Pool use

Date of use	Time of use	Duration (minutes)	Maximum # in pool
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Hot tub use

Date of use	Time of use	Duration (minutes)	Maximum # in hot tub
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Did you shower before using the hot tub/pool? Y N
Did you shower after using the hot tub/pool? Y N Did you use soap? Y N
Did you share a towel with anyone? Y N
Does anyone else in your family have a rash? Y N Name: _____
Do you know anyone else with a rash? Y N Name/ph#: _____

How many other people stayed with you in your hotel room: _____
Did any of them go swimming or have a rash? Y N
Please fill out a form for all additional persons with a rash.

STATE OF ALASKA
DEPARTMENT OF HEALTH & SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY
3601 C STREET, SUITE 540
P.O. BOX 240249
ANCHORAGE, ALASKA 99524-0249
FRANK H. MURKOWSKI, GOVERNOR
INFECTIOUS DISEASES
AIDS/STD
TUBERCULOSIS
IMMUNIZATION
CHRONIC DISEASES
DIABETES
INJURY CONTROL
(907) 269-8000
(907) 562-7802

Folliculitis Fact Sheet

What is *Pseudomonas* folliculitis?
Pseudomonas folliculitis is an inflammation of the hair follicles caused by infection with the bacteria *P. aeruginosa*. It has been reported in persons using hot tubs, whirlpools, saunas, swimming pools, waterslides and physiotherapy pools.

Who gets *Pseudomonas* folliculitis?
Any person exposed to water contaminated with *P. aeruginosa* can get *Pseudomonas* folliculitis.

Where is *P. aeruginosa* found?
Pseudomonas aeruginosa thrives in warm and moist areas and is commonly found in soil, sinks and drains, shower-floors, carpeting and even tap water.

What are the symptoms of *Pseudomonas* folliculitis?
Pseudomonas folliculitis first appears as itchy bumps and develops into dark red tender nodules and/or small pus-filled pimples. The eruptions typically involve the trunk and upper parts of the arms and legs. The rash can be extensive and may affect all areas of the body except the palms of the hands and soles of the feet. Headache, nausea, vomiting, abdominal cramps, sore throat, rhinitis, sore eyes, and fever may accompany the rash.

How soon after exposures do symptoms of *Pseudomonas* folliculitis appear?
The incubation period for "*Pseudomonas* folliculitis" is usually 48 hours (range 8 hours to 5 days) after exposure to contaminated water.

How can *Pseudomonas* folliculitis be diagnosed?
Pseudomonas aeruginosa can often be cultured from pus-filled pustules on the skin.

What is the treatment for *Pseudomonas* folliculitis?
The rash associated with this infection will usually go away on its own and treatment may not be needed. "Anti-itch" medications may be used to control the itching.

How can *Pseudomonas* folliculitis be prevented?
Be aware that hot tubs and spas have warmer water than pools, so chlorine or other disinfectants evaporate faster. This leaves hot tubs and spas at risk for the spread of *Pseudomonas* folliculitis. Therefore, ask your pool manager about the bromine/chlorine and pH-testing program at your hot tub or pool. Ensuring frequent testing, control of bromine/chlorine levels, and pH control are likely to prevent the spread of dermatitis.

DEPARTMENT OF HEALTH
& HUMAN SERVICES
Centers for Disease Control
and Prevention
National Center for Infectious Diseases
Atlanta, GA 30333

WATERBORNE DISEASES OUTBREAK REPORT

This form should be used to report outbreaks of illness after consumption or use of water intended for drinking, as well as outbreaks associated with exposure (ingestion, contact or inhalation) to recreational water.

CDC USE ONLY
–
___ ___ ___ ___ ___ ___

Form Approved
OMB No. 0920-0004

SUBMITTED COPIES OF THIS FORM SHOULD INCLUDE AS MUCH INFORMATION AS POSSIBLE; BUT THE COMPLETION OF EVERY ITEM IS NOT REQUIRED.

1. TYPE of EXPOSURE:
- ☐ Drinking water
- ☐ Recreational water
- ☐ Other: _____

2. LOCATION of OUTBREAK:
State: _____
City or Town: _____
County: _____

3. DATE of OUTBREAK:
(Date first case became ill):
Mo. ___ Day ___ Yr. ___

4. NUMBERS OF:

	Actual	Estimated
Persons exposed:		
Persons ill:		
Hospitalized:		
Fatalities:		

5. HISTORY of EXPOSED PERSONS:
Enter the no. of persons with the following symptoms:

NO. OF PERSONS INTERVIEWED: ___ NO. OF INTERVIEWED PERSONS WHO WERE ILL: ___

Diarrhea (≥3 stools/day): ___ Diarrhea (other): ___ /(Specify definition): _____
Visible blood in stools: ___ Nausea: ___ Fever: ___ Vomiting: ___ Cramps: ___
Eye infections: ___ Ear infections: ___ Skin infections: ___ Rash: ___ Dermatitis: ___
Respiratory symptoms: ___ Other, specify: _____

6. INCUBATION PERIOD:

	Hrs.	Days
Shortest:	☐	☐
Longest:	☐	☐
Median:	☐	☐
Mean:	☐	☐

7. DURATION of ILLNESS:

	Hrs.	Days
Shortest:	☐	☐
Longest:	☐	☐
Median:	☐	☐
Mean:	☐	☐

8. SPECIMENS EXAMINED from PATIENTS: (stool, vomitus, serum, etc.)

SPECIMEN	No. PERSONS	FINDINGS
EXAMPLE *Stool*	*11*	*8 Giardia intestinalis 3 negative*

9. ETIOLOGY of OUTBREAK:

Agent (If not known enter "Unk.")	Diagnostic Certainty: Confirmed	Suspected
Pathogen:	☐	☐
Chemical:	☐	☐
Other:	☐	☐

Comments: .....

10a. EPIDEMIOLOGIC DATA: (e.g., vehicle/source - specific attack rates; dose-response curve, **attach local and/or state report if available**)

EXPOSURE (vehicle/source)	Number of Persons EXPOSED: ILL	NOT ILL	TOTAL	% ILL	Number of Persons NOT EXPOSED: ILL	NOT ILL	TOTAL	% ILL	ODDS/RISK RATIO (If available)	p VALUE or CONFIDENCE INTERVAL (If available)

☐ **No data were collected from comparison groups to estimate risk but water was the only common source shared by persons who were ill.**

10b. Comments: .....

11. WATER SUPPLY CHARACTERISTICS: *(check all that apply for drinking water or recreational water)*

*If recreational water outbreak, this refers to recreational water treatment

a) TYPE OF DRINKING WATER SUPPLY:
- ☐ Community or Municipal
  - ☐ City or County (Name: _____)
  - ☐ Subdivision
  - ☐ Trailer Park
- ☐ Noncommunity (does not obtain water from a community water system, but has developed/maintained its own water supply)
  - ☐ Camp, Cabin, Recreational area
  - ☐ School
  - ☐ Restaurant
  - ☐ Hotel, Motel
  - ☐ Church
  - ☐ Other: _____
- ☐ Individual household supply
- ☐ Bottled water
- ☐ Other: _____
- ☐ Unknown

b) WATER SOURCE OR SETTING:
- ☐ Well
- ☐ Spring/Hot spring
- ☐ River, Stream
- ☐ Lake, Pond, Reservoir
- ☐ Ocean
- ☐ Pool
  - ☐ Waterpark
  - ☐ Community/municipal
  - ☐ Subdivision/neighborhood apartment
  - ☐ Hotel/motel
  - ☐ Membership club
  - ☐ Private home
  - ☐ Kiddie/wading
- ☐ Fountain
  - ☐ Interactive
  - ☐ Ornamental
  - ☐ Waterpark
- ☐ Hot tub
- ☐ Whirlpool/spa pool
- ☐ Other: _____
- ☐ Unknown

c) WATER TREATMENT PROVIDED:*
- ☐ No treatment
- ☐ Disinfection
  - ☐ Chlorine
  - ☐ Chlorine and Ammonia (chloramine)
  - ☐ Bromine
  - ☐ Ozone
  - ☐ U.V.
  - ☐ Other: _____
  - ☐ Unknown
- ☐ Coagulation and/or Flocculation
- ☐ Settling (sedimentation)
- ☐ Filtration at purification plant (**don't** include home filters) or pool
  - ☐ Rapid sand
  - ☐ Slow sand
  - ☐ Diatomaceous earth
  - ☐ Other: _____
  - ☐ Unknown
- ☐ Other: _____
- ☐ Unknown

IF RECREATIONAL EXPOSURE, PROCEED TO QUESTION (13), OTHERWISE PROCEED TO (12a).

12. FACTORS CONTRIBUTING TO DRINKING WATER CONTAMINATION: (check **all** that apply) *See 16

a) Contamination at the water source:

- ☐ Overflow of sewage
- ☐ Underground seepage of sewage
- ☐ Septic system drainage
- ☐ Flooding, heavy rains
- ☐ Use of a back-up source of water by a water utility
- ☐ Improper construction or location of well or spring
- ☐ Contamination of wells through limestone or fissured rock
- ☐ Contamination from wild/domestic animals
- ☐ Chemical pollution
- ☐ Algal bloom
- ☐ Other: _____
- ☐ Unknown

b) Water treatment deficiencies:

- ☐ No disinfection
- ☐ Temporary interruption of disinfection
- ☐ Chronically inadequate disinfection
- ☐ No filtration
- ☐ Inadequate filtration
- ☐ Deficiencies in other treatment processes
- ☐ Other: _____
- ☐ Unknown

c) Contamination in the water distribution system or home plumbing:

- ☐ Cross connection of potable and non-potable water pipes resulting in back siphonage (negative pressure or backflow)
- ☐ Contamination of mains during construction or repair
- ☐ Contamination of storage facility
- ☐ Contamination in building/home
- ☐ Other: _____
- ☐ Unknown

d) OTHER REASONS/CONTRIBUTING FACTORS FOR CONTAMINATION OF WATER (eg. corrosive water):

.....

13. ROUTE OF ENTRY FOR RECREATIONAL EXPOSURE:

- ☐ Accidental ingestion
- ☐ Intentional ingestion
- ☐ Contact
- ☐ Inhalation
- ☐ Other: _____
- ☐ Unknown

14. FACTORS CONTRIBUTING TO RECREATIONAL WATER CONTAMINATION : (check **all** that apply) *See 16

a) FRESH OR MARINE WATER (e.g. lakes, rivers, oceans):

- ☐ High bather density/load
- ☐ Fecal accident by bather(s)
- ☐ Use by diaper/toddler aged children
- ☐ Overflow or release of sewage
- ☐ Flooding, heavy rains
- ☐ Stagnant water
- ☐ Water Temperature ≥ 30°C
- ☐ Chemical pollution
- ☐ Algal bloom
- ☐ Animal feces observed near site
- ☐ Agricultural/animal production in watershed
- ☐ Unprotected watershed
- ☐ Other: _____
- ☐ Unknown

b) FILTERED AND/OR DISINFECTED SWIMMING VENUES (e.g. swimming pools, water parks, hot tubs, whirlpools/spa pools):

- ☐ High bather density/load
- ☐ Fecal accident by bather(s)
- ☐ Use by diaper/toddler aged children
- ☐ No disinfection
- ☐ Inadequate disinfection
- ☐ Poor monitoring of disinfection levels
- ☐ Cross contamination (specify _____)
- ☐ Combined adult/child pool filtration systems
- ☐ No filtration
- ☐ Inadequate filtration
- ☐ Other: _____
- ☐ Unknown

15. WATER SPECIMENS EXAMINED: (provide information for routine samples collected **before** and **during** the outbreak investigation as well as for any special lab studies)

☐ NONE TESTED

ITEM	DATE	LABORATORY RESULTS: MICROBIOLOGY	DISINFECTANT RESIDUAL	TURBIDITY
EXAMPLES Tap Water	10/11/01	Total coliforms - none found in two 100ml samples; Giardia - 10 cysts/100L	0.5 mg/L	0.1 NTU
Untreated Raw Water	11/02/01	23 fecal coliforms per 100 ml	Not Done	10.0 NTU
System History	Prev. 3 mos	MCL for total coliforms exceeded month before outbreak	NA	>MCL
Source Water	Prev. 2 wks	Heavy runoff, high turbidity	NA	5.0 NTU

16. REMARKS: Clarify for sections 12 and 14 which checked items are confirmed or are suspected factors

Briefly describe the unusual aspects of the outbreak and/or the outbreak investigation not covered above. Attach epidemic curve and summary report, if available.

.....

.....

.....

Person to contact for information about water quality or water system:

_____

_____

Person completing form: (please print)

NAME: _____

AGENCY: _____

E-MAIL: _____

TEL. NO: (_____) ___ ___ ___ - ___ ___ ___ ___
area code

DATE OF REPORT: ___ ___ / ___ ___ / ___ ___
MO. DAY YR.

Date investigation initiated:

___ ___ / ___ ___ / ___ ___
MO. DAY YR.

Note: Epidemic and laboratory assistance for the investigation of a waterborne outbreak is available upon request by the State Health Department to the Centers for Disease Control and Prevention. To improve national surveillance of outbreaks of waterborne diseases, please send a copy of this report, your internal report, and the questionnaire used in the epidemiologic investigation (if available) to:

Centers for Disease Control and Prevention
Division of Parasitic Diseases
Attention: Waterborne Disease Coordinator
4770 Buford Highway, NE, Mailstop F22
Atlanta, GA 30341-3724

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0004). <––DO NOT MAIL CASE REPORTS TO THIS ADDRESS–

GI & Foodborne Illnesses

Gastrointestinal Illness of Unknown Etiology

Everybody's vomiting, everybody's got diarrhea, something is wrong with the water supply.

(Note: If norovirus is suspected, see **Norovirus**)

Interview Person Reporting Illness

- Phone number of caller
- How many ill?
- Symptoms
- Date and time of onset
- Ask for stool samples – keep refrigerated
- Advise not to discard any foods which may be useful for testing
- Ask whether there is any suspicious common event or exposure
- Begin a line list of ill persons

Interview Ill Persons (Complete an interview form for each ill person.)

Determine Need for and Size of Response

- Responses may range from taking information without any human specimens to requesting DEC to inspect food outlet to full scale EPI Investigation.
- If it appears that it is a cluster of GI illness, notify RNM, DEC, discuss with EPI team to assign team leader for outbreak investigation.
- Create a specific questionnaire for each outbreak.

Laboratory Specimens

- It is critical to obtain stool or vomitus specimens early in the investigation to determine the agent.
- Collect stool specimens for at least these two tests at the outset: bulk stool for norovirus and enteric transport media for enteric bacteria.
- Determine need for other special media or special lab instructions based on initial information symptoms.
- If hepatitis A is suspected, collect 1 (one) red top tube on the ill persons.

Reporting Requirements

- FTR:
  - Full write up of all outbreaks; foodborne, waterborne or person-to-person.
  - Write up any investigation of large clusters of illness, even if agent is not identified.
- Morbidity database: enter all lab-confirmed cases and Epi-linked cases if there is any reportable agent. Give the outbreak an Outbreak Number and Name. Assign this number to each outbreak case.

References

MMWR, April 16, 2004, Diagnosis and Management of Foodborne Illnesses
http://www.cdc.gov/mmwr/PDF/rr/rr5304.pdf

Alaska Section of Epidemiology Enteric Disease Questionnaire

Patient Name: _____ **Phone:** Home:(____) ____-_____

Address: _____ **Phone:** Other:(____) ____-_____

Guardian Name: _____ **Relation:**_____

Alaska Resident: **Yes** **No** **Disease:** _____

Investigator:		**Interview Date:**
1. Date of birth: Unknown Month Day Year	**2. Age:** Years Months Days	**3. Sex:** Male Female Unknown
4. Race: White . American Indian or Alaska Native . Black . Asian or Pacific Islander . Unknown		**5. Ethnicity:** Hispanic Non-Hispanic Unknown
6. Occupation: _____	**Location:** _____	**Phone:** _____
8. Onset of illness: Month Day Year	**9. Onset of diarrhea:** Month Day Year	**10. Duration of illness:** Hours Days
11. Patient treated: Yes No Med(s):_____	**12. Patient hospitalized:** Yes No Where:_____ Admit Date: ___/____/_____ Dischg Date:___/____/_____	**13. Specimen collection date:** Month Day Year
14. Submission information: Submitting Lab:_____ Submitting Physician: _____ ph: _____		**15. Date Specimen Received:** Month Day Year

16. Specimen Source: Stool Blood Nasopharyngeal CSF Other:_____

Result(s): _____

17. Symptoms

Fever (max_____ºF)	Nausea	Anorexia
Chills	Vomiting	Still Symptomatic
Diarrhea	Bloating/Flatulence	Others:
Bloody	Malaise	
Watery	Headache	
Mucousy	Dizziness	
Pale Stools	Muscle Aches	
Abdominal Pain	Weight Loss	

18. Anyone in the household employed or attend:

Daycare Health Care Food Service No

Name	Where	Age	Ill
_____	_____	_____	Yes No
Name	Where	Age	Ill
_____	_____	_____	Yes No

19. Cared for any diaper aged children: Yes When: _____ No Unknown	**20. House guests from out of town recently:** Yes Date(s):_____ No If No→20 Unknown	20A. Were any of your house guests ill: Yes Date(s):_____ No Unknown
21. Recent Travel: Yes No (If No→21)	21A. Travel Location Date _____ _____ _____ _____ _____ _____	**22. Attend any gatherings, parties, or special events:** Yes Date:_____ No If No→ 22
22A. Anyone from the gathering ill? Yes No	**23. Taking any new medications:** Yes No Type: _____	**24. Anyone else you know with similar symptoms?** Yes No If No→ 24

24A. Information on others that are/were ill:

Name: _____ Relationship: _____ Phone number: _____
Name: _____ Relationship: _____ Phone number: _____
Name: _____ Relationship: _____ Phone number: _____

25. Been around any animals? Yes No (If No→ 25) Unknown	25A. What kind of animals? _____ _____ _____	25B. What kind of setting? Home Farm Zoo/Petting zoo Other_____
25C. Did the animals have diarrhea? Yes No Unknown	**26. Consumption of water from:** Stream Well Lake Other: Reservoir _____ Spring Date(s): _____	**27. Home water source:** Public Municipality Private Well Community Well Bottled Unknown
28. Swimming **Date_____** Stream Lake Pool/Hot Tub None	**29. Prepare any meals while ill?** Yes For who_____ No Unknown	**30. Restaurants ≤5 days b/f onset?** _____ _____ _____ _____
Breakfast (day of onset) _____ _____ _____ _____	**Lunch (& snacks)** _____ _____ _____ _____	**Dinner** _____ _____ _____ _____
Breakfast (one day prior to onset) _____ _____ _____ _____	**Lunch (& snacks)** _____ _____ _____ _____	**Dinner** _____ _____ _____ _____
Breakfast (two days prior to onset) _____ _____ _____ _____	**Lunch (& snacks)** _____ _____ _____ _____	**Dinner** _____ _____ _____ _____

Alaska Section of Epidemiology Enteric Disease Questionnaire-Abbreviated

Reported By:_____ **Phone: (____) _____-_____**

Patient Name: _____

Address: _____ **Phone: (____) _____-_____**

_____ **(____) _____-_____**

Guardian Name: _____ **Relation:** _____

Alaska Resident: ☐ **Yes** ☐ **No** **Disease:** _____

Investigator:		**Interview Date:**
1. Date of birth: ☐ Unknown Month ☐☐ Day ☐☐ Year ☐☐☐☐	**2. Age:** ☐☐☐ ☐ Years ☐ Months ☐ Days	**3. Sex:** ☐ Male ☐ Female ☐ Unknown
4. Race: ☐ White ☐ American Indian or Alaska Native ☐ Black ☐ Asian or Pacific Islander ☐ Unknown		**5. Ethnicity:** ☐ Hispanic ☐ Non-Hispanic ☐ Unknown
6. Occupation	**7. Address**	**8. Phone**
9. Onset of illness: Month ☐☐ Day ☐☐ Year ☐☐☐☐	**10. Patient treated:** ☐ Yes ☐ No Med(s):_____	**11. Specimen collection date:** Month ☐☐ Day ☐☐ Year ☐☐☐☐

12. Symptoms

☐ Fever (max_____ºF)
☐ Chills
☐ Diarrhea
☐ Abdominal Pain
☐ Nausea
☐ Vomiting
☐ Bloating/Flatulence
☐ Underlying medical conditions:
_____
_____

13. Anyone in the household employed or attend:

☐ Daycare ☐ Health Care ☐ Food Service ☐ No

Name	Where	Age	Ill?
_____	_____	_____	☐ Yes ☐ No
Name	Where	Age	Ill?
_____	_____	_____	☐ Yes ☐ No

14. Any recent travel? ☐ Yes ☐ No

If yes, list dates and locations:

_____

_____

15. Anyone else you know with similar symptoms?

☐ Yes ☐ No

16. Information on others who are/were ill:

Name: _____ Relationship: _____Phone (____) _____-_____

Name: _____ Relationship: _____Phone (____) _____-_____

Name: _____ Relationship: _____Phone (____) _____-_____

Patient Subjective Information:

Recommendations:

Disposition:

Foodborne Illness Investigation: Food Worker Interview

Interviewer:	**Date of Interview:**
Food Worker Name:	**Position:**
Address:	**Phone:**

WORK HISTORY

How long have you worked at this establishment?

Do you work as a food worker anywhere else? Yes ☐ No ☐ | If yes, where?

Time period of concern (usually 10 days prior to the suspect meal):

When did you work during this time period?

Su	M	T	W	Th	F	Sa
Su	M	T	W	Th	F	Sa
Su	M	T	W	Th	F	Sa

Did you handle/prepare any of the suspect foods? (Provide a list of foods.) Yes ☐ No ☐

If yes, list the foods on the reverse side of this page.

Did you eat any foods prepared on the date of the suspect meal? Yes ☐ No ☐

If yes, indicate the foods eaten:

ILLNESS HISTORY

Did you have any of the following symptoms between _____ and today?
(Usually ask about symptoms from two weeks prior to suspect meal.)

CHECK ALL THAT APPLY:

Nausea ☐	**Vomiting** ☐		**Diarrhea** ☐	**# of episodes/day**
Muscle aches ☐	**Headaches** ☐	**Fever** ☐	**Chills** ☐	**Abdominal cramps** ☐

If any symptoms, ask:
When did the symptoms begin? (Date/time)

When did the symptoms end? (Date/time)

See a doctor / go to the hospital? Yes ☐ No ☐ | If yes, Name of HCP

Diagnosis? | Date you returned to work:

Sick leave pay? Yes ☐ No ☐

Must you tell your employer/manager when you are ill with diarrhea or vomiting? Yes ☐ No ☐

Has anyone else in your household been ill during the same period? Yes ☐ No ☐
(If more than one person was ill, list all information on the reverse side of this page.)

If yes, which symptoms did they experience?

When did the symptoms begin?

When did the symptoms end?

Occupation of this household member:

STOOL SPECIMEN

Provide food worker with a stool kit. | **Date kit given:**

- **Instruct food worker that the stool must be submitted within 48 hours or the worker may be excluded from work.**
- **Employee's name must be on the specimen vial and on the paperwork inside the kit.**

Facility:	Date of Suspect Meal:
Phone:	

Master List of Food Employees/Duties

(Include: Servers, Dishwashers, Food Preparation Workers, Bartenders, Kitchen Supervisor, Kitchen Manager, and anyone who is associated with food service or who has access to the kitchen.

List all who worked or were absent from work between _____and the present. Note any workers who were out sick two weeks before or after the suspect meal.

Manager in charge of the facility on the date of the suspect meal/event:

Person in charge of the kitchen on the date of the suspect meal/event:

Name(s) of the Certified Food Protection Manager(s):

Name	Phone	Foods Prepared and/or Duties Performed	Shift Worked / Days Out Sick

Foodborne Illness Investigation: Food Worker Interview

Interviewer:	**Date of Interview:**
Food Worker Name:	**Position:**
Address:	**Phone:**

WORK HISTORY

How long have you worked at this establishment?

Do you work as a food worker anywhere else? Yes ☐ No ☐ | If yes, where?

Time period of concern (usually 10 days prior to the suspect meal):

When did you work during this time period?

Su	M	T	W	Th	F	Sa
Su	M	T	W	Th	F	Sa
Su	M	T	W	Th	F	Sa

Did you handle/prepare any of the suspect foods? (Provide a list of foods.) Yes ☐ No ☐

If yes, list the foods on the reverse side of this page.

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If yes, indicate the foods eaten:

ILLNESS HISTORY

Did you have any of the following symptoms between _____ and today?
(Usually ask about symptoms from two weeks prior to suspect meal.)

CHECK ALL THAT APPLY:

Nausea ☐	**Vomiting** ☐		**Diarrhea** ☐	**# of episodes/day**
Muscle aches ☐	**Headaches** ☐	**Fever** ☐	**Chills** ☐	**Abdominal cramps** ☐

If any symptoms, ask:
When did the symptoms begin? (Date/time)

When did the symptoms end? (Date/time)

See a doctor / go to the hospital? Yes ☐ No ☐ | If yes, Name of HCP

Diagnosis? | Date you returned to work:

Sick leave pay? Yes ☐ No ☐

Must you tell your employer/manager when you are ill with diarrhea or vomiting? Yes ☐ No ☐

Has anyone else in your household been ill during the same period? Yes ☐ No ☐
(If more than one person was ill, list all information on the reverse side of this page.)

If yes, which symptoms did they experience?

When did the symptoms begin?

When did the symptoms end?

Occupation of this household member:

STOOL SPECIMEN

Provide food worker with a stool kit. | **Date kit given:**

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Facility:	Date of Suspect Meal:
Phone:	

Master List of Food Employees/Duties

(Include: Servers, Dishwashers, Food Preparation Workers, Bartenders, Kitchen Supervisor, Kitchen Manager, and anyone who is associated with food service or who has access to the kitchen.

List all who worked or were absent from work between _____and the present. Note any workers who were out sick two weeks before or after the suspect meal.

Manager in charge of the facility on the date of the suspect meal/event:

Person in charge of the kitchen on the date of the suspect meal/event:

Name(s) of the Certified Food Protection Manager(s):

Name	Phone	Foods Prepared and/or Duties Performed	Shift Worked / Days Out Sick

Foodborne Illnesses

RANKING PERCEIVED SERIOUSNESS
OF A
FOODBORNE ILLNESS CALL

FACTORS	LOW	HIGH
People ill	1	>1
Age of Potentially Exposed	Healthy adults	Young or Elderly
Unique event. Other complaint within last 8 weeks for this facility	0	≥ 1
Large number potentially involved	Small party One event function	On-going large volume operation
Households with ill individuals	1	>1
Onset of symptoms from time of phone call	>48 hours	<24 hours
Morbidity; severity of illness	Discomfort < 12 hours	Presently ill Saw MD Hospitalized Death

The **Cyclosporiasis Surveillance Case Report Form** in PDF format is available at this website:

http://health.utah.gov/epi/forms/cyclosporiasis.pdf

It has been copy-protected and could not be included in this manual.

Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Bacterial Form

Local Case ID (Medical Record #): _____ **Isolated Bacteria:** _____

Patient's name: _____
Last First

Address: _____ **Phone No**: ( ) _____ - _____
Number/ Street City State ZIP

PHLIS ID # (Patient-Specimen): □□□□□□□□-□□□□□□□□□□-□□□-□□
Site ID **Patient ID** **Spec ID** **Aliquot ID**

Local ID: _____-□□□□

NEDSS ID: PSN1-□□□□□□-□□-□□ **CAS1-□□□□□□□-□□-□□**
Patient ID **State** **Installation** **Investigation ID** **State** **Installation**

1) COUNTY (residence of patient):
_____
_____

2) SEX:
☐ Male ☐ Female ☐ Unknown

3) DATE OF BIRTH:
_____ /_____ /_____
month day year

4) RACE: (original categories)
☐ **White**
☐ **Black**
☐ **American Indian/ Native Alaskan**
☐ **Unknown**
☐ **Asian or Pacific Islander**

4a) RACE: (additional FN categories)
☐ Asian
☐ Pacific Islander or Native Hawaiian
☐ Multi-racial
☐ Other

5) ETHNICITY:
☐ Hispanic
☐ Non-Hispanic
☐ Unknown

6) SPECIMEN COLLECTION DATE
_____/_____/ 200____
month day

7) AGE:_____ years

8) IF < 1 YEAR, AGE: _____ months

9) SUBMITTING LAB:
_____
_____
Laboratory

9a) SUBMITTING PHYSICIAN:
_____
Phone: ( ) _____ -_____

Informant _____ **Date Report Received in Lab** _____/_____/ 200____
month day

10) SOURCE OF SPECIMEN: ☐ Stool ☐ Blood ☐ CSF ☐ Urine ☐ Unknown ☐ Other site (specify):_____
_____

11) ISOLATED BACTERIA:

☐ ***Salmonella*** (serogroup_____) serotype_____)
☐ ***Shigella*** (serogtype/species_____)
☐ ***Campylobacter*** (species_____)
☐ ***E. coli***
Biochemically identified? ☐ Yes ☐ No ☐ Unknown
O157 positive? ☐ Yes ☐ No ☐ Unsure/Not Tested
O antigen number _____
H7 positive? ☐ Yes ☐ No ☐ Unsure/Not Tested
H Antigen Number _____
Isolate non-motile? ☐ Yes ☐ No ☐ Unsure/Not Tested
Shiga toxin-positive? ☐ Yes ☐ No ☐ Unsure/Not Tested
National database PFGE Pattern _____

☐ ***Vibrio*** (species_____)
☐ ***Yersinia*** (species_____)
☐ ***Listeria monocytogenes*** (serotype_____)
Pregnant? ☐ Yes ☐ No ☐ Unknown
Outcome of Fetus?
☐ Abortion/stillbirth
☐ Induced abortion
☐ Live birth/neonatal death
☐ Survived-clinical infection
☐ Survived-no apparent illness
☐ Unknown

☐ Other Bacteria (specify:)_____

FORM APPROVED
OMB NO.0920-0004

CDC USE ONLY
__ __-__ __ __ __ __ __

STATE USE ONLY
_____

INVESTIGATION OF A FOODBORNE OUTBREAK

This form is used to report foodborne disease outbreak investigations to CDC. A foodborne outbreak is defined as the occurrence of **two or more cases** of a similar illness resulting from the ingestion of a common food in the United States. This form has **two** parts: Part 1 asks for the minimum data needed and Part 2 asks for additional information. For this investigation to be counted in the CDC annual summary, Part 1 must be completed. **We encourage you to complete as much of Part 1 and Part 2 as you can.**

Part 1: Required Information

1. Location of Exposure:

State: ___ ___
☐ Multi-state exposure

County: _____
☐ Multi-county exposure

List other states/counties in Comments, bottom of this page

2. Dates:

Date first case became ill: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Date of first known exposure: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Date of last known exposure: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

3. Numbers of Cases Exposed:

Lab-confirmed cases: _____ *(A)*

Probable cases: _____ *(B)*

Estimated total ill: _____
(If greater than sum of A+B)

4. Approximate Percentage of Total Cases in Each Age Group:

<1 year: _____%
1-4 yrs: _____%
5-19 yrs: _____%
20-49 yrs: _____%
≥ 50 yrs: _____%

5. Sex: (Estimated percent of total cases)

Male: _____ %

Female: _____ %

6. Investigation Methods: (Check all that apply)

☐ Interviews of cases only
☐ Case-control study
☐ Cohort study
☐ Food preparation review
☐ Food product traceback
☐ Investigation at factory or production plant
☐ Investigation at original source (farm, marine estuary, etc.)
☐ Environment / food sample cultures

7. Implicated Food(s): (based on Reasons listed in Item 15 on page 3)

_____
_____
_____
_____
_____

☐ Could not be determined

8. Etiology: (Name the bacteria, virus, parasite, or toxin. If available, include details such as phage type, virulence factors, molecular fingerprinting, antibiogram, metabolic profile.

Etiology	**Serotype** (if avail.)	**Other Characteristics** (if avail.)

☐ Confirmed*
☐ Suspected

☐ Unknown etiology
☐ Multiple etiologies (list in Comments)

Isolated/identified from (check all that apply)
☐ Patient specimen(s)
☐ Food specimen(s)
☐ Environment specimen(s)
☐ Food Worker specimen(s)

* see criteria at http://www.cdc.gov/ncidod/dbmd/outbreak/ or MMWR2000/Vol 49/SS-1/Appendix B

9. Contributing Factors: (See list on page 2, check all that apply)

☐ Contributing factors unknown

Contamination Factor:
☐ C1 ☐ C2 ☐ C3 ☐ C4 ☐ C5 ☐ C6 ☐ C7 ☐ C8 ☐ C9
☐ C10 ☐ C11 ☐ C12 ☐ C13 ☐ C14 ☐ C15 *(describe in Comments)* ☐ N/A

Proliferation/Amplification Factor (bacterial outbreaks only):
☐ P1 ☐ P2 ☐ P3 ☐ P4 ☐ P5 ☐ P6 ☐ P7 ☐ P8 ☐ P9
☐ P10 ☐ P11 ☐ P12 *(describe in Comments)* ☐ N/A

Survival Factor (microbial outbreaks only):
☐ S1 ☐ S2 ☐ S3 ☐ S4 ☐ S5 *(describe in Comments)* ☐ N/A

Was food-worker implicated as the source of contamination? ☐ Yes ☐ No
If yes, please check ***only one*** of following:
☐ laboratory *and* epidemiologic evidence
☐ epidemiologic evidence (w/o lab confirmation)
☐ lab evidence (w/o epidemiologic confirmation)
☐ prior experience makes this the likely source *(please explain in Comments)*

10. Agency reporting this outbreak:

_____

Contact Person:

NAME: _____
TITLE: _____
PHONE NO: _____
FAX NO: _____
E-MAIL: _____

Date of completion of this form:

___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

☐ **Initial Report**
☐ **Updated Report**
☐ **Final Report**
☐ **Additional data suggests this is not a foodborne outbreak**

Comments: _____

CDC 52.13 REV. 10/2000

This questionnaire is authorized by law (Public Health Service Act, 42 USC §241). Although response to the questions asked is voluntary, cooperation of the patient is necessary for the study and control of disease. Public reporting burden for this collection of information is estimated to average 15 minutes per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to PHS Reports Clearance Officer; Rm 721-H, Humphrey Bg; 200 Independence Ave. SW; Washington, DC 20201; ATTN: PRA, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

The following codes are to be used to fill out Part 1 (question 9) and Part 2 (question 15).

Contamination Factors:[1]

C1 - Toxic substance part of tissue (e.g., ciguatera)
C2 - Poisonous substance intentionally added (e.g., cyanide or phenolphthalein added to cause illness)
C3 - Poisonous or physical substance accidentally/incidentally added (e.g., sanitizer or cleaning compound)
C4 - Addition of excessive quantities of ingredients that are toxic under these situations (e.g., niacin poisoning in bread)
C5 - Toxic container or pipelines (e.g., galvanized containers with acid food, copper pipe with carbonated beverages)
C6 - Raw product/ingredient contaminated by pathogens from animal or environment (e.g., *Salmonella enteriditis* in egg, Norwalk in shellfish, *E. coli* in sprouts)
C7 - Ingestion of contaminated raw products (e.g., raw shellfish, produce, eggs)
C8 - Obtaining foods from polluted sources (e.g., shellfish)
C9 - Cross-contamination from raw ingredient of animal origin (e.g., raw poultry on the cutting board)
C10 - Bare-handed contact by handler/worker/preparer (e.g., with ready-to-eat food)
C11 - Glove-handed contact by handler/worker/preparer (e.g., with ready-to-eat food)
C12 - Handling by an infected person or carrier of pathogen (e.g., *Staphylococcus*, *Salmonella*, Norwalk agent)
C13 - Inadequate cleaning of processing/preparation equipment/utensils – leads to contamination of vehicle (e.g., cutting boards)
C14 - Storage in contaminated environment – leads to contamination of vehicle (e.g., store room, refrigerator)
C15 - Other source of contamination (*please describe in Comments*)

Proliferation/Amplification Factors:[1]

P1 - Allowing foods to remain at room or warm outdoor temperature for several hours (e.g., during preparation or holding for service)
P2 - Slow cooling (e.g., deep containers or large roasts)
P3 - Inadequate cold-holding temperatures (e.g., refrigerator inadequate/not working, iced holding inadequate)
P4 - Preparing foods a half day or more before serving (e.g., banquet preparation a day in advance)
P5 - Prolonged cold storage for several weeks (e.g., permits slow growth of psychrophilic pathogens)
P6 - Insufficient time and/or temperature during hot holding (e.g., malfunctioning equipment, too large a mass of food)
P7 - Insufficient acidification (e.g., home canned foods)
P8 - Insufficiently low water activity (e.g., smoked/salted fish)
P9 - Inadequate thawing of frozen products (e.g., room thawing)
P10 - Anaerobic packaging/Modified atmosphere (e.g., vacuum packed fish, salad in gas flushed bag)
P11 - Inadequate fermentation (e.g., processed meat, cheese)
P12 - Other situations that promote or allow microbial growth or toxic production (*please describe in Comments*)

Survival Factors:[1]

S1 - Insufficient time and/or temperature during initial cooking/heat processing (e.g., roasted meats/poultry, canned foods, pasteurization)
S2 - Insufficient time and/or temperature during reheating (e.g., sauces, roasts)
S3 - Inadequate acidification (e.g., mayonnaise, tomatoes canned)
S4 - Insufficient thawing, followed by insufficient cooking (e.g., frozen turkey)
S5 - Other process failures that permit the agent to survive (*please describe in Comments*)

Method of Preparation:[2]

M1 - Foods eaten raw or lightly cooked (e.g., hard shell clams, sunny side up eggs)
M2 - Solid masses of potentially hazardous foods (e.g., casseroles, lasagna, stuffing)
M3 - Multiple foods (e.g., smorgasbord, buffet)
M4 - Cook/serve foods (e.g., steak, fish fillet)
M5 - Natural toxicant (e.g., poisonous mushrooms, paralytic shellfish poisoning)
M6 - Roasted meat/poultry (e.g., roast beef, roast turkey)
M7 - Salads prepared with one or more cooked ingredients (e.g., macaroni, potato, tuna)
M8 - Liquid or semi-solid mixtures of potentially hazardous foods (e.g., gravy, chili, sauce)
M9 - Chemical contamination (e.g., heavy metal, pesticide)
M10 - Baked goods (e.g., pies, eclairs)
M11 - Commercially processed foods (e.g., canned fruits and vegetables, ice cream)
M12 - Sandwiches (e.g., hot dog, hamburger, Monte Cristo)
M13 - Beverages (e.g., carbonated and non-carbonated, milk)
M14 - Salads with raw ingredients (e.g., green salad, fruit salad)
M15 - Other, does not fit into above categories *(please describe in Comments)*
M16 - Unknown, vehicle was not identified

[1] Frank L. Bryan, John J. Guzewich, and Ewen C. D. Todd. Surveillance of Foodborne Disease III. Summary and Presentation of Data on Vehicles and Contributory Factors; Their Value and Limitations. Journal of Food Protection, 60; 6:701-714, 1997.
[2] Weingold, S. E., Guzewich JJ, and Fudala JK. Use of foodborne disease data for HACCP risk assessment. Journal of Food Protection, 57; 9:820-830, 1994.

Part 2: Additional Information (Please complete as much as possible)

11. Numbers of:

OUTCOME / SYMPTOM	**Cases** with **Outcome / Symptom**	**Total** cases for whom you have information available
Healthcare Provider Visit		
Hospitalization		
Death		
Vomiting		
Diarrhea		
Bloody stools		
Feverish		
Abdominal cramps		
*		
*		
*		
*		

12. Incubation Period:

(circle appropriate units)

Shortest: _____ (Hours, days)

Longest: _____ (Hours, days)

Median: _____ (Hours, days)

☐ Unknown

13. Duration of Acute Illness Among Those Who Recovered:

(circle appropriate units)

Shortest: _____ (Hours, days)

Longest: _____ (Hours, days)

Median: _____ (Hours, days)

☐ Unknown

* Use the following terms, if appropriate, to describe other common characteristics of cases:

anaphylaxis
arthralgia
bradycardia
bullous skin lesions
bradycardia
cough
coma
diplopia
descending paralysis
flushing
headache
hemolytic uremic syndrome (HUS)
hypotension
itching
jaundice
lethargy
myalgia
paresthesia
septicemia
sore throat
tachycardia
thromobocytopenia
temperature reversal
urticaria
wheezing

14. If Cohort Investigation Conducted:

Event-specific Attack Rate = _____ / _____ x 100 = _____ %

 # ill **total # of persons for whom you have illness info.**

15. Implicated Food(s): (Please provide known information.)

Name of Food	Main Ingredients	Contaminated Ingredient	**Reason(s) Suspected** (see below)	**Method of Preparation** (see list on page 2)
e.g., lasagna	*pasta, sauce, eggs, beef*	*eggs*	*4*	*M1*

☐ Food vehicle could not be determined

Reason Suspected (choose all that apply):

1 - Statistical evidence from epidemiological investigation
2 - Laboratory evidence (e.g., identification of agent in food)
3 - Compelling supportive information
4 - Other data (e.g., same phage type found on farm that supplied eggs)
5 - Specific evidence lacking but prior experience makes this likely source

16. Where was Food Prepared? (Check all that apply)

☐ Restaurant or deli
☐ Day care center
☐ School
☐ Church, temple, etc.
☐ Camp
☐ Caterer
☐ Grocery store
☐ Hospital
☐ Workplace cafeteria
☐ Nursing home
☐ Prison, jail
☐ Private home
☐ Picnic
☐ Fair, festival, other temporary/mobile service
☐ Contaminated food imported into U.S.
☐ Commercial product, served without further preparation
☐ Other (please describe)

_____

17. Where was Food Eaten? (Check all that apply)

☐ Restaurant or deli
☐ Day care center
☐ School
☐ Church, temple, etc.
☐ Camp
☐ Grocery Store
☐ Hospital
☐ Workplace cafeteria
☐ Nursing home
☐ Prison, jail
☐ Private home
☐ Picnic
☐ Fair, festival, or mobile location
☐ Other (please describe)

_____

18. Other Available Info:

☐ Unpublished agency report (please attach)
☐ Epi-Aid
☐ Publication (please reference)

_____

☐ Not available

19. Remarks: Briefly describe important aspects of the outbreak not covered above

(e.g., restaurant closure, product recall, immunoglobulin administration, economic impact, etc.)

_____
_____
_____
_____
_____

State Health Departments: Please FAX this document to Foodborne and Diarrheal Diseases, DBMD, CDC, at (404) 639-2205.

CDC 52.13 REV. 10/2000

Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Bacterial Form

Data Entry: ☐ NEDSS ☐ PHLIS ☐ STATE SYSTEM ☐ CASE-CONTROL STUDY ☐ EPI INFO

A. Hospital Follow-up:

12) PATIENT STATUS AT THE TIME OF SPECIMEN COLLECTION:

☐ Hospitalized (*go to 14*) ☐ Unknown (*go to 14c*)

☐ Outpatient (*go to 13*)

---

13) IF OUTPATIENT, WAS THE PATIENT SUBSEQUENTLY HOSPITALIZED?

☐ Yes (*go to14*) ☐ No (*go to 14c*) ☐ Unknown (*go to 14c*)

---

14) IF PATIENT WAS HOSPITALIZED
(that is, if answered "Hospitalized" to #12 or "Yes" to #13):

Hospital name:_____

Date of first admission: _____ /_____ / 200___
month day

Date of last discharge: _____ /_____ / 200___
month day

14a) TRANSFERRED TO ANOTHER HOSPITAL?

☐ Yes ☐ No ☐ Unknown

14b) If Yes, TRANSFER HOSPITAL NAME:

_____

14c) HOW WAS THE INFORMATION (from #12,13, or 14) DETERMINED?

☐ Patient / relative contacted

☐ Physician contacted or chart review / medical records review

☐ Did not follow up

☐ County provided information

---

15) OUTCOME: ☐ Alive ☐ Dead ☐ Unknown

15a) HOW WAS THIS INFORMATION (from #15) DETERMINED?

☐ Patient / relative contacted

☐ Physician contacted or chart review/medical records review

☐ Did not follow up

☐ County provided information

B. Health Department Follow-up:

If the isolate was further characterized by the State Lab, please update #11.

16) DID THE STATE LAB RECEIVE THE ISOLATE?

☐ Yes ☐ No ☐ Unknown

16a) If Yes, STATE LAB ISOLATE ID NUMBER:

_____

17) DID THE PATIENT TRAVEL OUTSIDE THE U.S. WITHIN THE LAST

- **30 days if infected with *S.* Typhi or *Listeria***
- **7 days if infected with other bacterial pathogen**

☐ Yes (*go to 17a*) ☐ No (*go to 18*) ☐ Unknown (*go to 18*)

17a)
Date of departure from the U.S. : _____ /_____ / 200___
month day

Date of return to the U.S. : _____ /_____ / 200___
month day

---

18) WAS CASE FOUND DURING AN AUDIT?

☐ Yes ☐ No ☐ Unknown

---

19) WAS THE CASE PART OF AN OUTBREAK?

☐ Yes (*go to 19a*) ☐ No (*go to 20*) ☐ Unknown (*go to 20*)

19a) IF OUTBREAK RELATED, WAS IT A FOODBORNE OUTBREAK?

☐ Yes (*go to 19b*) ☐ No (*go to 20*) ☐ Unknown (*go to 20*)

19b) CDC EFORS NUMBER: _____

---

20) WAS CASE ENROLLED IN A CASE-CONTROL STUDY?

☐ Yes ☐ No ☐ Unknown

If No, Reason: _____

Reason Code: _____

---

21) IS CASE REPORT COMPLETE? ☐ Yes ☐ No

21a) If Yes, DATE CASE REPORT COMPLETED:

_____ /_____ / 200____
month day

21b) INITIALS OF PERSON COMPLETING CASE REPORT:
_____

Comments_____

_____

_____

_____

_____

_____

_____

_____

Revised 5/17/05

Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Parasitic Form

Local Case ID (Medical Record #): _____ **Isolated Parasite:** _____

Patient's name: _____
Last First

Address: _____ **Phone No**: ( ) _____ - _____
Number/ Street City State ZIP

PHLIS ID # (Patient-Specimen): □□□□□□□□-□□□□□□□□□□-□□□-□□
Site ID **Patient ID** **Spec ID** **Aliquot ID**

Local ID: _____-□□□□

NEDSS ID: PSN1-□□□□□□-□□-□□ **CAS1-□□□□□□□-□□-□□**
Patient ID **State** **Installation** **Investigation ID** **State** **Installation**

---

1) COUNTY (residence of patient):
_____
_____

2) SEX:
☐ Male ☐ Female ☐ Unknown

3) DATE OF BIRTH:
_____ /_____ /_____
month day year

4) RACE: (original categories)
☐ **White**
☐ **Black**
☐ **American Indian/ Native Alaskan**
☐ **Unknown**
☐ **Asian or Pacific Islander**

4a) RACE: (additional FN categories)
☐ Asian
☐ Pacific Islander or Native Hawaiian
☐ Multi-racial
☐ Other

5) ETHNICITY:
☐ Hispanic
☐ Non-Hispanic
☐ Unknown

6) SPECIMEN COLLECTION DATE
_____/_____/ 200____
month day

7) AGE:_____
years

8) IF < 1 YEAR, AGE: _____
months

9) SUBMITTING LAB:
_____
_____
Laboratory

9a) SUBMITTING PHYSICIAN:
_____
Phone: ( ) _____ -_____

Informant _____ **Date Report Received in Lab** _____/_____/ 200____
month day

10) SOURCE OF SPECIMEN: ☐ Stool ☐ GI Aspirate ☐ Small Bowel Biopsy ☐ Unknown ☐ Other site (specify):_____
_____

11) ISOLATED PARASITIC ORGANISM:

☐ ***Cryptosporidium***

How identified? (Please check all that apply):
- ☐ Wet mount, not stained
- ☐ Wet mount, temporary stain, type: _____
- ☐ Acid fast, type: _____
- ☐ FA (Direct immunofluorescence)
- ☐ ELISA, specify immunoassay method:_____
- ☐ PCR
- ☐ Other, please specify:_____

☐ ***Cyclospora***

How identified? (Please check all that apply):
- ☐ Wet mount, not stained
- ☐ Wet mount, temporary stain, type: _____
- ☐ Wet mount, autofluorescence
- ☐ Acid fast, type: _____
- ☐ Safranin, type: _____
- ☐ PCR
- ☐ Other, please specify:_____

Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Parasitic Form

Data Entry: ☐ NEDSS ☐ PHLIS
☐ STATE SYSTEM ☐ CASE-CONTROL STUDY
☐ EPI INFO

A. Hospital Follow-up:

12) PATIENT STATUS AT THE TIME OF SPECIMEN COLLECTION:

☐ Hospitalized (*go to 14*) ☐ Unknown (*go to 14c*)

☐ Outpatient (*go to 13*)

12a) OISD (Other immunosuppressive diseases):

☐ Yes ☐ No ☐ Not available

13) IF OUTPATIENT, WAS THE PATIENT SUBSEQUENTLY HOSPITALIZED?

☐ Yes (*go to14*) ☐ No (*go to 14c*) ☐ Unknown (*go to 14c*)

14) IF PATIENT WAS HOSPITALIZED
(that is, if answered "Hospitalized" to #12 or "Yes" to #13):

Hospital name:_____

Date of first admission: _____ /_____ / 200___
month day

Date of last discharge: _____ /_____ / 200___
month day

14a) TRANSFERRED TO ANOTHER HOSPITAL?

☐ Yes ☐ No ☐ Unknown

14b) If Yes, TRANSFER HOSPITAL NAME:

_____

14c) HOW WAS THE INFORMATION (from #12,13, or 14) DETERMINED?

☐ Patient / relative contacted

☐ Physician contacted or chart review / medical records review

☐ Did not follow up

☐ County provided information

15) OUTCOME: ☐ Alive ☐ Dead ☐ Unknown

15a) HOW WAS THIS INFORMATION (from #15) DETERMINED?

☐ Patient / relative contacted

☐ Physician contacted or chart review/medical records review

☐ Did not follow up

☐ County provided information

B. Health Department Follow-up:

If the isolate was further characterized by the State Lab, please update #11.

16) DID THE STATE LAB RECEIVE THE ISOLATE?

☐ Yes ☐ No ☐ Unknown

16a) If Yes, STATE LAB ISOLATE ID NUMBER:

_____

17) DID THE PATIENT TRAVEL OUTSIDE THE U.S. WITHIN THE LAST 15 DAYS?

☐ Yes (*go to 17a*) ☐ No (*go to 18*) ☐ Unknown (*go to 18*)

17a)

Date of departure from the U.S. : _____ /_____ / 200___
month day

Date of return to the U.S. : _____ /_____ / 200___
month day

18) WAS CASE FOUND DURING AN AUDIT?

☐ Yes ☐ No ☐ Unknown

19) WAS THE CASE PART OF AN OUTBREAK?

☐ Yes (*go to 19a*) ☐ No (*go to 20*) ☐ Unknown (*go to 20*)

19a) IF OUTBREAK RELATED, WAS IT A FOODBORNE OUTBREAK?

☐ Yes (*go to 19b*) ☐ No (*go to 20*) ☐ Unknown (*go to 20*)

19b) CDC EFORS NUMBER: _____

20) IF AVAILABLE, PLEASE INDICATE:

Date of illness onset: ____ /_____ / 200___ ☐ Not Available
month day

Date of diarrhea onset: ____ /_____ / 200__ ☐ Not Available
month day

21) WAS CASE ENROLLED IN A CASE-CONTROL STUDY?

☐ Yes ☐ No ☐ Unknown

If No, Reason: _____

Reason Code: _____

22) IS CASE REPORT COMPLETE? ☐ Yes ☐ No

22a) If Yes, DATE CASE REPORT COMPLETED:

_____ /_____ / 200____
month day

22b) INITIALS OF PERSON COMPLETING CASE REPORT:

_____

Comments_____

_____

_____

_____

_____

Revised 5/17/05

Haemophilus Influenzae-Meningitis/Invasive Disease

Haemophilus Influenzae–Meningitis/Invasive Disease

Organism:	*Haemophilus influenzae* (most commonly type b). Type a has recently been seen in Alaska
Incubation period:	Unknown, probably short, 2-4 days.
Infectious period:	Prolonged, as long as organisms are present, even without nasal discharge. Non-communicable after 24-48 hr of effective antibiotic treatment.
Transmission routes:	Respiratory inhalation of droplet discharges from nose and throat. Most common portal of entry is nasopharynx.
Treatment:	Ampicillin has been drug of choice (parenteral 200-400 mg/kg/day). About 30% of strains are now beta-lactam resistant; ceftriaxone, cefotaxime or chloramphenicols are recommended concurrently or singly until antibiotic sensitivities are known. Patient should also be given rifampin prior to discharge from hospital to assure elimination of the organism from the nasopharynx.

Information Needed for the Investigation

Verify the Diagnosis

- Most cases are sporadic. Prophylaxis of contacts depends on age of other household sibs (see algorithm).
- Most common types of invasive Hi disease: meningitis, epiglottitis, septic arthritis, cellulitis, and pneumonia.
- Educate parents about watching other siblings less than 4 years-old for stiff neck or fever; seek medical care immediately.
- Routine childhood immunization against type b, dosing depends on vaccine. Alaska Immunization Program currently supplies Pediatrix™. Schedule is 1 dose each at 2, 4 and 6 months. See Epi Bulletin 39, Dec 30, 2003 for discussion.

Laboratory Specimens

- Gram stain of infected body fluid may show gram-negative coccobacilli.
- Culture CSF, blood, pleural fluid, joint fluid for organism.
- Latex agglutination is rapid method to detect Hib capsular polysaccharide antigen.
- Isolate should be sent to State PH Lab–Anchorage for serotyping. Notify State Lab of specimen shipment.
- CDC–AIP will do PCR on CSF.

Contact and Control Measures

(**Note:** Applies to type b, whether to extend to type a is currently under discussion.)

- Rifampin, 20 mg/kg qd x 4 days, max 600 mg/day for all household contacts (including adults) in households where there are one or more infants (other than the index case) less than 12 months of age or with a child 1-3 years of age who is inadequately immunized.
- When 2 or more cases of invasive disease have occurred within 60 days and unimmunized or incompletely immunized children attend a childcare facility, administration of rifampin to all attendees and supervisory personnel is indicated. Immunization of children should be encouraged.
- When a single case has occurred in a childcare facility, use of rifampin prophylaxis is controversial, and not recommended in Alaska. Encourage on-time immunization of children.

Reporting Requirements

- FTR: write up all *confirmed* and *probable* cases.
- Write a case summary and file for all suspected negative cases.
- Morbidity Database: enter all *confirmed* and *probable* cases. Be sure to enter type when known.
- CDC Case Definition is used to define *confirmed* and *probable* cases.

Note: CDC – AIP has an investigation protocol to investigate household contacts of Haemophilus influenzae cases.

Haemophilus lnfluenzae Type b Fact Sheet

What is Haemophilus influenzae type b (Hib) disease?
Until recently, Hib was one of the most important causes of bacterial infection in young children. Hib may cause a variety of diseases such as meningitis (inflammation of the coverings of the spinal column and brain), blood stream infections, pneumonia, arthritis and infections of other parts of the body.

Who gets Hib disease?
Hib disease can occur in any age group. Due to widespread use of Hib vaccine in children, very few cases of Hib are reported each year in Alaska. Hib is diagnosed more often in the elderly, unimmunized children and people who are immunocompromised.

How is Hib disease spread?
Hib disease may be transmitted through contact with mucus or droplets from the nose and throat of an infected person.

What are the symptoms of Hib disease?
Symptoms may include fever, lethargy, vomiting and a stiff neck. Other symptoms depend upon the part of the body affected.

How soon do symptoms appear?
The incubation period for Hib disease is unknown, but is probably less than one week.

When and for how long is a person able to spread Hib disease?
The contagious period varies. Unless treated, it may be transmitted for as long as the organism is present in the nose and throat, even after symptoms have disappeared.

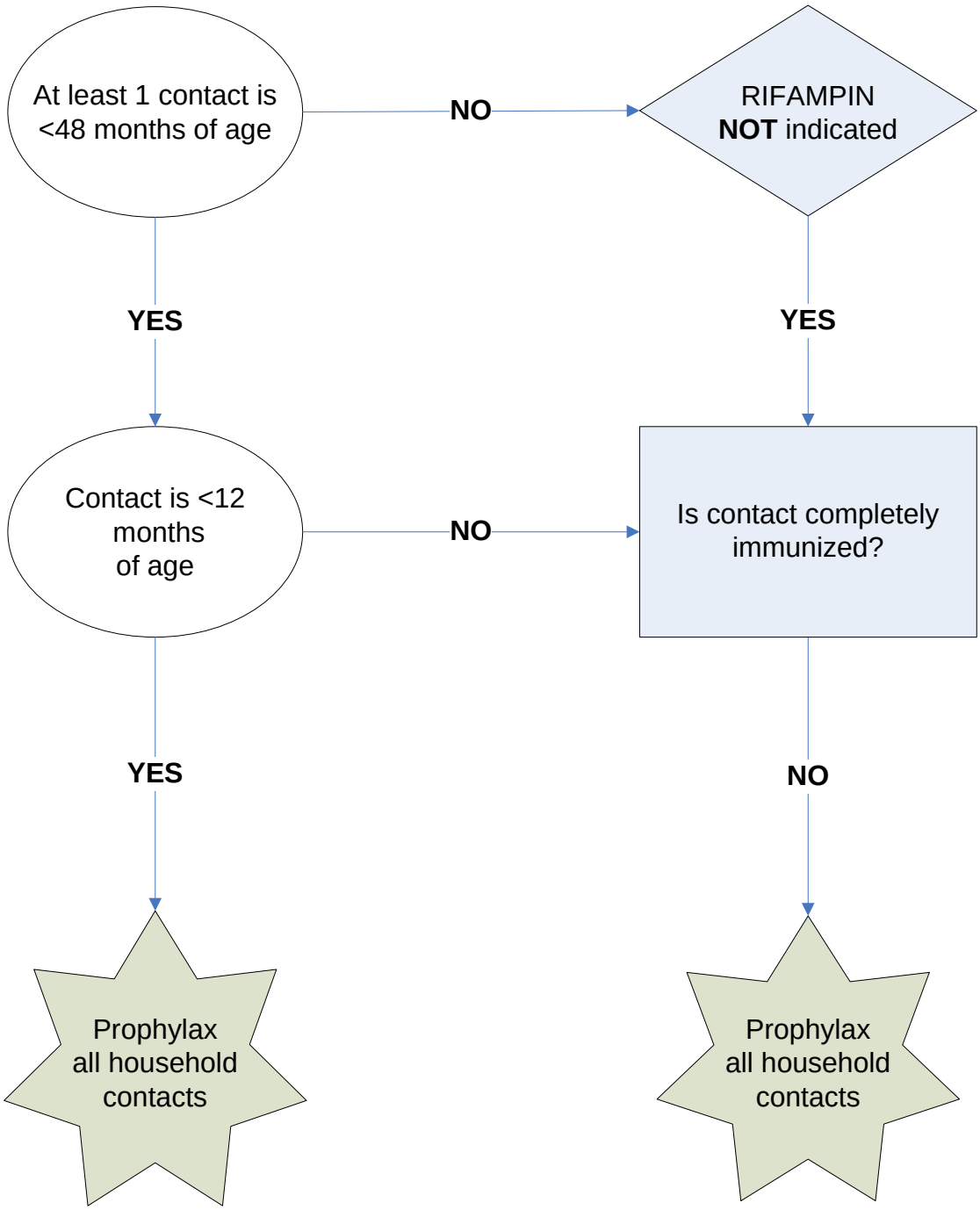
Does past infection with Hib disease make a person immune?
Children who had Hib disease when younger than 24 months of age may be at risk of getting Hib disease again. Children and adults who had Hib disease when 24 months of age or older are likely to be immune.

What is the treatment for Hib disease?
Antibiotics such as cefotaxime, ceftriaxone, or ampicillin with chloramphenicol, are generally used to treat serious infections. Rifampin is used in some circumstances as preventive treatment for persons who have been exposed to Hib disease.

What are the possible complications associated with Hib disease?
If Hib meningitis occurs, a certain proportion of those who recover may suffer long-lasting neurological problems. In some instances, cases may be fatal.

What can be done to prevent the spread of Hib disease?
There are currently several Hib vaccines licensed by the U. S. Food and Drug Administration for use in children as early as two months of age. Immunization authorities recommend that all children be immunized with an approved Hib vaccine beginning at two months of age. Recommendations for scheduling of subsequent doses vary depending on the manufacturer. Therefore, it is important to consult with your physician.

Haemophilus Influenzae Rifampin Prophylaxis for Household Contacts



Dosage Calculation Guidelines for Rifampin Prophylaxis To Prevent Invasive Hib Disease

Recommended oral dosage is 20 mg/kg as a singe dose once a day for four (4) days. Maximum daily dose is 600mg. Adult dose is 600 mg daily. The dose for neonates less that one (1) month of age has not been established; some experts recommend lowering the dosage to 10 mg/kg once daily for four days. [1]

Weight		**Dosage**		**Dosage (Neonate >1 month)**	
Pounds	KG	20MG/KG	Rounded	10MG/KG	Rounded
5	2.3	46	45	23	25
10	4.5	90	90	46	45
15	6.8	136	135	68	70
20	9.1	182	180		
25	11.4	228	225		
30	13.6	272	275		
35	15.9	318	320		
40	18.2	364	365		
45	20.5	410	410		
50	22.7	454	455		
55	25.0	500	500		
60	27.3	546	545		
65	29.5	590	590		
≥70	≥32	600	600		

For patients unable to swallow capsules, a liquid suspension (1% in simple syrup) or preweighed aliquots of rifampin powder can be prepared by the pharmacist (see package insert.)

1. Red Book, AAP, 2003, p. 296.

Haemophilus Influenza Type b Meningitis Case Questionnaire

Name of person reporting: _____ Phone: _____

Name of patient: _____ Phone: _____

Residence: _____

DOB: ____/____/_____ Sex: M☐F☐ Race:_____

Symptoms:
(**Y**=Yes, **N**=No, **U**=Unknown)

Onset:

Sudden fever	Y	N	U	Date:	Time:
Headache	Y	N	U	Date:	Time:
Nausea	Y	N	U	Date:	Time:
Vomiting	Y	N	U	Date:	Time:
Stiff neck	Y	N	U	Date:	Time:
Petechial rash	Y	N	U	Date:	Time:

CSF/Blood obtained prior to administration of antibiotics? Y N

CSF Results: Appearance_____Cell count_____Glucose_____Protein_____

CSF/Blood sent to Lab: _____

Isolate sent to State Lab for Serotyping: **Y N**

Isolate sent to CDC-AIP for Serotyping: **Y N**

Provider or ER where care was obtained: _____

Household/Socially Close Contacts:	**Daycare Contacts:**

Patient's Name: _____ (Last, First, M.I.) Phone No.: ( ) _____

Address: _____ (Number, Street, Apt. No.) Patient Chart No.: _____

_____ (City, State) _____ (Zip Code) Hospital: _____

– Patient identifier information is not transmitted to CDC –

DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
ATLANTA, GA 30333

ACTIVE BACTERIAL CORE SURVEILLANCE (ABCs) CASE REPORT

A CORE COMPONENT OF THE EMERGING INFECTIONS PROGRAM NETWORK

CDC SAFER • HEALTHIER • PEOPLE™

– SHADED AREAS FOR OFFICE USE ONLY –

OMB No. 0920-0009

1. STATE: (Residence of Patient) ☐☐

2. COUNTY: (Residence of Patient) _____

3. STATE I.D.: ☐☐☐☐☐☐☐

4a. HOSPITAL/LAB I.D. WHERE CULTURE IDENTIFIED: ☐☐☐☐☐

4b. HOSPITAL I.D. WHERE PATIENT TREATED: ☐☐☐☐☐

5. WAS PATIENT HOSPITALIZED? 1 ☐ Yes 2 ☐ No

If YES, date of admission: Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

Date of discharge: Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

6a. Was patient transferred from another hospital? 1 ☐ Yes 2 ☐ No 9 ☐ Unk

6b. If YES, hospital I.D. ☐☐☐☐☐

7a. Was patient a resident of a nursing home or other chronic care facility at the time of first positive culture? 1 ☐ Yes 2 ☐ No 9 ☐ Unk

7b. If yes, name _____

8. DATE OF BIRTH: Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

9a. AGE: ☐☐☐

9b. Is age in day/mo/yr? 1 ☐ Days 2 ☐ Mos. 3 ☐ Yrs.

10a. SEX: 1 ☐ Male 2 ☐ Female

10b. RACE: (Check all that apply)
1 ☐ White
1 ☐ Black
1 ☐ American Indian/ Alaskan Native
1 ☐ Asian
1 ☐ Native Hawaiian/ Pacific Islander
1 ☐ Other
1 ☐ Unk

10c. ETHNIC ORIGIN: 1 ☐ Hispanic 9 ☐ Unk 2 ☐ Non-Hispanic

11. OUTCOME: 1 ☐ Survived 9 ☐ Unk 2 ☐ Died

12. Was patient pregnant/post-partum at time of first positive culture? 1 ☐ Yes 2 ☐ No 9 ☐ Unk

If YES, outcome of fetus:
1 ☐ Survived, no apparent illness
2 ☐ Survived, clinical infection
3 ☐ Live birth/neonatal death
4 ☐ Abortion/stillbirth
5 ☐ Induced abortion
9 ☐ Unk

13. If patient <1 month of age:
Gestational age: ☐☐ (wks) Birthweight: ☐☐☐☐ (gms)

14. TYPES OF INFECTION CAUSED BY ORGANISM: (Check all that apply)
1 ☐ Bacteremia without Focus
1 ☐ Meningitis
1 ☐ Otitis media
1 ☐ Pneumonia
1 ☐ Cellulitis
1 ☐ Epiglottitis
1 ☐ Hemolytic uremic syndrome (HUS)
1 ☐ Abscess (not skin)
1 ☐ Peritonitis
1 ☐ Pericarditis
1 ☐ Septic abortion
1 ☐ Chorioamnionitis
1 ☐ Septic arthritis
1 ☐ Osteomyelitis
1 ☐ Endometritis
1 ☐ STSS
1 ☐ Necrotizing fasciitis
1 ☐ Puerperal sepsis
1 ☐ Other *(specify)* _____

15a. BACTERIAL SPECIES ISOLATED FROM ANY NORMALLY STERILE SITE:
1 ☐ *Neisseria meningitidis*
2 ☐ *Haemophilus influenzae*
3 ☐ Group B Streptococcus
4 ☐ *Listeria monocytogenes*
5 ☐ Group A Streptococcus
6 ☐ *Streptococcus pneumoniae*

15b. OTHER BACTERIAL SPECIES ISOLATED FROM ANY NORMALLY STERILE SITE: *(specify)*
_____
_____

16. STERILE SITES FROM WHICH ORGANISM ISOLATED: (Check all that apply)
1 ☐ Blood
1 ☐ CSF
1 ☐ Pleural fluid
1 ☐ Peritoneal fluid
1 ☐ Pericardial fluid
1 ☐ Joint
1 ☐ Bone
1 ☐ Muscle
1 ☐ Internal body site *(specify)* _____
1 ☐ Other normally sterile site *(specify)* _____

17. DATE FIRST POSITIVE CULTURE OBTAINED:
(Date Specimen Drawn)
Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

18. OTHER SITES FROM WHICH ORGANISM ISOLATED: (Check all that apply)
1 ☐ Placenta
1 ☐ Amniotic fluid
1 ☐ Wound
1 ☐ Other *(specify)* _____
1 ☐ Middle ear
1 ☐ Sinus

– *IMPORTANT* – PLEASE COMPLETE THE BACK OF THIS FORM –

Submitted By: _____ Phone No.: ( ) _____ Date: ____/____/____

Physician's Name: _____ Phone No.: ( ) _____

Public reporting burden of this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0009). **Do not send the completed form to this address.**

19. UNDERLYING CAUSES OR PRIOR ILLNESS: *(Check all that apply)* *(If none or chart unavailable, check appropriate box)* 1 ☐ None 1 ☐ Unknown

1 ☐ Current Smoker
1 ☐ Multiple Myeloma
1 ☐ Sickle Cell Anemia
1 ☐ Splenectomy/Asplenia
1 ☐ Immunoglobulin Deficiency
1 ☐ Immunosuppressive Therapy (Steroids, Chemotherapy, Radiation)
1 ☐ Leukemia
1 ☐ Hodgkin's Disease

1 ☐ Asthma
1 ☐ Emphysema/COPD
1 ☐ Systemic Lupus Erythematosus (SLE)
1 ☐ Diabetes Mellitus
1 ☐ Nephrotic Syndrome
1 ☐ Renal Failure/Dialysis
1 ☐ HIV Infection
1 ☐ AIDS or CD4 count <200

1 ☐ Cirrhosis/Liver Failure
1 ☐ Alcohol Abuse
1 ☐ Atherosclerotic Cardiovascular Disease (ASCVD)/CAD
1 ☐ Heart Failure/CHF
1 ☐ Burns
1 ☐ CSF Leak
1 ☐ IVDU
1 ☐ Cerebral Vascular Accident (CVA) / Stroke

1 ☐ Cochlear Implant
1 ☐ Deaf/Profound Hearing Loss
1 ☐ Other Malignancy *(specify)* _____
1 ☐ Organ Transplant *(specify)* _____
1 ☐ Other Prior Illness *(specify)* _____

– *IMPORTANT* – PLEASE COMPLETE FOR THE RELEVANT ORGANISMS:

HAEMOPHILUS INFLUENZAE

20. If <15 years of age and serotype 'b' or 'unk' did patient receive *Haemophilus influenzae* b vaccine? 1 ☐ Yes 2 ☐ No 9 ☐ Unk

If YES, please complete the list below.

DOSE	DATE GIVEN Mo.	Day	Year	VACCINE NAME/MANUFACTURER	LOT NUMBER
1					
2					
3					
4					

21. What was the serotype?

1 ☐ b
2 ☐ Not Typeable
3 ☐ a
4 ☐ c
5 ☐ d
6 ☐ e
7 ☐ f
8 ☐ Other *(specify)* _____
9 ☐ Not Tested or Unk

NEISSERIA MENINGITIDIS

22. What was the serogroup?

1 ☐ A 3 ☐ C 5 ☐ W135 9 ☐ Unk
2 ☐ B 4 ☐ Y 6 ☐ Not groupable 8 ☐ Other *(specify)* _____

23. Is patient currently attending college? (15 – 24 years only)

1 ☐ Yes 2 ☐ No 9 ☐ Unk

STREPTOCOCCUS PNEUMONIAE

24. Oxacillin zone size: ☐☐ (mm)

Interpretation:
1 ☐ Sensitive 2 ☐ Resistant
9 ☐ Not tested or Unk

25. Penicillin E-test MIC results ☐☐☐.☐☐☐

Interpretation:
1 ☐ S 2 ☐ I 3 ☐ R
9 ☐ Not tested or Unk

26. Penicillin broth MIC results ☐☐☐☐.☐☐☐

Interpretation:
1 ☐ S 2 ☐ I 3 ☐ R
9 ☐ Not tested or Unk

27. Has patient received 23-valent pneumococcal polysaccharide vaccine?

1 ☐ Yes 2 ☐ No 9 ☐ Unk

If YES, list date most recently given and vaccine name

Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

VACCINE NAME: _____

How many doses has patient received? _____

28. If <15 years of age did patient receive pneumococcal conjugate vaccine? 1 ☐ Yes 2 ☐ No 9 ☐ Unk **If YES, please complete the list below.**

DOSE	DATE GIVEN Mo.	Day	Year	VACCINE NAME/MANUFACTURER	LOT NUMBER
1					
2					
3					
4					

29. Does this patient have persistent disease as defined by positive sterile site cultures 2–7 days after the first positive culture?

1 ☐ Yes 2 ☐ No 9 ☐ Unk

If YES, additional culture dates:

	Mo.	Day	Year
1			
2			

Sites from which *S. pneumoniae* isolated: (Check all that apply)

1 ☐ Blood 1 ☐ CSF 1 ☐ Other normally sterile site
1 ☐ Blood 1 ☐ CSF 1 ☐ Other normally sterile site

GROUP A STREPTOCOCCUS

(#30–32 refer to the 7 days prior to first positive culture)

30. Did the patient have surgery ? 1 ☐ Yes 2 ☐ No 9 ☐ Unk

If YES, date of surgery: Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

31. Did the patient deliver a baby (vaginal or C-section)?

1 ☐ Yes 2 ☐ No 9 ☐ Unk

If YES, date of delivery: Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

32. Did patient have:

1 ☐ Varicella?
1 ☐ Penetrating trauma?
1 ☐ Blunt trauma?
1 ☐ Surgical wound? (post operative)

– SURVEILLANCE OFFICE USE ONLY –

33. Was case first identified through audit?

1 ☐ Yes 2 ☐ No
9 ☐ Unk

34. CRF Status:

1 ☐ Complete
2 ☐ Incomplete
3 ☐ Edited & Correct
4 ☐ Chart unavailable after 3 requests

35. Does this case have recurrent disease with the same pathogen?

1 ☐ Yes 2 ☐ No
9 ☐ Unk

If YES, previous (1st) state I.D. ☐☐☐☐☐☐☐

36. Date reported to EIP site

Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

37. Initials of S.O. _____

38. COMMENTS: _____

Hepatitis A

Hepatitis A

Organism:	RNA virus
Incubation period:	15-50 days (average 28-30)
Infectious period:	Maximum infectivity during latter half of incubation period (14 days before onset of symptoms), continuing for a few days after onset of jaundice. Most people are non-infectious after first week of jaundice.
Transmission routes:	Fecal-oral by person-to-person, food, or water
Treatment:	None, except symptomatic

Information Needed for the Investigation

Verify the Diagnosis

(Beware: Total antibody or IgG antibody to Hepatitis A is often erroneously reported as a case. False IgM positives have also been identified among recent patients.)

- Immunoglobulin M (IgM) antibody to hepatitis A virus (anti-HAV-IgM) positive.
- Clinical criteria: an acute illness with discrete onset of symptoms (e.g. fatigue, abdominal pain, loss of appetite, intermittent nausea, vomiting), **and** jaundice or elevated serum aminotransferase levels.
- *Confirmed:* a case meets the clinical case definition and is laboratory confirmed or a case meets the clinical case definition and occurs in a person who has an epidemiologic link with a person who has lab confirmed hepatitis A (i.e., household or sexual contact with an infected person during the 15-50 days before the onset of symptoms).

Determine the Extent of Illness

- Determine if household or other close contacts are, or have been ill by contacting the PHNs, health care providers, etc.

Laboratory Specimens

- Clinical: Obtain serum from 1 red top tube from suspect case(s). Request Hepatitis A IgM and IgG. If contacts ill, obtain 1 red top tube from each. Send to State Virology Lab-Fairbanks. Use a hepatitis request form.
- Environmental: usually none. In outbreak, may identify food for testing. Send to State Lab – Anchorage for forwarding to CDC.

Contact and Control Measures

- Prophylaxis should only be offered if original case is lab confirmed (IgM).
- Close contacts include: all household and sexual contacts, anyone sharing food, eating or drinking utensils during the period of infectivity, and anyone consuming ready to eat foods (foods that are not cooked between when they are handled by the food worker and when they are eaten) prepared by an infected food worker with diarrhea during the period of infectivity. (See Restaurants, below.)
- Close contacts should be offered IG if within 2 weeks of last exposure. Persons who have received one dose of hepatitis A vaccine at least one month prior to exposure do not need IG. We can GoldStreak IG from Vaccine Depot if needed.
- For persons not previously vaccinated, hepatitis A vaccine can be given simultaneously with IG but at a different anatomical site. (See Immunization Manual, Recommended Immunization Schedules, Section II.) Hepatitis A vaccine alone has not proven efficacious for post exposure prophylaxis, but has been used to curb community outbreaks.

Child Care Facilities

- If one or more cases of hepatitis A are associated with a center or if cases are recognized in two or more households of center attendees, IG should be given to staff and attendees. In this instance, we may go into childcare center with PHN to assure all get treated. Many childcare center attendees are now immunized with hepatitis A. Check immunization records prior to recommending IG.

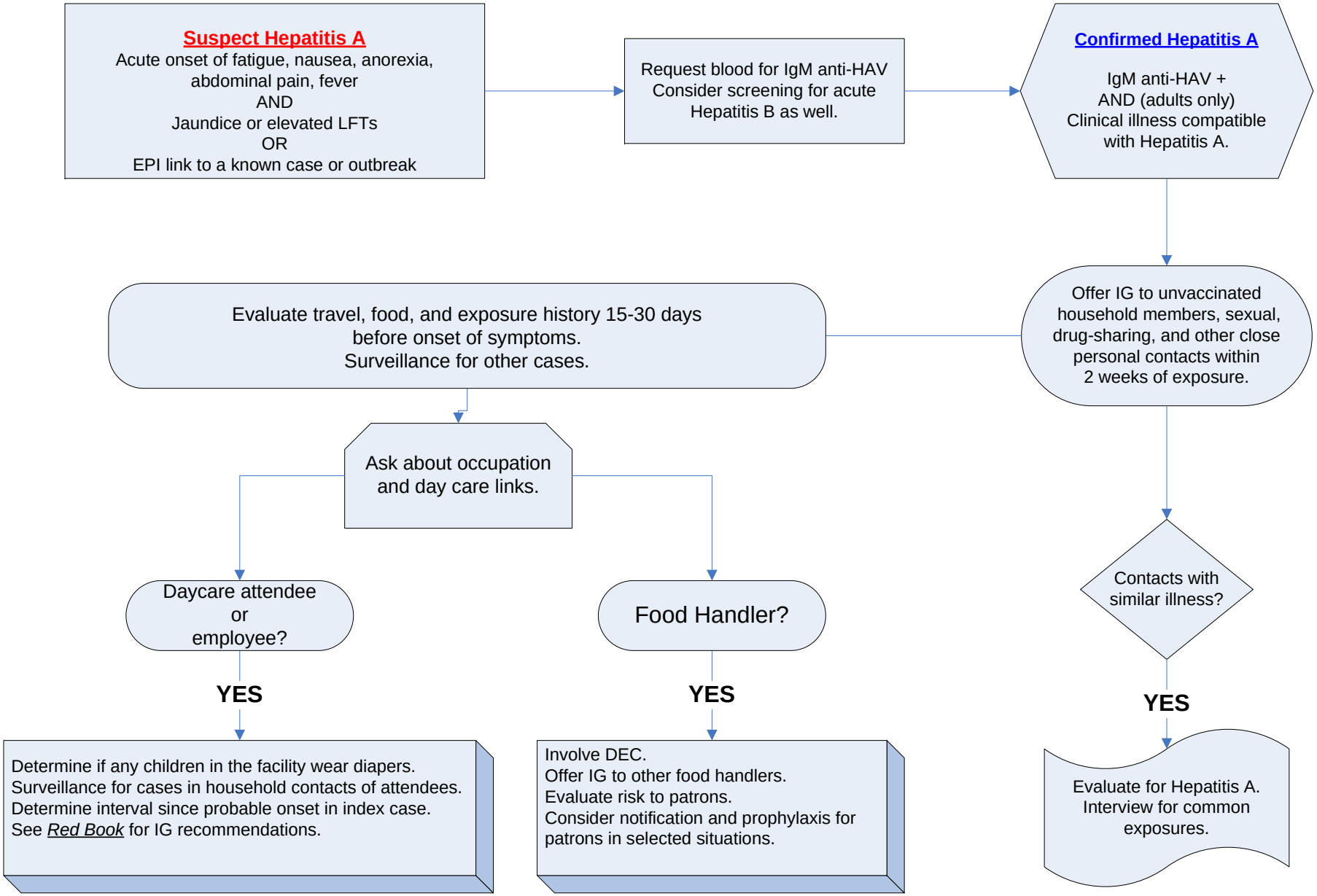
Restaurants

- In a common source outbreak, if a food handler is diagnosed with hepatitis A, IG should be given to other food handlers at the restaurant. The decision to notify restaurant patrons should be discussed with epi-team members.
- Food handlers with confirmed hepatitis A should not work until their diarrhea has cleared and/or they have been jaundiced for one week. The greatest risk for transmission to patrons exists if patient had diarrhea while working, has poor hygiene, handles food without gloves and the food is subsequently not cooked (sandwiches, salads) or if there has been illness in co-workers.
- Dose of IG: 0.02 ml/kg IM
- Emphasize handwashing among family members, day care staff, and restaurant employees.

Reporting Requirements

- FTR: write up all *confirmed* outbreaks of hepatitis A.
- Morbidity Database: enter all *confirmed* cases.
- CDC Case Definition is used to define *confirmed* cases

Hepatitis A Investigation



Hepatitis A Questionnaire

Name of Patient_____DOB ____/____/_____

Address_____City_____State_____

Phone (___)_____

Name of Health Care Provider_____Phone (___)_____

Symptoms:					Date of onset
	Abd pain	Y	N	U	____/____/_____
	Nausea	Y	N	U	____/____/_____
	Vomiting	Y	N	U	____/____/_____
	Diarrhea	Y	N	U	____/____/_____
	Dark urine	Y	N	U	____/____/_____
	Light stool	Y	N	U	____/____/_____
	Jaundice	Y	N	U	____/____/_____

Patient's Hepatitis A Immunization History:

Dose 1 ___/___/_____ Dose 2 ___/___/_____ None _____

Does the patient work in food service? Y N U

If yes, name of food service establishment _____

If YES, fill out the supplemental <u>Questionnaire for High Risk Occupation</u> and notify patient that they may not work until cleared for work by this office.

Is patient a childcare worker? Y N U
Family members in childcare? Y N U

If yes to either question, name of childcare center_____

Is patient a personal care giver or attendant in a residential care facility? Y N U

If yes, name of facility_____

Has patient traveled in previous month? Y N U

If yes, list where_____

Household water system: running tap___ haul water___ other_____
Household sewer system: flush___ honey bucket___ other_____

Number in Household_____ Are any family members ill? Y N U

If yes, list ill family members:
Name_____DOB___/____/_____
Name_____DOB___/____/_____
Name_____DOB___/____/_____
Name_____DOB___/____/_____

Hepatitis A – Questionnaire for High Risk Occupation

Please indicate the last day worked: ___/___/_____
Did the patient have diarrhea on any of the days worked during the infectious period? Y N
If yes, please specify the date(s) worked while having diarrhea: _____

_____

Ask the patient to describe his/her handwashing technique in detail:
_____

_____

Does patient wash hands with soap after having bowel movements? (Please circle one)

Never Sometimes Usually Always

Does patient wash hands with soap before beginning work? (Please circle one)

Never Sometimes Usually Always

Ask patient to describe handwashing and toilet facilities he/she uses at work (i.e., location of sinks, availability of soap, type of soap (liquid vs. bar), method of drying hands (paper towels vs. cloth towels vs. hot air drier), availability of toilet paper, availability of towels.)
_____

_____

_____

Questions for Food Service Workers Only

Ask patient to describe in general his/her food handling activities. Check any of the following job duties that the patient performed during his/her infectious period:

____prepared salads or did bulk prep salads.

____prepared cold sandwiches.

____prepared or handled other uncooked foods (cold cuts, fruits/vegetables, cake/pastry icing, etc.)

____handled garnishes for food and drinks (e.g., lime wedge, parsley, olives, etc.)

____handled any other food that was not subsequently cooked before being served.

Specify: _____

____handled ice without utensils (i.e., with bare hands.)

If the patient handled any of the above items, did he/she wear gloves? (please circle one)

Always Usually Sometimes Never

Did co-workers eat food handled by the patient? Y N

Specify any other food-related duties, including deviations from routine job duties, during infectious period:

_____

_____

_____

History of Hepatitis A Immunizations

Dose 1___/___/_____

Dose 2___/___/_____

None ____

CONSENT FORM FOR IMMUNE GLOBULIN

Name_____ DOB ____ / ____ / _____

Address _____

Phone ( )_____

If under 18 yrs, parent's name_____

Were you_____ **Yes** **No**
If **No**, **STOP** here. You do not need IG.

Have you ever been vaccinated for hepatitis A virus? **Yes** **No**
If **Yes, STOP** here. You do not need IG.

Do you have laboratory confirmation of hepatitis A virus infection? **Yes** **No**
If **Yes, STOP** here. You do not need IG.

I understand that I may have been exposed to hepatitis A virus_____
and that I may have a small risk of developing hepatitis A.

Hepatitis A is an infection of the liver. Symptoms include tiredness, low-grade fever, nausea, loss of appetite, diarrhea, and a tender enlarged liver. Jaundice (yellow skin and eyes) may or may not occur. Severe acute hepatitis A with liver failure rarely occurs. In 5-10% of patients, persistent jaundice and itching may take months to resolve. Chronic hepatitis A or becoming a carrier does not occur.

Immune Globulin (IG) is 85% effective in preventing hepatitis A if administered within 2 weeks of exposure to the hepatitis virus. The protective effect lasts for approximately 6-8 weeks. IG is derived from human blood. Side effects may include soreness at the injection site and itching. If you have a low platelet count or are currently on blood thinners, excessive bleeding may occur. Allergic reactions are rare. Women who are pregnant or breastfeeding can still receive IG. If you receive IG, do not receive an MMR or varicella for the next 3 months; receiving IG may decrease the efficacy of these vaccines. If you have received an MMR or varicella vaccine in the previous 3 weeks, these should be repeated in 3 months.

I consent to receive Immune Globulin. _____
Signature

I am the parent or guardian and consent for this child to receive IG.

_____ Date____ / ____ / _____
Signature

_____Weight in pounds x 0.01ml/lb = _____ml / IG

Administration site_____ Administered by_____

STATE OF ALASKA
DEPARTMENT OF HEALTH & SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY
3601 C STREET, SUITE 540
P.O. BOX 240249
ANCHORAGE, ALASKA 99524-0249
FRANK H. MURKOWSKI, GOVERNOR
INFECTIOUS DISEASES
AIDS/STD
TUBERCULOSIS
IMMUNIZATION
CHRONIC DISEASES
DIABETES
INJURY CONTROL
(907) 269-8000
(907) 562-7802

Hepatitis A Fact Sheet

What is Hepatitis A?

Hepatitis A is an infection of the liver caused by the hepatitis A virus.

What are the symptoms?

- Symptoms usually begin 2 to 6 weeks after exposure to the virus and last 1 to 2 weeks.
- Early symptoms in adults include
  - nausea (upset stomach)
  - loss of appetite
  - vomiting
  - fatigue
  - fever
  - abdominal cramps (stomach or side pain).
- Dark yellow or brown urine, pale or white bowel movements, and jaundice (yellow eyes or skin) may also be present but do not occur in all cases.
- Persons can have all or only a few of these symptoms.
- Most young children have only a mild flu-like illness without jaundice, or no symptoms at all.
- Rarely, illness can be much more severe, and even result in death.
- Hepatitis A infection does not cause long-term liver damage.

How is hepatitis A spread?

- The virus leaves the body by way of the stool and enters another person when hands, food, or objects contaminated with the stool are put in the mouth.
- A person can spread the virus about a week before symptoms appear and during the first week of symptoms.
- People without symptoms can still spread hepatitis A virus.
- Hepatitis A is not spread by kissing, sneezing, or by saliva.

How is hepatitis A diagnosed and treated?

- Hepatitis A infection is diagnosed with a blood test.
- There is no medicine or other treatment that will make the symptoms go away faster.

How can hepatitis A be prevented?

- The illness can be prevented by a shot of immune globulin within 2 weeks of exposure.
- There is a vaccine to prevent hepatitis A virus infection that is available for persons over 2 years of age. To be fully immunized, persons need a series of two vaccines given at least 6 months apart.

What about Immune Globulin (IG)?

Immune globulin (IG) can prevent someone who has been exposed to hepatitis A from getting the disease if given within 14 days from exposure. IG is effective 80-90% of the time and protects against hepatitis A for about 3 months. **Persons who have only received one dose of vaccine at least one month prior to exposure do NOT need immune globulin.**

Immune globulin is necessary only if any of the following applies to you:

- You live with someone who has hepatitis A.
- You have eaten food or put objects in your mouth handled by the person infected with hepatitis A.
- You have had sexual contact, or other intimate contact, with a person who has hepatitis A.
- You are traveling to an area where hepatitis A is common.
- You are a child or an employee at a childcare program in which another child or employee has hepatitis A.

Childcare Programs and Food Establishments

Because hepatitis A can spread quickly in these settings, notify Public Health immediately about anyone with hepatitis A who attends or works at a childcare program, or works as a food handler.

Hepatitis A, Acute

2000 Case Definition

Clinical case definition

An acute illness with a) discrete onset of symptoms **and** b) jaundice or elevated serum aminotransferase levels

Laboratory criteria for diagnosis:

Immunoglobulin M (IgM) antibody to hepatitis A virus (anti-HAV) positive

Case classification

Confirmed: a case that meets the clinical case definition and is laboratory confirmed

or

a case that meets the clinical case definition and occurs in a person who has an epidemiologic link with a person who has laboratory-confirmed hepatitis A (i.e., household or sexual contact with an infected person during the 15-50 days before the onset of symptoms)

See also:

- 1996 Case Definition
- 1995 Case Definition
- 1990 Case Definition

Hepatitis A
Fact Sheet

www.cdc.gov/hepatitis
1-888-4HEP-CDC

CDC
Centers for Disease Control and Prevention

SIGNS & SYMPTOMS	▪ jaundice ▪ fatigue ▪ abdominal pain ▪ loss of appetite ▪ nausea ▪ diarrhea ▪ fever Adults will have signs and symptoms more often than children.
CAUSE	Hepatitis A Virus (HAV)
LONG-TERM EFFECTS	▪ There is no chronic (long-term) infection. ▪ Once you have had hepatitis A you cannot get it again. ▪ About 15% of people infected with HAV will have prolonged or relapsing symptoms over a 6-9 month period.
TRANSMISSION	▪ HAV is found in the stool (feces) of persons with hepatitis A. ▪ HAV is usually spread from person to person by putting something in the mouth (even though it may look clean) that has been contaminated with the stool of a person with hepatitis A.
PERSONS AT RISK OF INFECTION	▪ Household contacts of infected persons. ▪ Sex contacts of infected persons. ▪ Persons, especially children, living in areas with increased rates of hepatitis A during the baseline period from 1987-1997. ▪ Persons traveling to countries where hepatitis A is common. ▪ Men who have sex with men. ▪ Injecting and non-injecting drug users.
PREVENTION	▪ Hepatitis A vaccine is the best protection. ▪ Short-term protection against hepatitis A is available from immune globulin. It can be given before and within 2 weeks after coming in contact with HAV. ▪ Always wash your hands with soap and water after using the bathroom, changing a diaper, and before preparing and eating food.
VACCINE RECOMMENDATIONS	Vaccine is recommended for the following persons 2 years of age and older: ▪ Travelers to areas with increased rates of hepatitis A ▪ Men who have sex with men ▪ Injecting and non-injecting drug users ▪ Persons with clotting-factor disorders (e.g. hemophilia) ▪ Persons with chronic liver disease ▪ Children living in areas with increased rates of hepatitis A during the baseline period from 1987-1997.
TRENDS & STATISTICS	▪ Occurs in epidemics both nationwide and in communities. ▪ During epidemic years, the number of reported cases reached 35,000. ▪ In the late 1990s, hepatitis A vaccine was more widely used and the number of cases reached historic lows. ▪ One-third of Americans had evidence of past infection (immunity).

This page last updated: June 15, 2004

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U.S. DEPARTMENT OF
HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE

VIRAL HEPATITIS CASE REPORT

CDC
Centers for Disease Control
and Prevention
Hepatitis Branch, (G37)
Atlanta, Georgia 30333

The following questions should be asked for every case of viral hepatitis

Prefix: (Mr. Mrs. Miss Ms. etc) _____ Last: _____ First: _____ Middle: _____

Preferred Name (nickname): _____ Maiden: _____

Address: Street: _____

City: _____ Phone: ( ) - Zip Code: ___ ___ ___ ___ ___ -- ___ ___ ___ ___

SSN # (optional) ___ ___ __ - ___ ___ - ___ ___ ___ ___

Only data from lower portion of form will be transmitted to CDC

State: _____ County: _____ Date of Public Health Report__ __ / __ __ / __ __ __ __

Was this record submitted to CDC through the NETSS system? Yes ☐ No ☐

If yes, please enter **NETSS ID NO.** ☐☐☐☐☐☐☐☐☐☐ If no, please enter **STATE CASE NO.** _____

DEMOGRAPHIC INFORMATION

RACE (check all that apply):

☐ Amer Indian or Alaska Native ☐ Black or African American ☐ White
☐ Asian ☐ Native Hawaiian or Pacific Islander ☐ Other Race, specify: _____

ETHNICITY:
Hispanic ..... ☐
Non-hispanic ..... ☐
Other/Unknown ..... ☐

SEX: Male ☐ Female ☐ Unk ☐ **PLACE OF BIRTH:** ☐USA ☐ Other:_____

DATE OF BIRTH: M M / D D / Y Y Y Y **AGE:** ___ ___ **(years)** **(00= <1yr , 99= Unk)**

CLINICAL & DIAGNOSTIC DATA

REASON FOR TESTING: (Check all that apply) ☐ Symptoms of acute hepatitis ☐ Evaluation of elevated liver enzymes
☐ Screening of asymptomatic patient with reported risk factors ☐ Blood / organ donor screening
☐ Screening of asymptomatic patient with no risk factors (e.g., patient requested) ☐ Follow-up testing for previous marker of viral hepatitis
☐ Prenatal screening ☐ Unknown ☐ Other: specify: _____

CLINICAL DATA:

Diagnosis date: M M / D D / Y Y Y Y

	Yes	No	Unk
Is patient symptomatic?	☐	☐	☐
if yes, onset date: M M / D D / Y Y Y Y			
Was the patient			
• Jaundiced?	☐	☐	☐
• Hospitalized for hepatitis?	☐	☐	☐
Was the patient pregnant ?	☐	☐	☐
due date : M M / D D / Y Y Y Y			
Did the patient die from hepatitis?	☐	☐	☐
• Date of death: M M / D D / Y Y Y Y			

DIAGNOSTIC TESTS: CHECK ALL THAT APPLY

	Pos	Neg	Unk
• Total antibody to hepatitis A virus [total anti-HAV]	☐	☐	☐
• IgM antibody to hepatitis A virus [IgM anti-HAV]	☐	☐	☐
• Hepatitis B surface antigen [HBsAg]	☐	☐	☐
• Total antibody to hepatitis B core antigen [total anti-HBc]	☐	☐	☐
• IgM antibody to hepatitis B core antigen [IgM anti-HBc]	☐	☐	☐
• Antibody to hepatitis C virus [anti-HCV]	☐	☐	☐
– anti-HCV signal to cut-off ratio _____			
• Supplemental anti-HCV assay [e.g., RIBA]	☐	☐	☐
• HCV RNA [e.g., PCR]	☐	☐	☐
• Antibody to hepatitis D virus [anti-HDV]	☐	☐	☐
• Antibody to hepatitis E virus [anti-HEV]	☐	☐	☐

LIVER ENZYME LEVELS AT TIME OF DIAGNOSIS

- ALT [SGPT] Result _____ Upper limit normal_____
- AST [SGOT] Result _____ Upper limit normal_____
- Date of ALT result M M / D D / Y Y Y Y
- Date of AST result M M / D D / Y Y Y Y

	Yes	No	Unk
• If this case has a diagnosis of hepatitis A that has not been serologically confirmed, is there an epidemiologic link between this patient and a laboratory-confirmed hepatitis A case?	☐	☐	☐

DIAGNOSIS: (Check all that apply)

☐ Acute hepatitis A
☐ Acute hepatitis B ☐ Chronic HBV infection ☐ Perinatal HBV infection ☐ Hepatitis Delta (co- or super-infection)
☐ Acute hepatitis C ☐ HCV infection (chronic or resolved)
☐ Acute hepatitis E ☐ Acute non-ABCD hepatitis

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Patient History- Acute Hepatitis A **NETSS ID NO.** ☐☐☐☐☐☐☐☐☐☐

STATE CASE NO. _____

During the **2-6 weeks** prior to onset of symptoms-

	Yes	No	Unk
Was the patient a contact of a person with confirmed or suspected hepatitis A virus infection?	☐	☐	☐
If yes, was the contact (check one)			
• household member (non-sexual)	☐	☐	☐
• sex partner	☐	☐	☐
• child cared for by this patient	☐	☐	☐
• babysitter of this patient	☐	☐	☐
• playmate	☐	☐	☐
• other _____	☐	☐	☐
Was the patient			
• a child or employee in a day care center, nursery, or preschool ?	☐	☐	☐
• a household contact of a child or employee in a day care center, nursery or preschool ?	☐	☐	☐
If yes for either of these, was there an identified hepatitis A case in the child care facility?	☐	☐	☐

Please ask both of the following questions regardless of the patient's gender.

In the **2- 6 weeks** before symptom onset how many

	0	1	2-5	>5	Unk
• male sex partners did the patient have?	☐	☐	☐	☐	☐
• female sex partners did the patient have?	☐	☐	☐	☐	☐

In the **2- 6 weeks** before symptom onset

	Yes	No	Unk
Did the patient inject drugs not prescribed by a doctor?	☐	☐	☐
Did the patient use street drugs but not inject?	☐	☐	☐
Did the patient **travel** outside of the U.S.A. or Canada	☐	☐	☐
• If yes, where? 1) _____ 2) _____ (Country) 3) _____			
In the **3 months** prior to symptom onset Did anyone in the patient's household travel outside of the U.S. A. or Canada?	☐	☐	☐
• If yes, where? 1) _____ 2) _____ (Country) 3) _____			
Is the patient suspected as being part of a common-source outbreak?	☐	☐	☐
If yes, was the outbreak			
Foodborne- associated with an infected food handler	☐	☐	☐
Foodborne - **NOT** associated with an infected food handler	☐	☐	☐
• specify food item _____			
Waterborne	☐	☐	☐
Source not identified	☐	☐	☐
Was the patient employed as a food handler during the **TWO WEEKS** prior to onset of symptoms or while ill?	☐	☐	☐

VACCINATION HISTORY

	Yes	No	Unk
Has the patient ever received the hepatitis A vaccine ?	☐	☐	☐

• If yes, how many doses? ..... **1** ☐ **≥ 2** ☐

• In what year was the last dose received? ..... Y Y Y Y

	Yes	No	Unk
Has the patient ever received immune globulin ?	☐	☐	☐

• If yes, when was the last dose received? ..... _____ / _____ (**mo** / **yr**)

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STATE CASE NO. _____

Patient History- Acute Hepatitis B

NETSS ID NO. ☐☐☐☐☐☐☐☐☐☐

During the **6 weeks- 6 months** prior to onset of symptoms was the patient a contact of a person with confirmed or suspected acute or chronic hepatitis B virus infection? **Yes** **No** **Unk**

If yes, type of contact

- Sexual ..... ☐ ☐ ☐
- Household [Non-sexual] ..... ☐ ☐ ☐
- Other: _____ ☐ ☐ ☐

Ask both of the following questions regardless of the patient's gender.

In the **6 months** before symptom onset how many **0** **1** **2-5** **>5** **Unk**

- male sex partners did the patient have? ..... ☐ ☐ ☐ ☐ ☐
- female sex partners did the patient have? ..... ☐ ☐ ☐ ☐ ☐

Was the patient ***EVER*** treated for a sexually-transmitted disease? ..... **Yes** ☐ **No** ☐ **Unk** ☐

- If yes, in what year was the most recent treatment ? __ __ __ __

During the **6 weeks- 6 months** prior to onset of symptoms

- inject drugs not prescribed by a doctor? ..... ☐ ☐ ☐
- use street drugs but not inject? ..... ☐ ☐ ☐

During the **6 weeks- 6 months** prior to onset of symptoms

Did the patient- **Yes** **No** **Unk**

- undergo hemodialysis? ..... ☐ ☐ ☐
- have an accidental stick or puncture with a needle or other object contaminated with blood? ..... ☐ ☐ ☐
- receive blood or blood products [transfusion] ..... ☐ ☐ ☐
  - if yes, when? M M / D D / Y Y Y Y
- receive any IV infusions and/or injections in the outpatient setting... ☐ ☐ ☐
- have other exposure to someone else's blood ..... ☐ ☐ ☐

  specify: _____

During the **6 weeks - 6 months** prior to onset of symptoms

- Was the patient employed in a medical or dental field involving direct contact with human blood ? ..... ☐ ☐ ☐

  If yes, frequency of direct blood contact?

  Frequent (several times weekly) ☐ Infrequent ☐
- Was the patient employed as a public safety worker (fire fighter, law enforcement or correctional officer) having direct contact with human blood? ..... ☐ ☐ ☐

  If yes, frequency of direct blood contact?

  Frequent (several times weekly) ☐ Infrequent ☐
- Did the patient receive a tattoo? ..... ☐ ☐ ☐

  where was the tattooing performed? (select all that apply)

  ☐ commercial parlor / shop ☐ correctional facility ☐ other _____

During the **6 weeks- 6 months** prior to onset of symptoms

- Did the patient have any part of their body pierced (other than ear)?

  where was the piercing performed? (select all that apply)

  ☐ commercial parlor / shop ☐ correctional facility ☐ other _____

Yes **No** **Unk**

- Did the patient have dental work or oral surgery? ..... ☐ ☐ ☐
- Did the patient have surgery ? (other than oral surgery) .. ☐ ☐ ☐
- Was the patient- ***Check all that apply***
  - hospitalized ? ..... ☐ ☐ ☐
  - a resident of a long term care facility ? ..... ☐ ☐ ☐
  - incarcerated for longer than 24 hours ? ..... ☐ ☐ ☐

    if yes, what type of facility (check all that apply)

    prison ..... ☐ ☐

    jail ..... ☐ ☐

    juvenile facility ..... ☐ ☐

During his/her lifetime, was the patient ***EVER***

- incarcerated for longer than 6 months ? ..... ☐ ☐ ☐
  - If yes,

    what year was the most recent incarceration ? ..... __ __ __ __

    for how long ? ..... __ __ __ **mos**

Did the patient ever receive hepatitis B vaccine? **Yes** ☐ **No** ☐ **Unk** ☐

If yes, how many shots? ..... **1** ☐ **2** ☐ **3+** ☐

- In what year was the last shot received? ..... Y Y Y Y

Was the patient tested for antibody to HBsAg (anti-HBs) within 1-2 months after the last dose? ..... **Yes** ☐ **No** ☐ **Unk** ☐

- If yes, was the serum anti-HBs ≥ 10mIU/ml? ..... ☐ ☐ ☐

  (answer 'yes' if the laboratory result was reported as ..... 'positive' or 'reactive')

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Perinatal Hepatitis B Virus Infection

NETSS ID NO. ☐☐☐☐☐☐☐☐☐☐

STATE CASE NO. _____

RACE OF MOTHER:

☐ Amer Ind or Alaska Native ☐ Black or African American ☐ White ☐ Unknown
☐ Asian ☐ Native Hawaiian or Pacific Islander ☐ Other Race, specify: _____

ETHNICITY OF MOTHER:

Hispanic ..... ☐
Non-hispanic ..... ☐
Other/Unknown ..... ☐

	Yes	No	Unk	
Was **Mother** born outside of United States?	☐	☐	☐	If yes, what country?_____
Was the **Mother** confirmed HBsAg positive prior to or at time of delivery ? ...	☐	☐	☐	
• If no, was the mother confirmed HBsAg positive after delivery?	☐	☐	☐	

Date of HBsAg positive test result ..... M M / D D / Y Y Y Y

How many doses of hepatitis B vaccine did the child receive ? 0 1 2 3

- When?
- Dose 1- M M / D D / Y Y Y Y
- Dose 2- M M / D D / Y Y Y Y
- Dose 3- M M / D D / Y Y Y Y

	Yes	No	Unk
Did the child receive hepatitis B immune globulin (HBIG)?	☐	☐	☐

- If yes, on what date did the child receive HBIG? ..... M M / D D / Y Y Y Y

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NETSS ID NO. ☐☐☐☐☐☐☐☐☐☐

STATE CASE NO. _____

Patient History- Acute Hepatitis C

During the **2 weeks- 6 months** prior to onset of symptoms was the patient a contact of a person with confirmed or suspected acute or chronic hepatitis C virus infection? **Yes** **No** **Unk**

If yes, type of contact

- Sexual ..... ☐ ☐ ☐
- Household [Non-sexual] ..... ☐ ☐ ☐
- Other: _____ ☐ ☐ ☐

Ask both of the following questions regardless of the patient's gender.

In the **6 months** before symptom onset how many **0** **1** **2-5** **>5** **Unk**

- male sex partners did the patient have? ..... ☐ ☐ ☐ ☐ ☐
- female sex partners did the patient have? ..... ☐ ☐ ☐ ☐ ☐

Was the patient ***EVER*** treated for a sexually transmitted disease? ..... **Yes** ☐ **No** ☐ **Unk** ☐

- If yes, in what year was the most recent treatment ? Y Y Y Y

During the **2 weeks- 6 months** prior to onset of symptoms

- inject drugs not prescribed by a doctor? ..... ☐ ☐ ☐
- use street drugs but not inject? ..... ☐ ☐ ☐

During the **2 weeks- 6 months** prior to onset of symptoms

Did the patient- **Yes** **No** **Unk**

- undergo hemodialysis? ..... ☐ ☐ ☐
- have an accidental stick or puncture with a needle or other object contaminated with blood? ..... ☐ ☐ ☐
- receive blood or blood products [transfusion] ..... ☐ ☐ ☐
  - if yes, when? M M / D D / Y Y Y Y
- receive any IV infusions and/or injections in the outpatient setting... ☐ ☐ ☐
- have other exposure to someone else's blood ..... ☐ ☐ ☐

  specify: _____

During the **2 weeks - 6 months** prior to onset of symptoms

- Was the patient employed in a medical or dental field involving direct contact with human blood ? ..... ☐ ☐ ☐

  If yes, frequency of direct blood contact?

  Frequent (several times weekly) ☐ Infrequent ☐
- Was the patient employed as a public safety worker (fire fighter, law enforcement or correctional officer) having direct contact with human blood? ..... ☐ ☐ ☐

  If yes, frequency of direct blood contact?

  Frequent (several times weekly) ☐ Infrequent ☐
- Did the patient receive a tattoo? ..... ☐ ☐ ☐

  where was the tattooing performed? (select all that apply)

  ☐ commercial parlor / shop ☐ correctional facility ☐ other _____

During the **2 weeks- 6 months** prior to onset of symptoms

- Did the patient have any part of their body pierced (other than ear)?

  where was the piercing performed? (select all that apply)

  ☐ commercial parlor / shop ☐ correctional facility ☐ other _____

Yes **No** **Unk**

- Did the patient have dental work or oral surgery? ..... ☐ ☐ ☐
- Did the patient have surgery ? (other than oral surgery) .. ☐ ☐ ☐
- Was the patient- ***Check all that apply***
  - hospitalized ? ..... ☐ ☐ ☐
  - a resident of a long term care facility ? ..... ☐ ☐ ☐
  - incarcerated for longer than 24 hours ? ..... ☐ ☐ ☐

    if yes, what type of facility (check all that apply)

    prison ..... ☐ ☐

    jail ..... ☐ ☐

    juvenile facility ..... ☐ ☐

During his/her lifetime, was the patient ***EVER***

- incarcerated for longer than 6 months ? ..... ☐ ☐ ☐
  - If yes,

    what year was the most recent incarceration ? ..... Y Y Y Y

    for how long ? ..... __ __ __ **mos**

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NETSS ID NO. | | | | | | | | | | |

Patient History- Hepatitis C Virus Infection (chronic or resolved)

STATE CASE NO. _____

The following questions are provided as a guide for the investigation of lifetime risk factors for HCV infection. Routine collection of risk factor information for persons who test HCV positive is not required. However, collection of risk factor information for such persons may provide useful information for the development and evaluation of programs to identify and counsel HCV-infected persons.

	Yes	No	Unk
• Did the patient receive a blood transfusion prior to 1992?	☐	☐	☐
• Did the patient receive an organ transplant prior to 1992?	☐	☐	☐
• Did the patient receive clotting factor concentrates produced prior to 1987?	☐	☐	☐
• Was the patient ever on long-term hemodialysis?	☐	☐	☐
• Has the patient ever injected drugs not prescribed by a doctor even if only once or a few times?	☐	☐	☐
• How many sex partners has the patient had (approximate lifetime) ? _____			
• Was the patient ever incarcerated?	☐	☐	☐
• Was the patient ever treated for a sexually transmitted disease?	☐	☐	☐
• Was the patient ever a contact of a person who had hepatitis ?	☐	☐	☐
If yes, type of contact			
• Sexual	☐	☐	☐
• Household [Non-sexual]	☐	☐	☐
• Other: _____	☐	☐	☐

	Yes	No	Unk
• Was the patient ever employed in a medical or dental field involving direct contact with human blood?	☐	☐	☐

Alaska State Virology Laboratory - Fairbanks
Division of Public Health
P.O. Box 60230
Fairbanks, Alaska 99706-0230
Phone (907)474-7017 FAX (907)474-4036

STATE OF ALASKA
HEPATITIS REQUEST FORM

PLEASE PRINT LEGIBLY

EXEMPTION # _____

INS/MEDICAID # _____

ACCESSION # _____

PATIENT INFORMATION

_____
LAST NAME FIRST NAME M.I.

OTHER PATIENT ID # _____

DATE OF BIRTH ____/____/____
month day year

*RACE _____ SEX _____ *RISK _____

SPECIMEN COLLECTION DATE ____/____/____
month day year

*SEE BACK OF FORM FOR RACE AND RISK CODES

PROVIDER INFORMATION

NAME

FACILITY

ADDRESS

PHONE #

FAX #

REMARKS _____

_____

TEST REQUESTED

- [ ] HEPATITIS A
- [ ] HEPATITIS B
- [ ] HEPATITIS C

REASON FOR TEST

- [ ] SCREEN
- [ ] PRENATAL
- [ ] POST VACCINE
- [ ] SYMPTOMATIC

- [ ] PREVIOUS SURFACE ANTIGEN POSITIVE

OF VACCINES _____

DATE OF ONSET mo ____ day ____ year ____

DATE RECEIVED	RECEIVED BY
CONDITION/COMMENTS	

Influenza

Influenza, Seasonal

[If avian flu is suspected, see Section 2–Avian Influenza Infections in Humans]

Organism:	Influenza virus, usually types A and B, sometimes type C. Classed based on hemagglutinin (H) and neuraminidase (N) glycoproteins. Variants arise yearly. Currently circulating: H3N2, H1N1, and B.
Incubation period:	1-3 days.
Infectious period:	3-5 days, up to 7 in children.
Transmission route:	Airborne predominately, some may occur through direct contact.
Treatment:	For currently circulating strains, generally none. Some high-risk individuals may be offered antivirals (see antiviral information in AK Pandemic Influenza Plan). If Avian Influenza is suspected, turn to Avian Influenza Section. If pandemic influenza has started, see AK Pandemic Influenza Plan.

Information Needed for the Investigation

- During influenza season, consider investigating clusters of influenza like illness, especially in nursing homes or other congregational settings.
- Do not investigate sporadic or single cases.

Verify the Diagnosis

- Laboratory culture should be encouraged at the start of the season and in geographic areas of Alaska where no isolates have been obtained that season.
- As the season progresses, rapid tests may also be relied on to count cases of influenza.
- If investigating a congregational setting, always try to obtain at least 3-5 viral culture specimens.

Determine the Extent of Illness

- During each flu season, request cultures on suspect cases from areas with no confirmed isolates.
- Influenza-like surveillance (ILI) is updated weekly to measure the magnitude and extent of illness.

Laboratory Specimens

- Obtain a respiratory sample (nasopharyngeal swab or aspirate) for culture and place in viral transport medium (VTM). Send to ASVL for processing.
- Many outpatient clinics and hospitals also conduct rapid tests for influenza A or influenza A/B.

Contact and Control Measures

- Annual influenza vaccinations are offered across Alaska.
- No effort to control spread of usual circulating strains in general population.
- Antivirals may be useful for certain high-risk cases or in congregational settings.

Reporting Requirements

- FTR: Congregational or other large outbreaks.
- Morbidity database: Individual cases not entered. Special CDC report system is part of database on a 0-5 scale, reported during flu season only.
- Other surveillance systems: ILI surveillance, school absenteeism rates.

Influenza Surveillance Group

First	Last	Company	Address	City		Zip	Work Phone	Fax
		Maniilaq Health Center	PO Box 43	Kotzebue	AK	99752	442-3321	442-7250
Lee	Asnin	SEARHC Mt. Edgecumbe Hosp.	222 Tongass Drive	Sitka	AK	99835	966-2411	NA
Jan	Beauchamp	Bartlet Regional Hospital	3260 Hospital Drive	Juneau	AK	99801	586-2611	463-4919
James	Briggs		3300 Providence Dr. Suite 212	Anchorage	AK	99508	561-4459	561-4767
Peggy	Brown	First Care Huffman	1301 Huffman Road; Suite 100	Anchorage	AK	99515	345-1199	
		First Care Spenard	3710 Woodland Drive	Anchorage	AK		248-1122	345-5931
Bruce	**Chandler**	**Anch. Neighborhood Health Ctr**	**1217 E. 10th Avenue**	**Anchorage**	**AK**	**99501**	**257-4600**	**257-4620**
Deborah	Dahlberg	Kanakanak Hospital	P.O. Box	Dillingham	AK	99576	842-5201	842-9409
Sharlane	Donaldson	Cross Roads Medical Center	P.O. Box 5	Glennallen	AK	99588	822-3203	822-5805
Eunice	Garzel	Valdez Hospital	P.O. Box 550	Valdez	AK	99686	835-2249	835-3735
Janet	**Gleason**	**Central Peninsula General Hosp'l**	**250 Hospital Place**	**Soldotna**	**AK**	**99669**	**262-3557**	**262-6505**
Kathie	**Glover**	**Ketchikan General Hospital**	**3100 Tongass Avenue**	**Ketchikan**	**AK**	**99901**	**225-5171x7426**	**228-8330**
Ellen	**Hodges**	**Y-K Delta Regional Hospital**	**P.O. Box 528, Suite 3000**	**Bethel**	**AK**	**99559**	**543-6304**	**543-6250**
Mary Ann	Jacobs	Medical Plaza Building	1200 Airport Heights Dr. , Ste 180	Anchorage	AK	99508	274-0274	274-7809
Mary	MacFarlane	Fairbanks Clinic	1919 Lathrop St, Ste 100	Fairbanks	AK	99701	452-1761	452-8935
James	MacFarlane		1919 Lathrop St., Ste 108	Fairbanks	AK	99701	452-7060	451-7258
John	**Quimby**	**Urgent Care Medical Clinic**	**5437 E. Northern Lights Blvd.**	**Anchorage**	**AK**	**99508**	**333-8561**	**333-8560**
John	**Salmon**	**Norton Sound Regional Hospital**	**306 W. 5th Ave/ PO Box 966**	**Nome**	**AK**	**99762**	**443-3311**	**443-3556**
Charles	**Steiner**	**Tanana Valley Clinic**	**1001 Noble**	**Fairbanks**	**AK**	**99701**	**459-3511**	**459-3588**
Kalpna	**Thuraisamy**	**Ketchikan Indian Tribal H'lth Clinic**	**2960 Tongass Ave**	**Ketchikan**	**AK**	**99901**	**228-4964**	**247-4808**
Pete	Wilda	Fairbanks Memorial Hospital	1650 Cowles Street	Fairbanks	AK	99701	458-5647	458-5324
Terry	Schmidt	Public Health Lab. - Virology	901 Koyukuk Ave., Rm 239	Fairbanks	AK	99706	474-7017	474-4036
Mary	Westcott	Public Health Lab. - Virology	901 Koyukuk Ave., Rm 239	Fairbanks	AK	99706	474-7017	474-4036

* Bolded names indicate both ILI and viral cx. surveillance providers

STATE OF ALASKA

DEPARTMENT OF HEALTH & SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY

3601 C STREET, SUITE 540
P.O. BOX 240249
ANCHORAGE, ALASKA 99524-0249

FRANK H. MURKOWSKI, GOVERNOR

INFECTIOUS DISEASES
AIDS/STD
TUBERCULOSIS
IMMUNIZATION
CHRONIC DISEASES
DIABETES
INJURY CONTROL

(907) 269-8000
(907) 562-7802

October 11, 2005

Dear Health Care Providers:

Thank you for your participation in monitoring the occurrence of influenza among your patients. To date, for the months of September and October, we have received five positive influenza rapid test results from the following areas of the state: Anchorage, Nome, and Juneau. However, in order to establish influenza in an area we also need to obtain viral culture results. Viral cultures are critical because only culture isolates can provide specific information regarding circulating influenza subtypes and strains. Culture results are also used to compare circulating influenza strains with vaccine composition and to monitor for antiviral resistance. I hope you can continue to participate in our viral culture surveillance program for the 2005-2006 influenza season. There is no cost to you or your patient for supplies and testing.

The State Virology Laboratory in Fairbanks will supply you with:

1. Viral transport media (VTM).
2. Swabs (Dacron throat and nasopharyngeal).
3. Biohazard bags for specimen and laboratory slips.
4. Refrigerant gel packs.
5. One to four shipping containers and postage-paid address labels. Each shipping container can hold 10-15 specimens.
6. Laboratory slips.

General instructions for influenza specimen collection and shipment:

1. Each health care provider should culture up to 10-12 patients per week who have symptoms suggesting influenza. A reasonable approach is to culture the first 5 patients each week that may have flu, and then culture an additional 5–7 patients who present with severe or atypical symptoms. The typical symptoms of influenza include: fever, cough, sore throat, myalgia, and malaise. Children with influenza usually have the above respiratory symptoms, which are sometimes accompanied by abdominal pain, nausea, diarrhea, or vomiting.
2. The preferred specimen is a nasopharyngeal (NP) swab. An instruction sheet for NP collection is attached. As an alternate to a NP swab, a throat swab may be collected; however, the yield is likely to be lower. For a throat swab, a Dacron swab should be vigorously rubbed against the posterior pharynx and tonsils.
3. The swab (whether a NP specimen or throat specimen) should be placed in the VTM. Break -off the swab's shaft short enough to be able to screw the VTM cap tightly so it does not leak in transport.

4. The VTM vial should be labeled with the patient's name and then the vial cap must be taped in a clockwise direction as an added protection from leakage. A laboratory submission slip should be completed. Place the specimen and completed laboratory slip in a biohazard bag. The specimen should be kept refrigerated until it is shipped.
5. Ship specimens once a week to the State Virology Laboratory, Monday or Tuesday is recommended. Put all specimens in a shipping container, place a (frozen) refrigerant gel pack on top of the specimens, and seal the box. Apply a "business reply" label and place a "diagnostic specimen" label on top of the box before mailing.
6. The virology laboratory will return an empty shipping container to you with another postage-paid label.

During the 2005-2006 influenza season, the Section of Epidemiology will continue to provide periodic statewide "influenza updates." This information will be posted on the Section's website: http://www.epi.hss.state.ak.us/ . We hope these updates, along with the individual results you will receive for the patients you culture, will be useful to you

Sincerely,

Donna Fearey

Donna Fearey ANP, MS

SOMETHING OF INTEREST

VIRAL TRANSPORT MEDIA (VTM)

Proper Storage Requirements

As the flu season approaches, many submitters are calling the State Virology Laboratory with questions concerning the storage and transport of Viral Transport Media (VTM). We thought it would be beneficial for our present and new submitters to review the requirements for sending viral cultures to the laboratory for identification.

Proper Storage of Viral Transport Media:

- Do NOT store in a frost free freezer. The freeze / thaw cycles will shorten the expiration date of the media. If the only freezer available to you is frost free, you can store the VTM in a styrofoam container with an ice pack to keep the media frozen.
- If the VTM is stored at -20°C, it may be used until the expiration date printed on the vial.
- VTM may be stored up to 30 days at 4°C (refrigerator temperature).
- If the VTM is thawed upon receipt, it can be refrozen once and will be usable up to the expiration date.
- Due to the presence of antibiotics in the VTM, it should not be left at room temperature.
- If the VTM has been allowed to thaw and remain at room temperature, discard any unused media after 7 days.

Transport of Viral Specimens to the Laboratory:

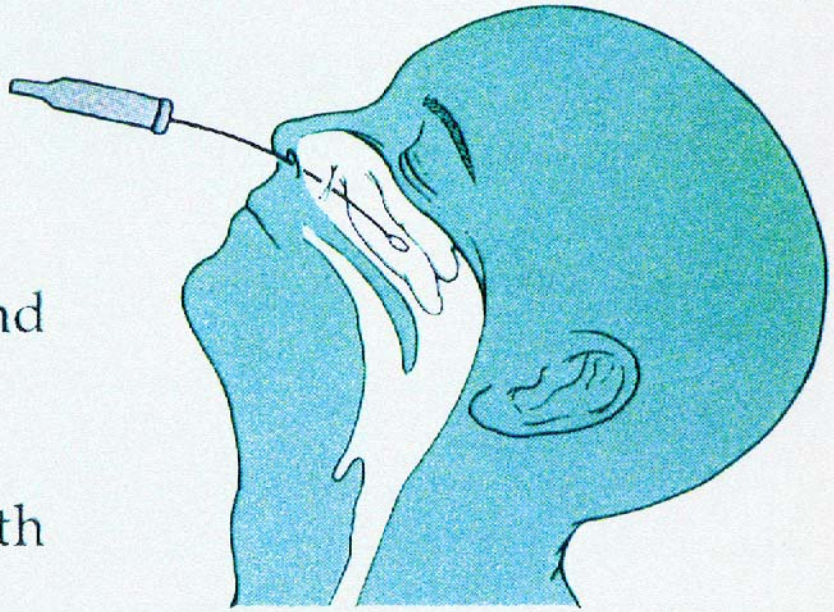
- Culture specimens must be received at the State Virology Laboratory in Fairbanks packed with cold packs within **96 hours** of collection for optimal chance of viral recovery.
- Lipid enveloped viruses; e.g. CMV, HSV, RSV, et., must *NOT* be frozen.
- When specimen submission will be delayed more than 96 hours, specimens must be frozen within 48 hours of collection and shipped frozen.
- The virologists will make every attempt to isolate viruses from less than optimal specimens.
- Be sure to label the vial with the patient's name or identification number. **UNLABELED SPECIMENS ARE UNSATISFACTORY and will not be processed.**
- Do not leave scalpel blades in the VTM; this can be toxic to the specimen.
- Break off the specimen swab below the rim of the vial so the cap can be **tightened securely** to prevent leakage.
- Place paperwork and specimen into separate leakproof bags with absorbent material around the specimen. Specimens which leak may be considered unsatisfactory.

** **NOTE**: Be careful to use **VTM** for viral cultures and **CTM** (Chlamydia Transport Media) for chlamydia cultures. They are NOT interchangeable.

If you have any questions or concerns about the storage, collections, or shipment of viral media and specimens, please contact the State Virology Laboratory in Fairbanks at (907)474-7017 or (888)474-7017.

Mary Westcott
Microbiologist III

Nasopharyngeal Swab Method



Materials: Mini-Tip **Culturette**® Brand Collection and Transport System ***or***

Nasopharyngeal swab with synthetic fiber tip
1-2 ml Viral Transport Medium (VTM)
Specimen container

1. Insert swab into one nostril.
2. Press swab tip on the mucosal surface of the mid-inferior portion of the inferior turbinate (see sketch), and rub the swab tip several times across the mucosal surface to loosen and collect cellular material.
3. Withdraw swab; insert into **Culturette**® or container with VTM.

Malaria

Malaria

Illness:	All species are transmitted by the bite of an infected female *Anopheles* mosquito. Occasionally, transmission occurs by blood transfusion or congenitally from mother to fetus. Although malaria can be a fatal disease, illness and death from malaria are largely preventable.
Infectious Agent:	Plasmodium spp.: *vivax, ovale, falciparum, malariae*
Incubation period:	Can vary depending on species, and also the person's immune status and whether they took prophylaxis; range 9–40 days.
Infectious period:	Persons are not infectious, however, persons who have had malaria are not allowed to donate blood for 3 years after treatment for malaria.
Symptoms:	Malaria is characterized by fever and influenza like symptoms, including chills, headache, myalgias, and malaise; these symptoms can occur at intervals. Malaria may be associated with anemia and jaundice, and *P. falciparum* infections can cause seizures, mental confusion, kidney failure, coma, and death. Malaria symptoms can develop as early as 6 days after initial exposure in a malaria-endemic area and as late as several months after departure from a malarious area, after chemoprophylaxis has been terminated.
Transmission routes:	Mosquito-borne; Anopheles spp. Malaria transmission occurs in large areas of Central and South America, Hispaniola, Africa, Asia (including the Indian Subcontinent, Southeast Asia, and the Middle East), Eastern Europe, and the South Pacific.
Treatment:	CDC has on-call physicians to advise on malaria treatment: **EST 8–4:30: 770-488-7788** **After-hours: 770-488-7100, ask to page the malaria MD.** Treatment guidelines available on-line: http://www.cdc.gov/malaria/pdf/treatmenttable.pdf

Information Needed for the Investigation

Verify the Diagnosis

- Thin and thick smears and EDTA whole blood from patients can be sent to ASPHL for parasite identification. ASPHL might also send slides or just digital images to CDC for further confirmation of species.

Environmental Investigation

- None, cases are imported.

Reporting Requirements

- CDC has case investigation forms that can be used to track a case: http://www.cdc.gov/malaria/pdf/malaria_form.pdf.
- Fill out a morbidity form and file as usual.

Fact Sheets Available

- CDC's website: http://www.cdc.gov/malaria/facts.htm.

MALARIA CASE SURVEILLANCE REPORT

Department of Health and Human Services, Centers for Disease Control and Prevention
Division of Parasitic Diseases (MS F-22), 4770 Buford Highway, N.E.
Atlanta, Georgia 30341

State Case No: ..... Case No: ..... Form Approved
DASH No: ..... County: ..... OMB 0920-0009

Patient name (last, first):

Date of symptom onset of **this** attack (mm/dd/yyyy): ____/ ____/ _____

Age (yrs): _____ (mos): _____ Sex: ☐ Male ☐ Female
Date of birth: ____/ ____/ _____
Is patient pregnant? ☐ Yes ☐ No

Physician name (last, first):

Telephone No: ( ) _____ – _____

Ethnicity:
☐ Hispanic or Latino
☐ Not Hispanic or Latino

Race (select one or more):
☐ American Indian or Alaska Native
☐ Native Hawaiian or Other Pacific Islander
☐ Black or African American
☐ Asian ☐ White ☐ Unknown

Lab results:
☐ Smear positive ☐ Smear Negative ☐ No Smear Taken
Species (check all that apply):
☐ Vivax ☐ Falciparum ☐ Malariae ☐ Ovale ☐ Not Determined

State/territory reporting this case: _____
Patient admitted to hospital: ☐ Yes ☐ No
Hospital: _____
Date: ____/ ____/ _____ Hospital record No.: _____

Laboratory name:
Telephone No: ( ) _____ – _____

Specimens being sent to CDC? ☐ Yes ☐ No
If yes: ☐ Smears ☐ Whole Blood ☐ Other: _____

Has the patient traveled or lived outside the U.S. during the past 4 years? ☐ Yes ☐ No If yes, specify:

Country:	1. _____	2. _____	3. _____
Date returned/arrived in U.S. (mm/dd/yyyy):	____/ ____/ _____	____/ ____/ _____	____/ ____/ _____
Duration of stay in foreign country (days):	_____	_____	_____

Did patient reside in U.S. prior to most recent travel?
☐ Yes, for ≥12 months
☐ Yes, for <12 months
☐ No, (specify country): _____
☐ Unknown

Principal reason for travel from/to U.S. for most recent trip:
☐ Tourism ☐ Visiting friends/relatives ☐ Student/teacher
☐ Military ☐ Airline/ship crew ☐ Other: _____
☐ Business ☐ Missionary or dependent
☐ Peace Corps ☐ Refugee/immigrant

Was malaria chemoprophylaxis taken? ☐ Yes ☐ No If yes, which drugs were taken?
☐ Chloroquine ☐ Mefloquine ☐ Doxycycline ☐ Primaquine ☐ Malarone® ☐ Other: _____

Were all pills taken as prescribed?
☐ Yes, missed no doses
☐ No, missed one to a few doses
☐ No, missed more than a few but less than half of the doses
☐ No, missed half or more of the doses
☐ No, missed doses but not sure how many
☐ Don't know

If doses were missed, what was the reason?
☐ Forgot
☐ Didn't think needed
☐ Had a side effect (specify): _____
☐ Was advised by others to stop
☐ Prematurely stopped taking once home
☐ Other (specify): _____

History of malaria in last 12 months (prior to this report)? ☐ Yes ☐ No Date of previous illness: ____/ ____/ _____
If yes, species (check all that apply): ☐ Vivax ☐ Falciparum ☐ Malariae ☐ Ovale ☐ Not Determined

Blood transfusion/organ transplant within last 12 months: ☐ Yes ☐ No If yes, date: ____/ ____/ _____

Clinical complications for this attack: ☐ Cerebral malaria ☐ ARDS ☐ None ☐ Renal failure ☐ Anemia (Hb<11, Hct<33) ☐ Other : _____

Was illness fatal: ☐ Yes ☐ No ☐ Unknown
If yes, date of death : _____/____/_____

Therapy for this attack (check all that apply):
☐ Chloroquine ☐ Tetracycline/doxycycline ☐ Mefloquine ☐ Exchange transfusion ☐ Unknown
☐ Primaquine ☐ Quinine/quinidine ☐ Pyrimethamine-sulfadoxine ☐ Malarone ☐ Other (specify): _____

Person submitting report: _____ Telephone No. : _____

Affiliation: _____ Date: _____/_____/_____

For CDC Use Only. Classification ☐ Imported ☐ Induced ☐ Introduced ☐ Congenital ☐ Cryptic

Public reporting burden of this collection of information is estimated to average 15 minutes per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Please send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Rd., NE (MS D-24); Atlanta, GA 30333; ATTN: PRA (0920-0009).

 If sending specimens, please forward blood smears (thick and thin) with this report.

Physicians and other health care providers with questions about diagnosis and treatment of malaria cases can call CDC's Malaria Hotline:

- Monday – Friday, 8:00 am to 4:30 pm, EST: call 770-488-7788 (Fax: 770-488-4206)
- Off-hours, weekends, and federal holidays: call 770-488-7100 and ask to have the malaria clinician on call paged

Information on malaria risk, prevention, and treatment is available at:

- CDC's Travelers' Health Web site http://www.cdc.gov/travel
- CDC's Travelers' Health Information Service: call 1-877-FYI-TRIP
- CDC's Malaria Web site http://www.cdc.gov/malaria

Health Information for International Travel **is available from the Public Health Foundation:**
Call 1-877-252-1200, or order on line at http://www.phf.org

 If sending specimens, please forward blood smears (thick and thin) with this report.

Malaria Case Surveillance Report form
(OMB 0920-0009)

This form is used for reporting smear-confirmed cases of malaria to the National Malaria Surveillance System. Completed forms should be sent to the attention of malaria surveillance at the address at the top of the form.

To complete the form:
The form is largely self-explanatory; however below are a few descriptions of variables to assist in completing the form.

State Case No:	Space provided for states that assign their own case numbers.
DASH No:	Please leave blank (for CDC use only).
Case No:	Please leave blank (for CDC use only).
County:	Space provided for states that classify cases by the reporting county.

Patient name:

Please provide, if allowed by local patient confidentiality regulations. No personal identifiers are used in the reporting of the surveillance summary. Because CDC often receives more than one report on a malaria case, names are useful to remove duplicate reports. If names are not permissible, then the patient's initials or birth date would be helpful.

Date of birth:

Will help identify duplicate cases if patient name or other identifiers have not been provided.

Is patient pregnant?

An attack of malaria in a pregnant woman may be more severe than in a non-pregnant woman. In addition, therapy recommendations may be different.

Lab results:

CDC defines a case of malaria as any smear-positive malaria diagnosed within the United States. Please report all smear-confirmed cases, even if other surveillance information is not available. Please note: A person who was diagnosed overseas but whose diagnosis was not confirmed in the United States by malaria smear, is not considered a U.S. case.

Specimens being sent to CDC?

This information allows CDC to coordinate its laboratory results with the surveillance form.

Country:

Please include all countries of travel or residence outside the United States. If the specific countries are unknown, then the region of the world may be used, i.e. southern Africa, Central America, etc.

Did patient reside in U.S. prior to most recent travel?

Yes, for ≥12 months: If the patient resided in the U.S. for 12 months or more before travel outside of the U.S.

Yes, for <12 months: If the patient resided in the U.S. before travel, but had lived in the U.S. less than 12 months before their travel.

No, (specify country): If the patient did not reside in the U.S. before traveling to the U.S.; specify the country of residence.

Unknown: If this information is not available.

Principal reason for travel from/to U.S. for most recent trip:

These categories apply to U.S. residents traveling overseas and to non-U.S. residents arriving in the U.S.

Tourism: If the travel was primarily for pleasure.

Military: If the traveler was either in the U.S. military and stationed overseas, or a member of foreign military while traveling to the U.S.

Business: If travel was primarily business related, e.g. oil companies, archeologists, etc.

Peace Corps: If the traveler was a member of the Peace Corps while overseas.

Visiting friends/relatives: If the travel overseas was primarily to visit family or friends (i.e. holidays, funeral, etc.).

Airline/ship crew: If the person traveled overseas as a part of flight or ship's crew.

Missionary or dependent: If the traveler or a family member was traveling for missionary purposes.

Refugee/immigrant: If the traveler arrived in the U.S. with the intention to establish residency in this country.

Student/teacher: If the travel was primarily for educational purposes.

Was malaria chemoprophylaxis taken?

This information captures whether an antimalarial drug was taken for prevention during travel. (Do **not** include treatment drugs used for this attack of malaria.) The questions on chemoprophylaxis are useful for determining compliance and the reasons for non-compliance with CDC antimalarial drug recommendations.

If yes, which drugs were taken?

Please check all drugs and drug combinations that apply.

History of malaria in last 12 months (prior to this report)?

Check "Yes" if malaria was diagnosed either overseas or in the U.S. in the past year.

Blood transfusion/organ transplant within last 12 months:

Information about previous transfusions is used to identify possible transfusion-induced malaria, especially among patients with no history of foreign travel. Do **not** check "Yes" if the transfusion was used to treat **this** attack of malaria. That information should be noted under "*Therapy for this attack*".

The back of the Malaria Case Surveillance form contains useful telephone numbers for contacting the Malaria Branch for treatment and prevention information.
If you have any questions or concerns about completing this form, please call CDC, Malaria Branch at 770-488-7788 (8 am - 4:30 pm, EST).

Meningococcal Disease

Meningococcal Disease

Organism: *Neisseria meningitidis.* Gram Negative diplococcus. Most common serogroups A, B, C and Y. Less common serogroups W-135, X and Z.

Incubation period: Varies from 2 to 10 days, commonly 3–4 days.

Infectious period: Until meningococci are no longer present in discharges from nose and mouth, usually within 24 hours after appropriate antimicrobial treatment begins.

Transmission route: Direct contact, including respiratory inhalation of droplets from nose and throat of infected persons.

Treatment:

- If CSF, Gram stain or rapid bacterial antigen tests support diagnosis, empiric antimicrobial therapy should be instituted.
- If no etiologic agent identified or if delay in lumbar puncture > 30 minutes, empiric therapy should be instituted based on patient's age and underlying disease status. **DO NOT DELAY TREATMENT.**
- Standard therapy is Penicillin G or ampicillin. Alternative therapies include third generation cephalosporins or chloramphenicol. Patient should also receive rifampin to eradicate pharyngeal carriage of *N. meningitidis*.
- Once confirmed by lab, respiratory isolation of patient until 24 hrs after start of antimicrobial therapy.

Information Needed for the Investigation

Verify the Diagnosis

- **Meningococcal disease is a Public Health emergency. Notify regional PHN of possible outbreak.**
- Clinical description: meningococcal disease manifests most commonly as meningitis and/or meningococcemia that may progress rapidly to purpura fulminans, shock and death. Other manifestations may be observed.
- *Confirmed:* isolation of *Neisseria meningitidis* from a normally sterile site–blood, CSF or, less commonly, joint, pleural or pericardial fluid, in a clinically compatible case.
- *Probable:* a clinically compatible case with a positive antigen test in CSF or clinical purpura fulminans in the absence of a positive blood culture.
- *Presumptive:* a clinically compatible case with gram-negative diplococci visualized in serum or CSF.
- CSF findings may include elevated opening pressure, elevated protein, decreased sugar (<40mg/dl), and negative Gram stain showing gram-negative diploccoci.

Determine the Extent of Illness

- Obtain contact list with locating information so that prophylaxis may be administered ASAP. The decision to treat contacts may be based at times on the clinical presentation of the case-patient.
- Determine if household or other close contacts are, or have been ill by contacting local PHNs, providers, etc.
- **Chemoprophylaxis is recommended for all persons who have had close contact with the suspected meningococcal case during the 7 days preceding the onset of symptoms. This should be done as soon as possible. High risk contacts** include: household contacts; contacts close enough to have shared food, drink, eating or drinking utensils, cigarettes, toothbrushes, water bottles, lipstick or other things that contain saliva, or have kissed the case on the mouth; children in childcare; health care personnel if mouth-to-mouth resuscitation given or unprotected contact during intubation or suctioning; and persons frequently sharing the same sleeping space - military personnel, college dormitories, prison, long-term care facilities, shelters, etc.
- No testing of contacts is warranted.

Laboratory Specimens

- Serum – Blood cultures should be obtained prior to the start of antibiotic therapy, but should not delay the initiation of treatment.
- CSF – Initial management includes lumbar puncture to determine if CSF findings are consistent with diagnosis.
- If suspect meningococcal disease, request Gram stain ASAP from petechiae or purpuric scraping, CSF or buffy coat smear.
- WBC usually elevated 1000-5000/mm^3 with a neutrophil predominance.
- Request that any isolate be sent to ASPHL from CSF/blood cultures for serogoup identification. Notify lab of specimen shipment.

Note: Positive antigen test results from urine or serum samples are unreliable for diagnosis.

Contact and Control Measures

- Once the case is lab-confirmed, the prophylactic antibiotic of choice for high-risk contacts is rifampin. *Note:* The decision to treat contacts may be based at times on the clinical presentation of the initial patient.
- Low risk contacts: Chemoprophylaxis is not recommended for casual contacts or health care workers with no history of direct exposure to index patient's oral secretions.

Chemoprophylaxis of Contacts to Meningococcal Disease		
Drug	Dose	Duration
Rifampin	<1 month old: 5mg/kg PO every 12 hrs >1 month old: 10 mg/kg (max. 600 mg) PO every 12 hrs Adults 600mg PO every 12 hrs	2 days
Ceftriaxone	<12 yrs old: 125 mg IM >12 yrs old: 250 mg IM	Single dose
Ciprofloxacin	>18 yrs old: 500mg PO (Not recommended for pregnant women.)	Single dose

- Close surveillance of high-risk contacts for at least 14 days will ensure prompt treatment of secondary cases that might occur in the absence of effective chemoprophylaxis.
- Exposed household, childcare and other close contacts should be carefully observed for early signs of illness, especially fever, with prompt initiation of treatment if needed.
- If multiple cases occur, notify parents, health care providers and emergency rooms in the area of the occurrence of *N. meningitidis*. See sample letters, Epi Bulletins and Fact Sheet.
- Vaccine – meningococcal vaccine is available that is effective against serogroups A, C, Y, and W-135 for persons 2 years of age and older. The vaccine does not contain a serogroup B component. Routine vaccination is not recommended because of the vaccine's relative ineffectiveness in children < 2 years of age and its relatively short duration of protection. Mass vaccination might be indicated in certain community-based or organization-based (e.g., university) outbreaks when certain criteria recommended by the Centers for Disease Control and Prevention are met.
- Many colleges routinely offer pre-exposure meningococcal vaccine to college students, and may provide vaccine in response to a single college student having meningococcal disease. For further information refer to June 30, 2000, Morbidity and Mortality Weekly Report, "Prevention and Control of Meningococcal Disease and Meningococcal Disease and College Students" (www.cdc.gov/mmwr//indrr_2000.html).

Reporting Requirements

- FTR: write up all *confirmed* and *probable* cases.
- Write a case summary and file for all suspected negative cases.
- Morbidity Database: enter all *confirmed* and *probable* cases. Be sure to enter type when known.
- CDC Case Definition is used to define *confirmed* and *probable* cases.

Invasive Meningococcal Disease Investigation

Report of Invasive Meningococcal Disease
Meningitis: acute onset fever, headache, stiff neck, nausea, vomiting.
Meningococcemia: acute onset fever, chills, malaise, rash, shock coma.

VERIFY THE DIAGNOSIS

- ✓ Blood for culture
- ✓ CSF for culture and PCR Gram stain
- ✓ Buffy coat smear

SUSPECT CASE

- CSF, gram stain, buffy coat support diagnosis
- LP, blood cultures not done or are done after onset of effective therapy
- Cultures pending

CONFIRMED CASE

- *Neisseria meningitidis* isolated from blood or CSF or positive PCR

TREATMENT AND CONTROL MEASURES

- Treat Suspect or Case ASAP
- Identify close contacts and provide prophylaxis ASAP
- Epidemiology Depot may provide medicines
- Observation of contacts for fever and symptoms for 14 days after exposure
- Treat secondary cases

Not consistent with invasive meningococcal disease

Consider other etiologies such as viral or other bacterial agents

Isolate to State Public Health Lab for serotyping

If serogroup is A, C, Y, or W-135 consider vaccine for high risk persons > 2 years old

NOTE FOR LARGE CLUSTERS

Notify *Director of Public Health* and *Public Information Officer* and consider initiating DPH emergency communication protocol.
Consider notification of local health care providers and or parents. Consider Health Alert Network message.

MENINGOCOCCAL DISEASE CASE QUESTIONNAIRE

Name of patient _____ Date____/____/_____

DOB ____/____/_____ Sex: **M F** Race_____

Address_____ Phone( )_____

Name of person reporting_____ Phone( )_____

Symptoms:

Sudden fever	**Y**	**N**	**U**	Date of onset____/____/_____
Headache	**Y**	**N**	**U**	Date of onset____/____/_____
Nausea	**Y**	**N**	**U**	Date of onset____/____/_____
Vomiting	**Y**	**N**	**U**	Date of onset____/____/_____
Stiff neck	**Y**	**N**	**U**	Date of onset____/____/_____
Petechial rash	**Y**	**N**	**U**	Date of onset____/____/_____

UCSF/Blood obtained prior to administration of antibiotics? Y N

CSF results: Appearance_____Cell count_____Glucose_____Protein _____

Bacterial rapid antigen test: Y (results_____) N Gram stain results_____

Household/Close Contacts	Date of last contact	Treatment/Medication

Childcare Contacts	Date of last contact	Treatment/Medication

Health Care Personnel (only if gave patient mouth to mouth or unprotected intubation or suctioning)

_____

_____

Congregate living situation (dormitory, barracks, shelter, prison, etc.)? **Y** **N**

If **YES**, include type, address_____

Provider or ER where care obtained_____

CSF/Blood sent to what lab_____

Isolate sent to state lab for serotyping: **Y** **N**

Date:

To: Parents of children who attend _____
(Name of child care center)

Dear Parent:

A child who attends the _____ in _____
(Name of child care center) (City)
has been diagnosed with **meningococcal meningitis, a serious bacterial disease**.

So that other children do not get this illness, the Alaska Division of Public Health recommends that children who attended this childcare center with the ill child on any day from _____to _____ receive medication for
(Beginning date) (Ending date)
preventive treatment. Preventive treatment will help protect your child from meningococcal meningitis.

An antibiotic called rifampin is the drug of choice for children and will be provided free-of-charge for your child. We will be in the childcare center today to distribute the medication. If you miss today's distribution, you may pick up the medication at
_____.
(Site for medication distribution, e.g., pharmacy, public health center and phone number)

Your child should start the medication immediately and take all 4 doses.

Symptoms of this disease may include fever, rash, severe headache, nausea, stiff neck, or any other unusual symptoms. In some cases, meningococcal disease may progress very rapidly and lead to severe illness and even death. If your child should develop any of these symptoms during this next week, please contact your health care provider and show him or her this letter.

If you have additional questions, please contact your health care provider or the Alaska Division of Public Health, Section of Epidemiology at 907-269-8000 during work hours or 1-800-478-0084 after hours.

Sincerely,

STATE OF ALASKA
DEPARTMENT OF HEALTH & SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY
3601 C STREET, SUITE 540
P.O. BOX 240249
ANCHORGE, ALASKA 99524-0249
FRANK H. MURKOWSKI, GOVERNOR
INFECTIOUS DISEASES
AIDS/STD
TUBERCULOSIS (907) 269-8000
IMMUNIZATION (907) 562-7802
CHRONIC DISEASES
DIABETES
INJURY CONTROL

Meningococcal Disease Fact Sheet

What is meningococcal disease?

Meningococcal disease is a bacterial infection caused by *Neisseria meningitidis*. When this bacterium affects the lining of the brain and spinal cord (the meninges), the condition is called meningococcal meningitis. It is a relatively rare disease and usually occurs as a single event. Meningococcal disease can be rapidly progressive. With early diagnosis and treatment, the likelihood of full recovery is increased. Early recognition and prompt initiation of antimicrobial therapy is crucial, as these infections may lead to death.

Who gets meningococcal disease?

Anyone can get meningococcal disease, but it is more common in infants and children.

What are the symptoms of meningococcal disease?

The symptoms may include any of the following: fever, severe sudden headache, nausea, vomiting, stiff neck, pain in the shoulders and back, and a red pinpoint rash are the most common signs of this disease. High fever and irritability are signs in a very young child. If the condition is meningococcemia, then a purplish skin rash that looks like bruising may occur.

How soon do symptoms appear?

The symptoms may appear 1 to 10 days after exposure, but usually within 3 to 4 days.

How is meningococcal disease spread?

The meningococci bacteria are spread by direct close contact with nose and throat discharges of an infected person. People may carry the bacteria in their noses and throats without becoming ill, these persons are known as healthy carriers. Healthy carriers are able to spread the bacteria to other people, who may develop meningococcal disease with serious symptoms.

When and for how long is a case infectious to other people?

A person may pass the bacteria from the time he/she is first infected and until the bacteria are no longer present in discharges from the nose and throat. Persons are usually no longer infectious after 24 hours of effective antibiotic treatment.

How can you reduce the risk of contracting meningococcal disease?

Everyone should be sensitive to public health measures that decrease exposure to oral secretions, such as covering one's mouth when coughing or sneezing and washing hands after contact with oral secretions. A healthy lifestyle that maximizes your body's own immune system response, through balanced diet, adequate sleep, appropriate exercise, and avoidance of excessive stress, is very important.

Presently there is a vaccine that will protect against four of the strains of meningococcal disease. The use of the vaccine is recommended in outbreak situations, for individuals with specific medical conditions, or for those traveling to areas where the illness is clearly in excess of normal expectancy.
The American College Health Association recommends immunization of college students. It is important to note that meningococcal vaccine should not be used in place of preventive treatment for those exposed to a meningococcal disease. The protection from immunization is too slowly generated in this situation.

What should you do if you suspect meningococcal disease?

Individuals who experience any of the symptoms described above should consult their physician immediately.

What should I do if I have been in contact with a diagnosed case of meningococcal disease?

The use of preventive treatment (such as rifampin or ciprofloxacin) is recommended for **close contacts** exposed to a person diagnosed with meningococcal disease. Anyone who suspects possible exposure should consult a physician immediately. Beginning preventive treatment more than 2 weeks after exposure to the case would be too late to prevent disease.

Who is considered a close contact?

Close contacts are those who are likely to have been exposed to the nose and throat secretions of the sick person. Close contacts include, but are not limited to the following:

- Those living in the same house as the ill person
- Those sharing sleeping arrangements with the ill person
- Children sharing toys, such as in the same child care or nursery school, as the ill person
- Those who shared cigarettes, food, drinks, or other things that contain saliva with the ill person
- Those who have kissed the ill person
- Those who have given mouth-to-mouth resuscitation to, intubated, or suctioned the nasopharyngeal secretions of the ill person

Casual contact, such as being in the same classroom, workplace, or sitting at the same table withan infected person is not usually significant enough to cause concern.

What is the treatment for this disease?

Certain antibiotics are very effective in the treatment of the disease and are available from your physician. Generally, penicillin is the drug of choice for meningococcal infections.

Important Information about Rifampin For Prevention of Meningococcal Disease

Rifampin is an antibiotic. The full prescribed dosage should be taken as directed.

Do Not take rifampin if:

- You are pregnant
- You are allergic to rifampin
- You wear contact lenses

Important Facts

- Rifampin may make you urine, sweat, or tears a red-orange color.
- Soft contact lenses may be permanently stained a red-orange color. They should not be worn while taking rifampin.
- Rifampin may reduce the effectiveness of oral contraceptives and other drugs.
- Studies have shown that rifampin interacts with certain HIV-AIDS medications. If you are taking any prescription medications for HIV-AIDS, please check with your health care provider prior to taking rifampin.

Side Effects

- Rifampin may cause nausea, vomiting, cramps and diarrhea in some individuals.
- Headache, fever, drowsiness, fatigue, dizziness, mental confusion and muscular weakness may occur.
- If any symptoms occur, please contact your health care provider.

Meningococcal Disease *(Neisseria meningitidis)*

2005 Case Definition

Clinical description

Meningococcal disease manifests most commonly as meningitis and/or meningococcemia that may progress rapidly to purpura fulminans, shock, and death. However, other manifestations might be observed.

Case classification

Suspect:

- Clinical purpura fulminans in the absence of a positive blood culture
- A clinically compatible case with gram negative diplococci from a normally sterile site (e.g., blood or CSF)

Probable: A clinically compatible case that has either:

- Evidence of *N. meningitidis* DNA using a validated polymerase chain reaction (PCR), obtained from a normally sterile site (e.g,. blood or CSF) [1],

OR

- Evidence of *N. meningitidis* antigen by immunohistochemistry (IHC) on formalin-fixed tissue or latex agglutination of CSF [2,3]

Confirmed : A clinically compatible case **AND** isolation of *Neisseria meningitidis* from a normally sterile site (e.g., blood or cerebrospinal fluid {CSF} or, less commonly, synovial, pleural, or pericardial fluid) or skin scrapings of purpuric lesions.

[1] Mothershed EA, Sacchi CT, Whitney AM, Barnett GA, Ajello GW, Schmink S, Mayer LW, Phelan M, Taylor TH Jr, Bernhardt SA, Rosenstein NE, Popovic T. 2004. Use of real-time PCR to resolve slide agglutination discrepancies in serogroup identification of *Neisseria meningitidis. J Clin Microbiol* 42:320-328.

[2] Guarner J. Greer PW. Whitney A. Shieh WJ. Fischer M. White EH. Carlone GM. Stephens DS. Popovic T. Zaki SR. Pathogenesis and diagnosis of human meningococcal disease using immunohistochemical and PCR assays; *American Journal of Clinical Pathology. 122(5):754-64, 2004 Nov.*

[3] Positive antigen test results from urine or serum samples are unreliable for diagnosing meningococcal disease.

LOCAL USE ONLY

– NATIONAL BACTERIAL MENINGITIS AND BACTEREMIA CASE REPORT –

APPENDIX 4

Patient's Name: _____ (Last, First, M.I.) Phone No.: ( ) _____

Address: _____ (Number, Street, City, State) _____ (Zip Code) Hospital: _____ Patient Chart No.: _____

DETACH HERE – Patient identifier information is not transmitted to CDC

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
ATLANTA, GA 30333

NATIONAL BACTERIAL MENINGITIS AND BACTEREMIA CASE REPORT

CDC

Form Approved OMB No. 0920-0009

1. STATE: (Residence of Patient) (1-2)

2. COUNTY: (Residence of Patient) (3-12)

5. HOSPITALIZED? (25) (If YES, date of admission)
1 ☐ Yes
2 ☐ No
(26-31) Mo. Day Yr.

3. STATE I.D.: (13-18)

4. CDC I.D.: (19-24)

6. DATE OF BIRTH: (32-37) Mo. Day Yr.

7a.) AGE: (38-39)

b.) Is age in day/mo/yr? (40)
1 ☐ Days
2 ☐ Mos.
3 ☐ Yrs.

c.) If <6 years of age is patient in daycare? (41)
1 ☐ Yes
2 ☐ No
9 ☐ Unknown
(Daycare is defined as a supervised group of 2 or more unrelated children for >4 hours/week).

8. SEX: (42)
1 ☐ Male
2 ☐ Female

9a. RACE: (43)
1 ☐ White
2 ☐ Black
3 ☐ American Indian/ Alaskan Native
4 ☐ Asian/Pacific Islander
9 ☐ Not Specified

9b. ETHNIC ORIGIN: (44)
1 ☐ Hispanic
2 ☐ Non-Hispanic

10. OUTCOME: (45)
1 ☐ Survived
2 ☐ Died
9 ☐ Unknown

11. PHYSICIAN'S NAME:

12. TYPE OF INFECTION CAUSED BY ORGANISM: (Check all that apply)

1 ☐ Primary Bacteremia (46)
1 ☐ Meningitis (47)
1 ☐ Otitis media (48)
1 ☐ Pneumonia (49)
1 ☐ Cellulitis (50)
1 ☐ Epiglottitis (51)
1 ☐ Peritonitis (52)
1 ☐ Pericarditis (53)
1 ☐ Septic arthritis (54)
1 ☐ Conjunctivitis (55)
1 ☐ Other (specify) (56) _____ (57-58)

13. BACTERIAL SPECIES ISOLATED FROM ANY NORMALLY STERILE SITE:* (59) (Check one)

1 ☐ *Neisseria meningitidis*
2 ☐ *Haemophilus influenzae*
3 ☐ Group B streptococcus
4 ☐ *Listeria monocytogenes*
5 ☐ *Streptococcus pneumoniae** (pneumococcus)
8 ☐ Other Bacterial Species* (Specify: include mycobacteria, fungi) _____

*(Report *ONLY* CSF Isolates for Pneumococcus or Other Bacterial Species) (60-61)

14. SPECIMEN FROM WHICH ORGANISM ISOLATED: (Check all that apply)

1 ☐ Blood (62)
1 ☐ CSF (63)
1 ☐ Pleural Fluid (64)
1 ☐ Peritoneal Fluid (65)
1 ☐ Pericardial Fluid (66)
1 ☐ Joint (67)
1 ☐ Placenta (68)
1 ☐ Other Normally Sterile Site (69) (specify) (70-71) _____

15. DATE FIRST POSITIVE CULTURE OBTAINED: *(Date Specimen Drawn)* (72-77) Mo. Day Yr.

- IMPORTANT - PLEASE COMPLETE FOR THE FOLLOWING ORGANISMS:

HAEMOPHILUS INFLUENZAE

16a. Did patient receive *Haemophilus b* vaccine? (78) 1 ☐ Yes 2 ☐ No 9 ☐ Unknown **If YES, Please Complete the List Below.**

DOSE	DATE GIVEN (Mo. Day Yr.)	VACCINE NAME/MANUFACTURER	LOT NUMBER
1	(79-84)	(85) _____ / _____	(86-95) _____
2	(96-101)	(102) _____ / _____	(103-112) _____
3	(113-118)	(119) _____ / _____	(120-129) _____
4	(130-135)	(136) _____ / _____	(137-146) _____

16b. What was the serotype? (147)
1 ☐ Type b
2 ☐ Not Typable
9 ☐ Not Tested or Unknown
8 ☐ Other (Specify) _____ (148-149)

16c. If *H. influenzae* was isolated from blood or CSF, was it resistant to:

Ampicillin	(150)	1 ☐ Yes	2 ☐ No	9 ☐ Not tested or Unknown
Chloramphenicol	(151)	1 ☐ Yes	2 ☐ No	9 ☐ Not tested or Unknown
Rifampin	(152)	1 ☐ Yes	2 ☐ No	9 ☐ Not tested or Unknown

NEISSERIA MENINGITIDIS

17a. What was the serogroup? (153)
1 ☐ Group A
2 ☐ Group B
3 ☐ Group C
4 ☐ Group Y
5 ☐ Group W135
6 ☐ Not groupable
9 ☐ Unknown
8 ☐ Other (Specify) _____ (154-155)

17b. If *N. meningitidis* was isolated from blood or CSF, was it resistant to:

Sulfa	(156)	1 ☐ Yes	2 ☐ No	9 ☐ Not tested or Unknown
Rifampin	(157)	1 ☐ Yes	2 ☐ No	9 ☐ Not tested or Unknown

(Please Print Clearly)

Submitted By: _____

Phone No.: ( ) _____ Date: ____/____/____

Return completed report to:
Meningitis and Special Pathogens Branch
Mailstop C-09
National Center for Infectious Diseases
Centers for Disease Control and Prevention
Atlanta, GA 30333

Public reporting burden of this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to PHS Reports Clearance Officer; ATTN: PRA; Hubert H. Humphrey Bldg., Rm. 737-F; 200 Independence Ave., SW; Washington, DC 20201, and to the Office of Management and Budget; Paperwork Reduction Project (0920-0009); Washington, DC 20503.

Patient's Name: _____ (Last, First, M.I.) Phone No.: ( ) _____

Address: _____ (Number, Street, Apt. No.) Patient Chart No.: _____

_____ (City, State) _____ (Zip Code) Hospital: _____

– Patient identifier information is not transmitted to CDC –

DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
ATLANTA, GA 30333

ACTIVE BACTERIAL CORE SURVEILLANCE (ABCs) CASE REPORT

A CORE COMPONENT OF THE EMERGING INFECTIONS PROGRAM NETWORK

CDC SAFER • HEALTHIER • PEOPLE™

– SHADED AREAS FOR OFFICE USE ONLY –

OMB No. 0920-0009

1. STATE: (Residence of Patient) ☐☐

2. COUNTY: (Residence of Patient) _____

3. STATE I.D.: ☐☐☐☐☐☐☐

4a. HOSPITAL/LAB I.D. WHERE CULTURE IDENTIFIED: ☐☐☐☐☐

4b. HOSPITAL I.D. WHERE PATIENT TREATED: ☐☐☐☐☐

5. WAS PATIENT HOSPITALIZED? 1 ☐ Yes 2 ☐ No

If YES, date of admission: Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

Date of discharge: Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

6a. Was patient transferred from another hospital? 1 ☐ Yes 2 ☐ No 9 ☐ Unk

6b. If YES, hospital I.D. ☐☐☐☐☐

7a. Was patient a resident of a nursing home or other chronic care facility at the time of first positive culture? 1 ☐ Yes 2 ☐ No 9 ☐ Unk

7b. If yes, name _____

8. DATE OF BIRTH: Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

9a. AGE: ☐☐☐

9b. Is age in day/mo/yr? 1 ☐ Days 2 ☐ Mos. 3 ☐ Yrs.

10a. SEX: 1 ☐ Male 2 ☐ Female

10b. RACE: (Check all that apply)
1 ☐ White
1 ☐ Black
1 ☐ American Indian/ Alaskan Native
1 ☐ Asian
1 ☐ Native Hawaiian/ Pacific Islander
1 ☐ Other
1 ☐ Unk

10c. ETHNIC ORIGIN: 1 ☐ Hispanic 9 ☐ Unk 2 ☐ Non-Hispanic

11. OUTCOME: 1 ☐ Survived 9 ☐ Unk 2 ☐ Died

12. Was patient pregnant/post-partum at time of first positive culture? 1 ☐ Yes 2 ☐ No 9 ☐ Unk

If YES, outcome of fetus:
1 ☐ Survived, no apparent illness
2 ☐ Survived, clinical infection
3 ☐ Live birth/neonatal death
4 ☐ Abortion/stillbirth
5 ☐ Induced abortion
9 ☐ Unk

13. If patient <1 month of age:
Gestational age: ☐☐ (wks) Birthweight: ☐☐☐☐ (gms)

14. TYPES OF INFECTION CAUSED BY ORGANISM: (Check all that apply)
1 ☐ Bacteremia without Focus
1 ☐ Meningitis
1 ☐ Otitis media
1 ☐ Pneumonia
1 ☐ Cellulitis
1 ☐ Epiglottitis
1 ☐ Hemolytic uremic syndrome (HUS)
1 ☐ Abscess (not skin)
1 ☐ Peritonitis
1 ☐ Pericarditis
1 ☐ Septic abortion
1 ☐ Chorioamnionitis
1 ☐ Septic arthritis
1 ☐ Osteomyelitis
1 ☐ Endometritis
1 ☐ STSS
1 ☐ Necrotizing fasciitis
1 ☐ Puerperal sepsis
1 ☐ Other *(specify)* _____

15a. BACTERIAL SPECIES ISOLATED FROM ANY NORMALLY STERILE SITE:
1 ☐ *Neisseria meningitidis*
2 ☐ *Haemophilus influenzae*
3 ☐ Group B Streptococcus
4 ☐ *Listeria monocytogenes*
5 ☐ Group A Streptococcus
6 ☐ *Streptococcus pneumoniae*

15b. OTHER BACTERIAL SPECIES ISOLATED FROM ANY NORMALLY STERILE SITE: *(specify)*
_____
_____

16. STERILE SITES FROM WHICH ORGANISM ISOLATED: (Check all that apply)
1 ☐ Blood
1 ☐ CSF
1 ☐ Pleural fluid
1 ☐ Peritoneal fluid
1 ☐ Pericardial fluid
1 ☐ Joint
1 ☐ Bone
1 ☐ Muscle
1 ☐ Internal body site *(specify)* _____
1 ☐ Other normally sterile site *(specify)* _____

17. DATE FIRST POSITIVE CULTURE OBTAINED:
(Date Specimen Drawn)
Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

18. OTHER SITES FROM WHICH ORGANISM ISOLATED: (Check all that apply)
1 ☐ Placenta
1 ☐ Amniotic fluid
1 ☐ Wound
1 ☐ Other *(specify)* _____
1 ☐ Middle ear
1 ☐ Sinus

– *IMPORTANT* – PLEASE COMPLETE THE BACK OF THIS FORM –

Submitted By: _____ Phone No.: ( ) _____ Date: ____/____/____

Physician's Name: _____ Phone No.: ( ) _____

Public reporting burden of this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0009). **Do not send the completed form to this address.**

19. UNDERLYING CAUSES OR PRIOR ILLNESS: *(Check all that apply)* *(If none or chart unavailable, check appropriate box)* 1 ☐ None 1 ☐ Unknown

1 ☐ Current Smoker
1 ☐ Multiple Myeloma
1 ☐ Sickle Cell Anemia
1 ☐ Splenectomy/Asplenia
1 ☐ Immunoglobulin Deficiency
1 ☐ Immunosuppressive Therapy (Steroids, Chemotherapy, Radiation)
1 ☐ Leukemia
1 ☐ Hodgkin's Disease

1 ☐ Asthma
1 ☐ Emphysema/COPD
1 ☐ Systemic Lupus Erythematosus (SLE)
1 ☐ Diabetes Mellitus
1 ☐ Nephrotic Syndrome
1 ☐ Renal Failure/Dialysis
1 ☐ HIV Infection
1 ☐ AIDS or CD4 count <200

1 ☐ Cirrhosis/Liver Failure
1 ☐ Alcohol Abuse
1 ☐ Atherosclerotic Cardiovascular Disease (ASCVD)/CAD
1 ☐ Heart Failure/CHF
1 ☐ Burns
1 ☐ CSF Leak
1 ☐ IVDU
1 ☐ Cerebral Vascular Accident (CVA) / Stroke

1 ☐ Cochlear Implant
1 ☐ Deaf/Profound Hearing Loss
1 ☐ Other Malignancy *(specify)* _____
1 ☐ Organ Transplant *(specify)* _____
1 ☐ Other Prior Illness *(specify)* _____

– *IMPORTANT* – PLEASE COMPLETE FOR THE RELEVANT ORGANISMS:

HAEMOPHILUS INFLUENZAE

20. If <15 years of age and serotype 'b' or 'unk' did patient receive *Haemophilus influenzae* b vaccine? 1 ☐ Yes 2 ☐ No 9 ☐ Unk

If YES, please complete the list below.

DOSE	DATE GIVEN Mo.	Day	Year	VACCINE NAME/MANUFACTURER	LOT NUMBER
1					
2					
3					
4					

21. What was the serotype?

1 ☐ b
2 ☐ Not Typeable
3 ☐ a
4 ☐ c
5 ☐ d
6 ☐ e
7 ☐ f
8 ☐ Other *(specify)* _____
9 ☐ Not Tested or Unk

NEISSERIA MENINGITIDIS

22. What was the serogroup?

1 ☐ A 3 ☐ C 5 ☐ W135 9 ☐ Unk
2 ☐ B 4 ☐ Y 6 ☐ Not groupable 8 ☐ Other *(specify)* _____

23. Is patient currently attending college? (15 – 24 years only)

1 ☐ Yes 2 ☐ No 9 ☐ Unk

STREPTOCOCCUS PNEUMONIAE

24. Oxacillin zone size: ☐☐ (mm)

Interpretation:
1 ☐ Sensitive 2 ☐ Resistant
9 ☐ Not tested or Unk

25. Penicillin E-test MIC results ☐☐☐.☐☐☐

Interpretation:
1 ☐ S 2 ☐ I 3 ☐ R
9 ☐ Not tested or Unk

26. Penicillin broth MIC results ☐☐☐☐.☐☐☐

Interpretation:
1 ☐ S 2 ☐ I 3 ☐ R
9 ☐ Not tested or Unk

27. Has patient received 23-valent pneumococcal polysaccharide vaccine?

1 ☐ Yes 2 ☐ No 9 ☐ Unk

If YES, list date most recently given and vaccine name

Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

VACCINE NAME: _____

How many doses has patient received? _____

28. If <15 years of age did patient receive pneumococcal conjugate vaccine? 1 ☐ Yes 2 ☐ No 9 ☐ Unk **If YES, please complete the list below.**

DOSE	DATE GIVEN Mo.	Day	Year	VACCINE NAME/MANUFACTURER	LOT NUMBER
1					
2					
3					
4					

29. Does this patient have persistent disease as defined by positive sterile site cultures 2–7 days after the first positive culture?

1 ☐ Yes 2 ☐ No 9 ☐ Unk

If YES, additional culture dates:

	Mo.	Day	Year
1			
2			

Sites from which *S. pneumoniae* isolated: (Check all that apply)

1 ☐ Blood 1 ☐ CSF 1 ☐ Other normally sterile site
1 ☐ Blood 1 ☐ CSF 1 ☐ Other normally sterile site

GROUP A STREPTOCOCCUS

(#30–32 refer to the 7 days prior to first positive culture)

30. Did the patient have surgery ? 1 ☐ Yes 2 ☐ No 9 ☐ Unk

If YES, date of surgery: Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

31. Did the patient deliver a baby (vaginal or C-section)?

1 ☐ Yes 2 ☐ No 9 ☐ Unk

If YES, date of delivery: Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

32. Did patient have:

1 ☐ Varicella?
1 ☐ Penetrating trauma?
1 ☐ Blunt trauma?
1 ☐ Surgical wound? (post operative)

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33. Was case first identified through audit?

1 ☐ Yes 2 ☐ No
9 ☐ Unk

34. CRF Status:

1 ☐ Complete
2 ☐ Incomplete
3 ☐ Edited & Correct
4 ☐ Chart unavailable after 3 requests

35. Does this case have recurrent disease with the same pathogen?

1 ☐ Yes 2 ☐ No
9 ☐ Unk

If YES, previous (1st) state I.D. ☐☐☐☐☐☐☐

36. Date reported to EIP site

Mo. ☐☐ Day ☐☐ Year ☐☐☐☐

37. Initials of S.O. _____

38. COMMENTS: _____

Norovirus

Norovirus

Organism:	Noroviruses are small RNA viruses classified as caliciviruses.
Incubation period:	12-72 hours (median 33-36 hours).
Infectious period:	Although presymptomatic viral shedding may occur, shedding usually begins with onset of symptoms and may continue for 2 weeks after recovery. It is unclear to what extent viral shedding over 72 hours after recovery signifies continued infectivity.
Transmission route:	Fecal-oral route. Person-to-person, foodborne, waterborne fomites.
Treatment:	Symptomatic. Severe dehydration can occur; however, long-term sequelae of norovirus infection have not been reported.

Information Needed for the Investigation

Verify the Diagnosis

- Clinical history: acute-onset vomiting, watery non-bloody diarrhea with abdominal cramps, and nausea in the absence of any other identified cause.
- Laboratory: norovirus detection from stool or vomitus by PCR analysis.

Determine the Extent of Illness

- Use a foodborne outbreak questionnaire, and ask all identified case-patients to name others known to have sudden onset of diarrhea and/or vomiting within the timeframe of the outbreak.
- Try to obtain a 3-day food history from case-patients (and controls) to determine potential foodborne or waterborne etiology.
- Always try to collect a stool sample from any ill food handler.
- Retrieve and refrigerate implicated food(s). If the food is a commercial product, obtain the brand name, lot number, and distributor.

Laboratory Specimens

- SOE staff must first approve clinical sample testing from clusters of two or more related cases of gastroenteritis.
- No more than eight stool samples should be routinely collected for a given outbreak. (Usually, 4-6 are adequate.)
- Collect ~10-50 ml of bulk stool and/or ~10-50 ml of vomitus.
- Collect suspected food samples and bag separately. Implicated foods can be tested at CDC for norovirus (contact Dr. Steve Monroe).

- Specimens should be refrigerated, not frozen. See Laboratory information.
- All specimens should be sent to the ASPHL in Fairbanks.
- A norovirus PCR request form should be completed for all clinical specimens sent to the ASPHL.
- A CDC laboratory form will need to be completed for each food specimen and sent to CDC.

Contact and Control Measures

- Determine the source of infection to prevent other cases. This is done through a 3-day food history, interviews, and epidemiology principles applied as in any foodborne outbreak.
- Sanitation/hygiene (see the norovirus prevention packet).
- Good evidence exists for transmission due to aerosolization of vomitus that presumably results in droplets contaminating surfaces or entering the oral mucosa and being swallowed.
- Noroviruses are highly contagious, and it is thought that an inoculum of as few as 10 viral particles may be sufficient to infect an individual.
- Wash hands carefully using soap and running water for 20 seconds after using the toilet, and before eating or preparing food.
- Food handlers with nausea, vomiting and diarrhea should stop working until symptom-free for 72 hours. Meticulous hand washing should be continued since the virus can be shed in stool for 5-13 days after symptoms resolve.
- Hard surfaces that are frequently touched by people (such as counter tops, bathroom surfaces, doorknobs, handrails, telephones, and floors) should be cleaned using standard cleaners and then disinfected using 6% unscented chlorine bleach at a concentration of 1000 ppm (5 tablespoons of bleach/gallon of water).
- Surfaces contaminated with vomit or stool should first receive an initial cleaning to remove all organic material, and then disinfected with 6% unscented chlorine bleach at a concentration of 1000 ppm (5 tablespoons bleach/gallon of water). Wear gloves when cleaning, and wash hands well afterward.

Reporting Requirements

- FTR: Write up all investigated outbreaks.
- Morbidity database: Not entered.

STATE OF ALASKA
DEPARTMENT OF HEALTH & SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY

3601 C STREET, SUITE 540
P.O. BOX 240249
ANCHORAGE, ALASKA 99524-0249

FRANK H. MURKOWSKI, GOVERNOR

INFECTIOUS DISEASES
AIDS/STD
TUBERCULOSIS
IMMUNIZATION
CHRONIC DISEASES
DIABETES
INJURY CONTROL

(907) 269-8000
(907) 562-7802

Norovirus Fact Sheet

What are Noroviruses?
Noroviruses are representative of a larger group of viruses called caliciviruses. Infection with these viruses is a common cause of gastrointestinal illness worldwide.

What are the symptoms of an infection with these viruses?
The most common symptoms are nausea with vomiting, diarrhea, and cramps.
These symptoms occur in all age groups although diarrhea is more common among adults and vomiting is more common in children. Many persons also experience headache, fever, chills and muscle aches.

How soon do symptoms appear?
The symptoms may appear from 12-72 hours after exposure to the virus, but usually within 24 to 48 hours.

How are these viruses spread?
Noroviruses are spread by eating or drinking food or water contaminated with feces from an infected person. Food associated outbreaks have been linked to cold prepared, ready to eat foods (e.g., salads, coleslaw, sandwiches) and shellfish harvested in contaminated water. Outbreaks have also been associated with drinking water and recreational water (e.g., swimming ponds, and beaches) where persons may have ingested water contaminated with feces from an infected person. These viruses are easily spread from person-to-person. Some medical reports suggest that the virus can spread through the air during vomiting.

For how long is a person infectious?
People are infectious while symptoms are present and at least four days after diarrhea or vomiting have stopped.

What is the treatment for this illness?
There is no treatment for this illness. Most people recover in two to three days after they become ill. Supportive treatment to prevent dehydration may be needed in severe cases.

What can be done to help prevent the spread of these viruses?
Thorough hand washing following toilet use and prior to handling food is the best way to prevent the spread of these viruses. Persons currently ill with diarrhea or vomiting should not handle food, work in day care centers or care for patients in a health care facility until these symptoms have stopped.

STATE OF ALASKA
DEPARTMENT OF HEALTH & SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY

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FRANK MURKOWSKI, GOVERNOR

INFECTIOUS DISEASES
AIDS/STD
TUBERCULOSIS
IMMUNIZATION
CHRONIC DISEASES
DIABETES
INJURY CONTROL

(907) 269-8000
(907) 562-7802

Controlling the Spread of Norovirus

Noroviruses are a group of viruses that cause gastrointestinal illness. The symptoms are nausea, vomiting, abdominal cramps and diarrhea. Some people also experience headache, fever, chills, muscle ache and general tiredness. Onset of illness is generally within 12-48 hours of exposure and symptoms can last 12-60 hours. Infected persons can be contagious for up to 2 weeks after they recover.

Illness can be caused by fewer than 100 viral particles. Noroviruses survive chlorine levels of less than 10 ppm, freezing, heating to 60º C (140º F), and can persist in the environment. Food and drink can easily become contaminated by direct contact with hands or work surfaces that are contaminated with stool or vomit, or by tiny droplets from nearby vomit that lands on food.

People can become infected with the virus by:

- eating food or drinking liquids that are contaminated.
- touching contaminated surfaces or objects, then placing their hands in their mouths.
- having direct contact with an infected person.

Prevention

The Department of Environmental Conservation, Food Safety and Sanitation Program, in cooperation with the Department of Health and Social Services, Section of Epidemiology, encourages you to take the following precautions to protect your staff, clients and business.

1. Do not allow ill employees to work in situations where food, beverages or ice can be contaminated or the illness can be spread person-to-person or through environmental contamination. Ill employees should be well for 3 days prior to returning to work. In addition, because the virus can be present in the stool for 2 to 3 weeks after the person feels better, strict hand washing is important to prevent the spread of the virus.

2. Ensure all employees follow strict hand washing procedures, especially after cleaning up after an illness incident, and after using the restroom. Hands (including wrists, between fingers and under nails) should be vigorously washed for 20 seconds using soap and warm running water, and dried with a single-use towel. Food employees handling ready to-eat food should wear disposable gloves.

3. Post hand washing procedures in both guest and employee restrooms.

4. Ensure employees wear disposable gloves when cleaning up following an incident, handling soiled linens, or emptying refuse containers.

5. Keep detergents and sanitation supplies available for immediate clean up of vomit or fecal material. Unscented chlorine based products are the most effective sanitizers against norovirus.

   - ✓ For all contaminated surfaces: a solution of 1,000 ppm should be used on hard, non-corrosive surfaces after thoroughly cleaning the surface with a detergent to remove the gross soil. This includes all possibly contaminated surfaces that could be touched by patrons such as rails, doorknobs, bathroom fixtures, counters, dining tables, etc. A 1000 ppm solution can be made by adding 5 tablespoons of unscented 6 % household bleach to 1 gallon of water. (If using commercial chlorine sanitizers, follow the directions on the label for making various concentrations). For maximum benefit, chlorine sanitizers should be allowed to air dry, or remain in contact with surfaces for several minutes before flushing or rinsing.

6. Advise guests:
   - to pay meticulous attention to hand-washing and to use toilet facilities in their assigned rooms where possible;
   - of the symptoms of norovirus, and to contact designated employees if they experience any of these symptoms;
   - of recommendations to prevent the spread of their illness such as not participating in public gatherings until 3 days after they have recovered.

7. Launder linens in 160°F water and add bleach to the rinse water; do not agitate linens soiled with vomit or fecal material, in order to minimize the risk of aerosolization of the virus.

8. Clean and sanitize other common items such as ice buckets between uses by guests.

How to Sanitize

1. Put on disposable gloves and wear eye protection.

2. Fill a clean container with 1 gallon of water.

3. Mix 5 tablespoons (1/3 cup) of 6% unscented household (6%) bleach with 1 gallon of water. (This makes a 1000 ppm sodium hypochlorite solution.)

4. Before using bleach solution, wipe off all surfaces. Use disposable towels to remove any vomit, stool, or other substances like food or grease.

5. Apply bleach solution to surface area and allow it to remain wet for 10 minutes. If possible, allow bleach solution to air dry.

6. Dispose of soiled paper towels and gloves in a plastic trash bag and place in garbage.

Alaska Department of Health and Social Services
Division of Public Health
Section of Epidemiology
907-269-8000

Norovirus Testing at the Alaska State Virology Laboratory

Norovirus outbreak testing should be pre-approved by the Section of Epidemiology. Please call the State of Alaska Section of Epidemiology at (907) 269-8000 or (800) 478-0084 after hours.

Collection of Specimens

1. Epidemiology will determine the number of specimens that need to be collected (usually 4-6).
2. Raw, loose, stool and vomitus are appropriate specimens to collect.
3. Collect 10-50 ml of specimen.
4. Collect specimen in a leak-proof container. Supplies can be obtained from Epidemiology or the Alaska State Virology Laboratory (ASVL).
5. Collection should begin as soon as symptoms appear (ideally 48-72 hours of onset).
6. **DO NOT** submit samples in viral transport media (VTM).

Storage and Transport

1. Store specimens at 4°C.
2. Complete all information on the norovirus requisition slip. Paperwork may be obtained from the Epidemiology, ASVL, or the Anchorage Public Health Laboratory, (907) 334-2100.
3. Specimen containers should be individually sealed and bagged with the appropriate amount of absorbent material. (Roughly two paper towels per 50 ml.)
4. Paperwork should be separated from the specimen.
5. Specimens should be shipped in an appropriately labeled, insulated, waterproof shipping container with refrigerant packs.
6. Arrange with Epidemiology for transportation.

Alaska State Virology Laboratory
901 Koyukuk Drive South
239 Arctic Health Research Building
Fairbanks, AK 99775

Note: Food, water or environmental samples are not tested at ASVL.

Please refer any further questions to the Alaska State Virology Laboratory at (907) 474-7018.

Alaska Section of Epidemiology Enteric Disease Questionnaire-Abbreviated

Reported By:_____ **Phone: (____) _____-_____**

Patient Name: _____

Address: _____ **Phone: (____) _____-_____**

_____ **(____) _____-_____**

Guardian Name: _____ **Relation:** _____

Alaska Resident: ☐ **Yes** ☐ **No** **Disease:** _____

Investigator:		**Interview Date:**
1. Date of birth: ☐ Unknown Month ☐☐ Day ☐☐ Year ☐☐☐☐	**2. Age:** ☐☐☐ ☐ Years ☐ Months ☐ Days	**3. Sex:** ☐ Male ☐ Female ☐ Unknown
4. Race: ☐ White ☐ American Indian or Alaska Native ☐ Black ☐ Asian or Pacific Islander ☐ Unknown		**5. Ethnicity:** ☐ Hispanic ☐ Non-Hispanic ☐ Unknown
6. Occupation	**7. Address**	**8. Phone**
9. Onset of illness: Month ☐☐ Day ☐☐ Year ☐☐☐☐	**10. Patient treated:** ☐ Yes ☐ No Med(s):_____	**11. Specimen collection date:** Month ☐☐ Day ☐☐ Year ☐☐☐☐

12. Symptoms

☐ Fever (max_____ºF)
☐ Chills
☐ Diarrhea
☐ Abdominal Pain
☐ Nausea
☐ Vomiting
☐ Bloating/Flatulence
☐ Underlying medical conditions:
_____
_____

13. Anyone in the household employed or attend:

☐ Daycare ☐ Health Care ☐ Food Service ☐ No

Name	Where	Age	Ill?
_____	_____	_____	☐ Yes ☐ No
Name	Where	Age	Ill?
_____	_____	_____	☐ Yes ☐ No

14. Any recent travel? ☐ Yes ☐ No

If yes, list dates and locations:

_____

_____

15. Anyone else you know with similar symptoms?

☐ Yes ☐ No

16. Information on others who are/were ill:

Name: _____ Relationship: _____Phone (____) _____-_____

Name: _____ Relationship: _____Phone (____) _____-_____

Name: _____ Relationship: _____Phone (____) _____-_____

Patient Subjective Information:

Recommendations:

Disposition:

Paralytic Shellfish Poisoning

Paralytic Shellfish Poisoning (PSP)

Disease Name: Paralytic shellfish poisoning syndrome

Organism: Saxitoxins produced by *Alexandrium* species and other dinoflagellates present in shellfish especially during algal blooms known as red tides; however, may occur without red tides.

Incubation period: 5 min-12 hours after consumption of shellfish.

Infectious period: No secondary transmission documented.

Transmission routes: Foodborne. In Alaska, all documented cases associated with consumption of clams and mussels, although toxin also found in crab viscera.

Treatment for patient: There is no antidote for the toxin, it is important that vomiting be induced at the first sign of symptoms, and medical attention be immediately sought. In severe cases, dyspnea, dysphagia, muscle weakness or frank paralysis, ataxia and respiratory insufficiency may occur. Symptomatic treatment, including ventilatory support, is crucial for successful outcomes. Recovery is complete, symptoms usually resolve within hours to days after shellfish ingestion.

Information Needed for the Investigation

Verify the Diagnosis

- Interview ill person or others who shared meal for symptoms: paresthesias (mouth, lips, face, extremities), nausea, vomiting, floating sensation.
- Symptoms, coupled with history of eating shellfish from Alaska beaches, equal probable PSP, a public health emergency.

Determine the Extent of Illness

- Obtain list of persons who shared meal from ill patient if possible. Contact local health care provider, PHN, or family member.
- Interview all who shared meal for symptoms, using PSP interview form.

Laboratory Specimens

- May obtain vomitus and freeze, otherwise no human specimens to obtain.
- Obtain suspect shellfish or crabs. Save supernatant also. Contact DEC, PHN, CHAs or family and ask to save suspect food in refrigerator until notified by state for further instructions. Notify DEC sanitarian who will usually work with you to obtain, package, and send food to DEC lab–Palmer for testing.
- Notify DEC Palmer laboratory regarding anticipated delivery of specimens, sanitarian may do this.

- Protocol for specimen collection:
  - ✓ Collect portions of the meal and store it in a Ziploc® freezer bag.
  - ✓ If the shellfish is still in the shell and can be sent immediately to DEC Palmer Laboratory, refrigerate, do not freeze.
  - ✓ If any delay is anticipated, do freeze the samples.
  - ✓ If the shellfish were steamed or boiled, collect and store the broth separately.
  - ✓ Document the date, time, and exact location where the shellfish were collected.
  - ✓ If gastric contents have been collected, freeze and save.

Contact and Control Measures

- Identify and evaluate all who shared suspect meal. Anyone with symptoms should be advised to seek medical care immediately.
- Advise all involved to not eat any of suspect food nor food collected from same area.
- Notify DEC Seafood (Manny Soares or Mike Ostasz, 269-7638) to discuss DEC issuance of PSP alert press release. They will want to know the beach area name and number of cases.

Important Information

- PSP is a public health emergency. The goal is to identify others at risk and evaluate for symptoms of PSP. Notify the regional PHN of a possible outbreak.
- Shellfish sold commercially are routinely tested and safe for consumption. PSP occurs widely in Alaska in connection with ingestion of non-commercial shellfish. Recreational beaches are not considered safe for shellfish gathering and consumption.

Reporting Requirements

- FTR: write up all confirmed and probable cases.
- Write up case summary and file for all suspected negative cases.
- Morbidity Database: enter all confirmed and Epi-linked cases.
- Epi case definition: a person with at least 2 of the following symptoms and a history of eating shellfish; paresthesias, vomiting, ataxia, dysphagia, dysarthria, dizziness, or floating sensation.

Paralytic Shellfish Poisoning Outbreak Questionnaire

Date___/___/_____

Health care provider reporting_____ Phone ( )_____

Name of patient_____Phone( ) _____

Address_____City_____ State_____

DOB___/___/___ Sex: M F Race_____

Symptoms:					
	Paresthesias (mouth, lips, face, extremities)	Y	N	U	Date of onset___/___/___
	Nausea	Y	N	U	Date of onset___/___/___
	Vomiting	Y	N	U	Date of onset___/___/___
	Weakness	Y	N	U	Date of onset___/___/___
	Ataxia	Y	N	U	Date of onset___/___/___
	Shortness of breath	Y	N	U	Date of onset___/___/___
	Dysarthria	Y	N	U	Date of onset___/___/___
	Dysphagia	Y	N	U	Date of onset___/___/___
	Dizzy	Y	N	U	Date of onset___/___/___
	Headache	Y	N	U	Date of onset___/___/___
	Floating sensation	Y	N	U	Date of onset___/___/___

Location of beach where shellfish were gathered_____

Date shellfish gathered ___/___/___ Date shellfish consumed ___/___/___

Time shellfish consumed_____AM/PM Number of shellfish eaten _____

Type of shellfish: Butter clams Mussels Cockles Razor clams Little Neck clams Crabmeat

Cooked: Y N Method_____

If boiled, was shellfish juice consumed separately? Y N

Were siphons or viscera removed prior to eating shellfish? Y N

If crabmeat, were any of the intestines eaten? Y N

Alcohol consumed with meal? Y N

(If YES, quantity consumed_____)

Specimens collected for shipping? Y N

Protocol for specimen collection

Collect portions of the meal and store it in a Ziploc® freezer bag.
If shellfish is still in the shell and can be sent immediately to DEC Palmer laboratory, refrigerate, do not freeze. If any delay anticipated, freeze the samples.
If shellfish were steamed or boiled, collect and store the broth separately.
Document the date, time of day, and exact the location where shellfish were collected.
If gastric contents have been collected, freeze and save.

STATE OF ALASKA
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SECTION OF EPIDEMIOLOGY
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Paralytic Shellfish Poisoning Fact Sheet

What is paralytic shellfish poisoning?
Paralytic shellfish poisoning (PSP) is a serious illness caused by eating shellfish contaminated with algae that contains a toxin harmful to humans. When this algae increases to high numbers in marine waters, the condition is sometimes (and somewhat erroneously) referred to as a "red tide". PSP can occur without a “red tide”.

What causes unsafe levels of PSP?
The amount of toxin increases when water conditions are favorable. However, the exact combination of conditions that cause “blooms” of poison-producing plankton is not known. We do not yet understand the interaction of the water conditions. Unlike bacterial contaminants like vibrio, warm water does not necessarily increase the level.

Which seafood can transmit PSP to humans?
All molluscan shellfish including clams, mussels, oysters, geoduck and scallops can have paralytic shellfish poison. Moon snails and other gastropods also can become toxic. Other marine species, such as sea cucumbers, might also be affected. Crabmeat is not known to contain the PSP toxin, but the guts can contain unsafe levels. To be safe, clean crab thoroughly and discard the guts.

Who is most at risk?
Anyone who eats PSP contaminated shellfish is at risk for illness or death.

What are the symptoms of PSP?
Early symptoms include tingling of the lips and tongue, which may begin within minutes of eating poisonous shellfish or may take an hour or two to develop. Depending upon the amount of toxin a person has ingested, symptoms may progress to tingling of fingers and toes and then loss of control of arms and legs, followed by difficulty in breathing. Some people have experienced a sense of floating or nausea. If a person consumes enough poison, muscles of the chest and abdomen become paralyzed. Death can result in as little as two hours, as muscles used for breathing become paralyzed.

If the water looks dirty or red, does that mean that shellfish are contaminated?
Not necessarily. Paralytic shellfish poison is rarely associated with a red tinge to the water. Reddish coloration of the water is more commonly associated with other, non-toxic organisms.

If the water is not red, does that mean that shellfish are <u>not</u> contaminated?
Not necessarily. PSP can be present in large amounts even if the water looks clear. Also, the toxin can remain in shellfish long after the algae bloom is over.

Can I tell if it's safe to gather shellfish by how they look?
No! Only laboratories can reliably test shellfish for PSP. Toxin can be present with no visible signs.

How can I protect my family from paralytic shellfish poisoning?
The only way to protect your family or yourself from PSP is by not eating shellfish collected from recreational beaches in Alaska. Commercial shellfish in Alaska are routinely tested and are considered safe for consumption.

What should I do if I think that I, or someone in my family, has paralytic shellfish poisoning?
PSP is a public health emergency. Medical care in a hospital may be needed to support an ill person until the toxin has worn off. Call 911 or have someone take you to the emergency room.

What is the treatment?
There is no medication available. The only treatment for severe cases is the use of a mechanical respirator and oxygen. Induced vomiting may help purge some of the toxin from the stomach.

Are there any other illnesses associated with shellfish?
Yes, a person may have an allergic reaction to shellfish or become ill due to bacteria or viruses in shellfish.

Pertussis

Pertussis

Organism:	*Bordetella pertussis,* a fastidious, gram-negative, pleomorphic bacillus.
Incubation period:	6-20 days, usually 7-10 days.
Infectious period:	Highly communicable in the early catarrhal stage before the paroxysmal cough begins. Thereafter, communicability gradually decreases and becomes negligible in about 3 weeks despite persisting spasmodic cough. When treated with erythromycin or other effective antibiotic, infectiousness usually is 5 days or less after onset of therapy.
Transmission Routes:	Person to person via aerosolized droplets produced from a cough or a sneeze or by direct contact with secretions from the respiratory tract of infectious individuals. Humans are the only known host for the bacteria.

Information Needed for the Investigation

Verify the Diagnosis

- Determine if the symptoms are compatible with the clinical case definition and/ or if there are lab results available (positive PCR or culture) to confirm the case.
- **Clinical case definition:** A cough illness lasting at least 2 weeks with one of the following: paroxysms of coughing, **or** inspiratory "whoop", **or** post-tussive vomiting **and** without other apparent cause (as reported by a health professional).
- Determine if household or other close contacts are, or have been ill by contacting the PHNs, health care providers, etc.
- **Clinical Stages and Symptoms**
  - **Catarrhal stage:** "cold-like" symptoms, coryza, sneezing, and occasional coughing, followed by increase in coughing over the next couple weeks**.**
  - **Paroxysmal stage**: coughing becomes frequent and severe, sometimes with a characteristic whoop and vomiting, often more frequently at night. Fever absent or minimal.
  - **Convalescent stage:** symptoms wane gradually over weeks to months.
- Disease in infants younger than 6 months of age may be atypical, apnea is a common manifestation and whoop is often absent.
- Older children and adults frequently have atypical manifestation with prolonged cough, with or without paroxysms and no whoop however, individuals can exhibit classic illness.

Determine the Extent of Illness

- See **Pertussis Investigation and Control Guidelines** in this section.

Laboratory Specimens

- The gold standard and preferred laboratory test for diagnosis of pertussis is **isolation of *B. pertussis* by culture**. Pertussis Testing Kits are available from the State Lab at 334-2100.
- Obtain a nasopharyngeal culture by aspiration or with a polyester-tipped nasopharyngeal swab (DO NOT use calcium alginate swab) and inoculate onto special media such as Regen-Lowe or fresh Bordet-Gengoe.
- Obtain a second nasopharyngeal swab for polymerase chain reaction (PCR) testing.
- An elevated absolute lymphocyte count (20,000 or more) may be present in classical disease. However, there may be no lymphocytosis in infants and children or in mild or modified cases of pertussis.
- The direct immunofluorescent assay (DFA) of nasopharyngeal secretions is no longer used.
- Serological tests are not standardized, are not diagnostic, and are not recommended.

Treatment of Cases

- Infants younger that 6 months of age often require hospitalization for supportive care to manage coughing, paroxysms, apnea, cyanosis, feeding difficulties, and other complications
- Drug of choice is erythromycin. Some experts prefer the estolate preparation. An association between orally administered erythromycin and infantile hypertrophic pyloric stenosis (IHPS) has been reported in infants younger than 6 weeks of age.

Alternative choices

- Trimethoprim-sulfamethoxazole (TMP-SMZ) CDC recommends TMP-SMZ as an alternative antibiotic. TMP-SMZ is not recommended for children under two months of age and should not be given to pregnant women at term, or nursing mothers.
- Azithromycin 10-12 mg/kg per day orally in 1 dose for 5-7 days.
- Clarithromycin 15-20 mg/kg per day orally in 2 divided doses, max 1 g/d. for 5-7 days

Contact and Control Measures

- See **Pertussis Investigation and Control Guidelines** in this section.
- Specific definitions of a contact are problematic and will vary according to the situation. Identification and prophylaxis of close contacts needs to be individualized and take into consideration the risk of pertussis to the individual and the specifics of the exposure.
- Refer to CDC's close contact definition in "Guidelines for the Control of Pertussis Outbreaks," pp 11-3, http://www.cdc.gov/nip/publications/pertussis/guide.htm

- **The following medications are recommended for all household contacts or other close contacts regardless of age and immunization status**.

Age group	**Erythromycin** (14-day course)	**Clarithromycin** (7-day course)	**Azithromycin** (5-day course)
≥6 months	40-50 mg/kg/day in 4 divided doses (maximum 2 gm/day) X 14 days.	15 mg/kg/day in 2 divided doses (maximum 500mg/dose) X 7 days.	10 mg/kg/day (maximum 500mg) in single dose on day 1 then 5mg/kg/day on Days 2 –5.
1-5 months	As above (estolate preparation preferred if available).	As above.	10mg/kg/day in single daily dose X 5 days.
<1 month	As above (Use as alternate drug in doses above. Drug use is associated with elevated risk of IHPS).	Not recommended (Safety data unavailable).	Preferred drug. 10mg/kg/day in a single daily dose X 5 days. Limited safety information.

TMP-SMZ may be used as an alternative agent in patients who are allergic to macrolides, who cannot tolerate macrolides, or who are infected, rarely, with a macrolide-resistant strain of *Bordetella pertussis*.
The recommended dose in children is trimethoprim 8 mg/kg/day, sulfamethoxazole 40 mg/kg/day in two divided doses for 14 days. For adults, the recommended dose is trimethoprim 320 mg/day, sulfamethoxazole 1600 mg/day in two divided doses for 14 days. Because of the risk of kernicterus, TMP-SMZ should not be given to pregnant women, nursing mothers, premature neonates, or infants <2 months of age.

Reporting Requirements

- FTR: write up all outbreaks of pertussis
- Write a case summary and file for all sporadic cases.
- Morbidity Database: enter all laboratory confirmed, probable and epi-linked cases.
- CDC Case Definition is used to define confirmed and probable cases.

Pertussis Investigation and Control Guidelines

Alaska Division of Public Health
Section of Epidemiology

CLINICAL CASE DEFINITION OF PERTUSSIS:

A cough illness lasting at least 14 days with **one** of the following: paroxysms of coughing, inspiratory "whoop", **or** post-tussive vomiting -- and without other apparent cause (as reported by a health professional)

1. **Investigate all suspected, probable, and confirmed pertussis reports. Evaluate whether reported case's symptoms are compatible with pertussis.**

2. **Identify close contacts:**
   a. Household contacts
   b. Other persons having direct prolonged exposure to the case while case was contagious and was coughing or sneezing.

3. **Recommend antibiotics for the index case, all household and close contacts. Antibiotics are recommended to:**
   a. Render the index case and symptomatic household or other close contacts non-infectious (note: administering appropriate antibiotics during the catarrhal stage may also reduce the severity of pertussis illness);
   b. Abort infection in asymptomatic household or other close contacts, especially if they have potential to expose young children.
   c. Table 1 (Page 3 of **Pertussis Overview**) has the current antibiotic recommendations.

4. **Give DTaP vaccine to children <7 years of age, who are contacts of a case, and are not age appropriately immunized or whose last DTP/DTaP dose was more than 3 years ago.**

5. **Evaluate close contacts for pertussis symptoms, and when possible collect specimens for lab testing from symptomatic persons.**
   Collect a nasal wash or nasopharyngeal swab from symptomatic persons for pertussis testing. It is especially important to collect specimens from symptomatic persons who may spread pertussis to a new setting or who are contacts to a probable case. Pertussis may be detected by PCR even if the person has been treated or has been coughing for some time. Pertussis testing is available at ASPHL Laboratory. Refer to "Pertussis Specimen Collection" for instructions.

6. **Recommend exclusion from work, childcare, or school for the following persons until they have completed 5 days of an appropriate antibiotic or until 21 days after cough onset if antibiotics are not taken:**
   a. Children reported as suspected, probable, or confirmed cases and children identified as symptomatic (including slight coughs) contacts.
   b. Adults reported as suspected, probable or confirmed cases and adults identified as symptomatic (including slight coughs) contacts that work in high-risk situations (e.g. school teacher, health care worker, childcare center staff).

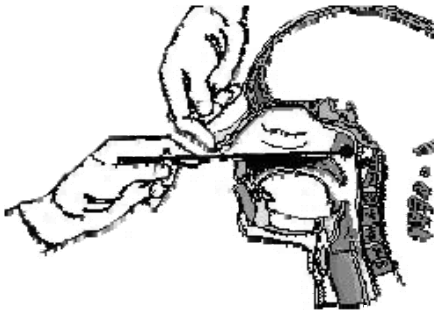
7. **Conduct follow up interviews on:**
   a. Reported suspected, probable, or confirmed pertussis cases to determine whether they meet the clinical case definition;
   b. Symptomatic contacts who coughed less than 14 days at the time of the initial interview to determine whether they meet the clinical case definition;
   c. Asymptomatic contacts 21 days following their exposure to determine whether they have remained disease-free.

8. **Submit a complete surveillance form for all individuals meeting the following criteria:**
    a. Culture positive (confirmed);
    b. PCR positive and meets clinical case definition (confirmed);
    c. Epidemiologically linked to a confirmed case (culture or PCR positive) and meets the clinical case definition (confirmed);
    d. Positive serology and meets clinical case definition (probable);
    e. Diagnosed by a health professional (who examined the case) and meets clinical case definition (probable);

9. **Complete a "For The Record" for all outbreaks and prophylaxis of large clusters.**

Sample Collection Instructions for Pertussis

Test Methods: Culture and PCR



Supplies Needed:
Dacron Nasopharyngeal Swab in Plain Dry Tube (Copan, yellow top)
Regan-Lowe Transport Media
Individually Paper-Wrapped Nasopharyngeal Dacron/Polyester Swab
Pertussis Requisition Form

Collection Instructions:
1. Assemble all supplies.
2. The nasopharyngeal swab used for collecting this sample type has a fine wire shaft.
3. Two swabs are collected during this procedure, one for PCR and the other for culture. Both swabs are collected in the same manner as described below.
4. Remove any mucus from the patient's nose.
5. Estimate the distance to the nasopharynx. *Prior to insertion of the swab, measure the distance from the corner of the nose to the front of the ear and insert the shaft ONLY* <u>*half this length*</u>*.*
6. Open package containing the NP swab in plain dry tube (yellow cap) and remove swab for sample collection.
7. Immobilize the patient's head. Have the patient sit with head against a wall, as there is a tendency to pull away during this procedure.
8. <u>Gently</u> insert the swab along the medial part of the septum, along the base of the nose, until it reaches the posterior nares. Gentle rotation of the swab may be helpful in accomplishing the insertion. (If resistance is encountered on one side, try the other nostril, as the patient may have a divided septum).
9. Leave swab in place in nasopharynx for 10 seconds, then gently rotate to remove columnar epithelial cells and remove swab.
10. Put NP swab back into its plain dry tube (yellow cap).
11. Using the other NP swab, collect a second sample as previously described in steps 8-10.
12. Insert this swab into the Regan-Lowe transport media by stabbing it into the media all the way to the bottom of the tube. Break off swab, leaving inoculated portion in the media, and recap tube.
13. Follow labeling and transport instructions below.

Labeling
1. Clearly label both tubes containing swabs, plain dry and Regan-Lowe transport media, with patient's name and collection date.
2. Complete the Pertussis Requisition Form.
3. Address the package to:

   Alaska Public Health Lab, 4500 Boniface Pkwy, Anchorage, AK 99507

   Call **907-334-2100** if you have questions.

Transport
1. Place tubes containing swabs in the Ziploc portion of a specimen transport bag and the completed requisition form in the adjacent pouch.
2. Package as a diagnostic specimen according to all current shipping regulations and transport to the State Public Health Laboratory-Anchorage as soon as possible. Ship at ambient temperature. Do not allow media containing specimen to freeze.

   NOTE: If transport will exceed 24 hours, pre-incubation of Regan-Lowe Transport media is recommended. Regan-Lowe transport is an enrichment media for *Bordetella spp*., and inhibits growth of normal flora. Incubating for 48 hours at 35-37°C, before transporting, increases the survival of *Bordetella* spp. by allowing them to multiply. Hold the PCR swab at 4°C until transport.

Screening for Pertussis

Date ____/____/_____ Interviewer _____

School _____

Student's Name _____ Phone ( )____-_____

Have you been coughing for ≥ 2 weeks? Y N Length of cough _____

Have you been around any children under two years of age during the time you were coughing? Y N

Are you in direct contact with someone who has been diagnosed with pertussis? Y N

If so, who? _____

Are you having spells of coughing?	Y	N
Are you coughing so hard that you vomit or gag?	Y	N
Is your coughing waking you up at night?	Y	N
Are other people in your household coughing?	Y	N

Do you baby-sit? Y N If so, name of family _____
Phone ( )____-_____

Total DPT/DTaP _____ Vaccination Dates

1. _____/_____/_____
2. _____/_____/_____
3. _____/_____/_____
4. _____/_____/_____
5. _____/_____/_____
6. _____/_____/_____

Pertussis Worksheet

Patient Name: _____ DOB ___/___/_____ Age_____
Sex:___ Race _____ Ethnicity _____
Address _____ Phone: (____) _____-_____
Healthcare Provider _____ Phone: (____) _____-_____
Contact to lab-confirmed case? Y N
Name of lab-confirmed case:_____

Symptoms:

Cold-like symptoms	Y	N	onset date _____
Cough	Y	N	onset date _____
Paroxysmal cough	Y	N	onset date _____
Whoop	Y	N	onset date _____
Post-tussive vomiting	Y	N	onset date _____
Apnea	Y	N	onset date _____

Meets CDC case Definition? Y N
(A cough illness lasting at least 2 weeks with one of the following: paroxysms of coughing, **or** inspiratory "whoop", **or** post-tussive vomiting **and** without other apparent cause (as reported by a health professional.)

Complications:

Y N (If yes, describe (e.g., pneumonia, seizures, etc.)_____

_____)

Chest X-ray Y N Date ____/____/_____

Laboratory: (Name of Lab: _____)

Culture	Y	N	Date _____
Specimen to State Lab	Y	N	Date _____
DFA	Y	N	Date _____
PCR	Y	N	Date _____

Treatment:
Antibiotic (Dose, duration)_____ Date _____
Weight_____
Vaccine History: (Request vaccine information) Immunized? Y N

Environment:

Number in Household ____ Anyone else coughing in Household? Y N
Infants in Household? Y N Attends day care? Y N
Day Care Address _____
Day Care Phone(____) _____-_____ Class/Teacher_____
Attends School: Y N Grade/Teacher_____
Address:_____
Babysits? Y N
List names of close contacts on Pertussis Contact Worksheet form if this is a case of pertussis.

PERTUSSIS CONTACT WORKSHEET

Case Name_____

Contact Name	Age	M	F	Relationship to Case	SYMPTOMS		Testing Status/ Confirmed Case?	Vaccine History
					COLD SYMPTOMS	Y☐ N☐		
				Household ☐	COUGH	Y☐ N☐		# DT(a)P_____
				Other ☐ (Specify)	COUGH ONSET DATE___/___/___			
Phone Number					COUGH FOR 2 WEEKS OR MORE	Y☐ N☐	Treatment	Date of Last DT(a)P
				Infants in Home Y☐N☐	PAROXYSM	Y☐ N☐	Type:_____	___/___/_____
					WHOOP	Y☐ N☐		
					VOMITING	Y☐ N☐	Start Date:__/__/___	Booster Advised ☐
					COLD SYMPTOMS	Y☐ N☐		
				Household ☐	COUGH	Y☐ N☐		# DT(a)P_____
				Other ☐ (Specify)	COUGH ONSET DATE___/___/___			
Phone Number					COUGH FOR 2 WEEKS OR MORE	Y☐ N☐	Treatment	Date of Last DT(a)P
				Infants in Home Y☐N☐	PAROXYSM	Y☐ N☐	Type:_____	___/___/_____
					WHOOP	Y☐ N☐		
					VOMITING	Y☐ N☐	Start Date:__/__/___	Booster Advised ☐
					COLD SYMPTOMS	Y☐ N☐		
				Household ☐	COUGH	Y☐ N☐		# DT(a)P_____
				Other ☐ (Specify)	COUGH ONSET DATE___/___/___			
Phone Number					COUGH FOR 2 WEEKS OR MORE	Y☐ N☐	Treatment	Date of Last DT(a)P
				Infants in Home Y☐N☐	PAROXYSM	Y☐ N☐	Type:_____	___/___/_____
					WHOOP	Y☐ N☐		
					VOMITING	Y☐ N☐	Start Date:__/__/___	Booster Advised ☐
					COLD SYMPTOMS	Y☐ N☐		
				Household ☐	COUGH	Y☐ N☐		# DT(a)P_____
				Other ☐ (Specify)	COUGH ONSET DATE___/___/___			
Phone Number					COUGH FOR 2 WEEKS OR MORE	Y☐ N☐	Treatment	Date of Last DT(a)P
				Infants in Home Y☐N☐	PAROXYSM	Y☐ N☐	Type:_____	___/___/_____
					WHOOP	Y☐ N☐		
					VOMITING	Y☐ N☐	Start Date:__/__/___	Booster Advised ☐

Comments:_____

_____

AMBST 06/04

STATE OF ALASKA
DEPARTMENT OF HEALTH & SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY
3601 C STREET, SUITE 540
P.O. BOX 240249
ANCHORAGE, ALASKA 99524-0249
FRANK H. MURKOWSKI, GOVERNOR
INFECTIOUS DISEASES
AIDS/STD
TUBERCULOSIS
IMMUNIZATION
CHRONIC DISEASES
DIABETES
INJURY CONTROL
(907) 269-8000
(907) 562-7802

Pertussis (Whooping Cough) Fact Sheet

What is pertussis (whooping cough)?
Pertussis (whooping cough) is an infection of the respiratory system caused by *Bordetella pertussis*, a bacterium.

Who gets pertussis (whooping cough)?
A person usually becomes ill 7 to 10 days after being exposed to someone with the disease, however, incubation can take up to 21 days. Transmission occurs when the ill person coughs around others. The most infectious time is the beginning stage of the disease. Individuals are almost never contagious after the third week of paroxysms (spells of coughing) or after 5 full days of antibiotic treatment.

What are the symptoms of pertussis (whooping cough)?
Classic symptoms of pertussis begin with "cold-like" symptoms and a mild cough. The cough in school age children, adults, and fully immunized children, pertussis may not be a severe illness. Adults may not have the "classic" symptoms but, instead, may have a cough that last for weeks or months and awakens them at night. In infants and young children, especially those who have not had 3 doses of vaccine, pertussis may be very severe, resulting in hospitalization, seizures long-term neurological problems, and even death. Infants do not develop the typical cough, so it is more difficult to know if they have pertussis or something else.

How soon after exposures do symptoms of pertussis (whooping cough) appear?
A person usually becomes ill 7 to 10 days after being exposed to someone with the disease; however, incubation can take up to 21 days.

How can pertussis (whooping cough) be diagnosed?
The best way to diagnose pertussis is through a laboratory culture of a specimen obtained from the nose.

What is the treatment for pertussis (whooping cough)?
Pertussis treatment includes an appropriate course of antibiotics prescribed by their health care provider and the patient should stay isolated from other people until he/she has taken the medication for at least 5 full days of the total course of antibiotics.

How can the spread of pertussis (whooping cough) be prevented?
Anyone who has symptoms of pertussis should not go to work, school, or day care, and should stay isolated from other people until he/she has taken appropriate antibiotics for at least 5 full days of the total course of antibiotics prescribed by their health care provider. If you choose not to treat the illness with antibiotics, you must stay away from others for 3 full weeks after the onset of paroxysms. Parents should inform childcare personnel and teachers if pertussis is suspected in their child. Pertussis should be reported to the local health department.

Drug Information: Azithromycin Oral

Brand name(s): Zithromax®

Why is this medication prescribed?

Azithromycin is an antibiotic used to treat certain infections caused by bacteria, such as pneumonia; venereal disease (VD); and ear, lung, skin, and throat infections. In acquired immunodeficiency syndrome (AIDS) patients, azithromycin is used to prevent pneumonia, called disseminated Mycobacterium avium complex (MAC) infection. Antibiotics will not work for colds, flu, or other viral infections. This medication is sometimes prescribed for other uses (i.e., pertussis) ask your doctor or pharmacist for more information.

How should this medicine be used?

Azithromycin comes as a capsule, tablet, and liquid to take by mouth. It is usually taken once a day for 2-5 days. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take azithromycin exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor. Shake the liquid well before each use to mix the medication evenly. The capsules and tablets should be taken with a full glass of water.
Continue to take azithromycin even if you feel well. Do not stop taking azithromycin without talking to your doctor.

What special precautions should I follow?

Before taking azithromycin:

- tell your doctor and pharmacist if you are allergic to azithromycin, clarithromycin (Biaxin), dirithromycin (Dynabac), erythromycin, or any other drugs.
- tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially other antibiotics, anticoagulants ('blood thinners') such as warfarin (Coumadin), astemizole (Hismanal), carbamazepine (Tegretol), cisapride (Propulsid), clozapine (clozaril), cyclosporine (Neoral, Sandimmune), digoxin (Lanoxin), disopyramide (Norpace), ergotamine, felodipine (Plendil), lovastatin (Mevacor), phenytoin (Dilantin), pimozide (Orap), terfenadine (Seldane), theophylline (Theo-Dur), triazolam (Halcion), and vitamins.
- tell your doctor if you have or have ever had liver disease, irregular heart beat, yellowing of the skin or eyes, colitis, or stomach problems.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking azithromycin, call your doctor.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking azithromycin.
- if you take antacids (Mylanta, Maalox), take them 2 hours after azithromycin.
- plan to avoid unnecessary or prolonged exposure to sunlight and to wear protective clothing, sunglasses, and sunscreen. Azithromycin may make your skin sensitive to sunlight.

What special dietary instructions should I follow?

Take azithromycin liquid at least 1 hour before or 2 hours after meals. The capsule and tablet may be taken with or without food. If it upsets your stomach, take it with food.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Although side effects from azithromycin are not common, they can occur. Tell your doctor if any of these symptoms are severe or do not go away:

- upset stomach
- diarrhea
- vomiting
- stomach cramps
- mild skin rash
- stomach pain

If you experience any of the following symptoms, call your doctor immediately:

- severe skin rash
- itching
- hives
- difficulty breathing or swallowing
- wheezing
- yellowing of the skin or eyes
- dark urine
- pale stools
- unusual tiredness
- vaginal infection

What storage conditions are needed for this medicine?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store the capsules and tablets at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Keep liquid medicine in the refrigerator, tightly closed, and throw away any unused medication after 10 days. Do not freeze. Talk to your pharmacist about the proper disposal of your medication.

ZITHROMAX
Generic Name: Azithromycin (az-ith-roe-MYE-sin)
Drug Class: Antibiotic, Macrolide

Description

This medicine is used to treat various bacterial infections, such as pneumonia or other respiratory conditions. In children, this medicine is commonly used to treat ear infections, pneumonia, sore throat or tonsillitis. In the case of Pertussis or whooping cough, Zithromax may be used to treat all who are sick and those who have come in contact with them.

Proper use of this medicine

Take the medicine orally as directed. This medicine can be taken with or without food. And remember to finish all medication unless the doctor or public health nurse has advised you otherwise. It is also important to avoid taking antacids together with this medicine. If you take antacids, separate them from your antibiotic by at least 2 hours. When giving the liquid Zithromax, shake the bottle before each use and measure the dose with the supplied oral syringe or dropper.

Storage

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom.) Throw away any medication that is not used.

Possible Side Effects

- Nausea, vomiting, and abdominal pain
- Diarrhea
- Hearing disturbances or ringing in the ears—notify your doctor if this happens

Warnings/Precautions

- If you develop a rash, hives, difficulty in breathing, or swallowing stop taking the medicine and see a doctor immediately.
- If you get a small rash from the medicine talk to your doctor or nurse.

Drug Interactions

If you are on any of the following medications: digoxin, carbamazepine (Tegretol), cyclosporine (Neoral, Sandimmune), or phenytoin (Dilantin), talk to your doctor before taking Zithromax.

Pregnancy/Nursing

This medications is generally thought to be safe during pregnancy and breast-feeding. If you are, or plan on becoming pregnant, talk to your doctor to discuss any risks.

More Information

For more information about this medicine, talk to your healthcare provider.

ZITHROMAX DOSING FOR PERTUSSIS
(BASED ON 10-12MG/KG/DAY)

WEIGHT	**DAILY/DOSAGE**	
170+ lbs	500 mg (qd)	
135-169 lbs	500 mg (qd)	
89-134 lbs	500 mg (qd)	Liquid=2.5 tsp of 200mg/5ml
70-88 lbs	400 mg	Liquid=2 tsp of 200mg/5ml

LIQUID DOSING BOTH IN ML AND CLOSEST TEASPOONFUL

68-69 lbs		8.5 ml	1 ¾ teaspoons 200mg/5ml
58-67 lbs		8 ml	1 ½ teaspoons 200mg/5ml
53-57 lbs		7 ml	1 ½ teaspoons 200mg/5ml
47-52 lbs		6 ml	1 ¼ teaspoons 200mg/5ml
37-46 lbs		5 ml	1 teaspoon 200mg/5ml
28-36 lbs		4 ml	¾ teaspoon 200mg/5ml
	OR	7.5m1	1 ½ teaspoons 100mg/5ml
20-27 lbs		5 ml	1 teaspoon 100mg/5ml
15-19 lbs		3.75ml	¾ teaspoon 100mg/5ml

PERTUSSIS PRESCRIPTIONS

NAME	DOB	WT	LAB	PRESCRIPTION

PROVIDER _____

DATE _____

ST/02/05

Pertussis *(Bordetella pertussis)* (Whooping Cough)

1997 Case Definition

Clinical case definition

A cough illness lasting at least 2 weeks with one of the following: paroxysms of coughing, inspiratory "whoop," or post-tussive vomiting, without other apparent cause (as reported by a health professional)

Laboratory Criteria for Diagnosis

- Isolation of *Bordetella pertussis* from clinical specimen
- Positive polymerase chain reaction (PCR) for *B. pertussis*

Case classification

Probable: meets the clinical case definition, is not laboratory confirmed, and is not epidemiologically linked to a laboratory-confirmed case

Confirmed: a case that is culture positive and in which an acute cough illness of any duration is present; or a case that meets the clinical case definition and is confirmed by positive PCR; or a case that meets the clinical case definition and is epidemiologically linked directly to a case confirmed by either culture or PCR

Comment

The clinical case definition above is appropriate for endemic or sporadic cases. In outbreak settings, a case may be defined as a cough illness lasting at least 2 weeks (as reported by a health professional). Because direct fluorescent antibody testing of nasopharyngeal secretions has been demonstrated in some studies to have low sensitivity and variable specificity (5, 6), such testing should not be relied on as a criterion for laboratory confirmation. Serologic testing for pertussis is available in some areas but is not standardized and, therefore, should not be relied on as a criterion for laboratory confirmation.

Both probable and confirmed cases should be reported nationally.

Active Laboratory-Based Pertussis Surveillance Worksheet

APPENDIX 10

NAME (Last, First)			Hospital Record No.
Address (Street and No.)	City	County	Zip / Phone

----------DETACH HERE and transmit only lower portion if sent to CDC----------

Active Laboratory-Based Pertussis Surveillance Worksheet

Hospital Lab/ID

Status: Is the form complete? Y = Yes, N = No

Update Date Month Day Year

County

State

Zip

State ID

Birth Date Month Day Year

Age

Age Type
0 = 0-120 years
1 = 0-11 months
2 = 0-52 weeks
3 = 0-28 days
9 = Age unknown

Race
N = Native Amer./Alaskan Native
A = Asian/Pacific Islander
B = African American
W = White
O = Other
U = Unknown

Ethnicity
H = Hispanic
N = Not Hispanic
U = Unknown

Sex
M = Male
F = Female
U = Unknown

CLINICAL DATA

Any Cough? Y = Yes, N = No, U = Unknown

Cough Onset Month Day Year

Paroxysmal Cough? Y = Yes, N = No, U = Unknown

Whoop? Y = Yes, N = No, U = Unknown

Posttussive Vomiting? Y = Yes, N = No, U = Unknown

Apnea? Y = Yes, N = No, U = Unknown

Final Interview Date Month Day Year

Cough at Final Interview? Y = Yes, N = No, U = Unknown

Duration of Cough at Final Interview Days

COMPLICATIONS

Chest X-ray for Pneumonia
P = Positive
N = Negative
X = Not Done
U = Unknown

Seizures Due to Pertussis Y = Yes, N = No, U = Unknown

Acute Encephalopathy Due to Pertussis Y = Yes, N = No, U = Unknown

Hospitalized? Y = Yes, N = No, U = Unknown

Days Hospitalized
0 - 998
999 - Unknown

Died? Y = Yes, N = No, U = Unknown

TREATMENT

Were Antibiotics Given? Y = Yes, N = No, U = Unknown

First Antibiotic Received
1 = Erythromycin (incl. pediazole, ilosone)
2 = Cotrimoxazole (bactrim/septra)
3 = Clarithromycin/azithromycin
4 = Tetracycline/Doxycycline
5 = Amoxicillin/Penicillin/ Ampicillin/Augmentin/Ceclor/Cefixime
6 = Other
9 = Unknown

Date Started First Antibiotic Month Day Year

Days First Antibiotic Actually Taken
0 - 98
99 - Unknown

Second Antibiotic Received See Choices for First Antibiotic Given

Date Started Second Antibiotic Month Day Year

Days Second Antibiotic Actually Taken
0 - 98
99 = Unknown

LABORATORY

Was Laboratory Testing for Pertussis Done? Y = Yes, N = No, U = Unknown

	Result	Date Specimen Taken (Month Day Year)
Culture		
DFA		
Serology		
PCR		

RESULT CODES
P = Positive
N = Negative
E = Pending
I = Indeterminate
X = Not Done
S = Parapertussis
U = Unknown

VACCINE HISTORY

Vaccinated? (Received any doses of diphtheria, tetanus, and/or pertussis-containing vaccines) Y = Yes, N = No, U = Unknown

Vaccination Date Month	Day	Year	Vaccine Type*	Vaccine Manuf.*	Lot Number

Vaccine Type Codes
W = DTP Whole Cell
A = DTaP
H = DTaP-Hib
P = Pertussis Only
D = DT or Td
T = DTP-Hib
O = Other
U = Unknown

Vaccine Manufacturer Codes
C = Connaught
L = Lederle
S = SmithKline Beecham
O = Other
M = Mass. Health Department
N = North American Vaccine
I = Mich. Health Department
U = Unknown

*Record for each dose (unlikely to be available if patient born before 1989)
*unknown = 9999999999

Date of Last Pertussis-Containing Vaccine Prior to Illness Onset Month Day Year

Number of Doses of Pertussis-Containing Vaccine Prior to Illness Onset
0 - 6
9 = Unknown

Reason Not Vaccinated With = 3 Doses of Pertussis Vaccine
1 = Religious Exemption
2 = Medical Contraindication
3 = Philosophical Exemption
4 = Previous Pertussis Confirmed by Culture or MD
5 = Parental Refusal
6 = Age Less Than 7 Months
7 = Other
9 = Unknown

Suspected source of infection: For cases < 1 yr, is another person with suspected pertussis * known? Y = Yes, N = No, U = Unknown

Source's Age Unk = 999

Source's Age Type
0 = 0-120 years
1 = 0-11 months
2 = 0-52 weeks
3 = 0-28 days
9 = Age unk

EPIDEMIOLOGIC INFORMATION

Date First Reported to a Health Department Month Day Year

Date Case Investigation Started Month Day Year

Outbreak Related? Y = Yes, N = No, U = Unknown

Epi-Linked? Y = Yes, N = No, U = Unknown

Outbreak Name (Name of outbreak this case is associated with)

Transmission Setting (Where did this case acquire pertussis)?
1 = Day Care
2 = School
3 = Doctor's Office
4 = Hospital Ward
5 = Hospital ER
6 = Hosp. Outpatient Clinic
7 = Home
8 = Work
9 = Unknown
10 = College
11 = Military
12 = Correctional Facility
13 = Church
14 = International Travel
15 = Other

Setting (Outside Household) of Further Documented Spread From This Case
Use same codes as for Transmission Settings, except:
7 = >1 Setting Outside Household
16 = No Documented Spread Outside Household

Site PFGE type:

Erythromycin susceptibility test results:
S = Susceptible
I = Intermediate
R = Resistant

Source's Sex
1 = Male
2 = Female
9 = Unk

Relation to case:
1 = Mother
2 = Father
3 = Sister
4 = Brother
5 = Neighbor
6 = Daycare
7 = Grandparent
8 = Friend
11 = Other
99 = Unknown

* Another person with a cough who was in contact with the case 7-20 days before the case's cough

----------DETACH HERE ----------

The information below is epidemiologically important, but not included on NETSS screens

Comments:

Setting	In which setting was pertussis acquired (Please Specify)	In which setting was there secondary spread (Please Specify)
Daycare		
School		
Doctor's Office		
Hospital (Ward/Outpatient/Clinic)		
Home		
Work		
Travel (International/Domestic)		
Other		
Unknown		

Name of Contact	Birthdate	Relation to the Case	Is it a Case ?	If it's a Case, Case ID #	Cough Onset Date (If Present)	# of PCVs*	Date of Last PCV	Parent's Name and Phone # (If Applicable)

Comments:

***PCV = Pertussis-Containing Vaccine**

Clinical Case Definition*:
A cough illness lasting ≥ 2 weeks with one of the following: paroxysms of coughing, inspiratory "whoop", or post-tussive vomiting, without other apparent cause.

Case Classification*:
Probable: A case that meets the clinical case definition, is not laboratory confirmed, and is not epidemiologically linked to a laboratory-confirmed case.
Confirmed: 1) A person with an acute cough illness of any duration who is culture positive, or
2) a case that meets the clinical case definition and is confirmed by PCR, or
3) a case that meets the clinical case definition and is epidemiologically linked directly to a case confirmed by either culture or PCR.

*CDC. Case Definitions for Infectious Conditions Under Public Health Surveillance. MMWR 1997;46(No.RR-10):39.

PERTUSSIS DEATH WORKSHEET

NETSS ID: ☐☐☐☐☐☐☐☐☐ **STATE ID:** ☐☐☐☐☐☐☐☐☐☐

Patients Initials: ☐☐☐ **Sex:** ❑ Male ❑ Female

Date of Birth: ☐☐☐ **Race*:** ☐ **Ethnicity*:** ☐

Date of Cough Onset: ☐☐☐ **Reporting State:** ☐

Date of Death: ☐☐☐ **Report Completed By:**
Telephone #:

Where did the patient die? ? Home ? Hospital ? En route to hospital ? Other (Specify) _____

Was an autopsy performed? ❑ Yes ❑ No ❑ Unknown

CHECKLIST OF DOCUMENTS TO BE SENT TO CDC

Send to: **The Pertussis Surveillance Coordinator, MS E61, BVPD Branch, Epidemiology and Surveillance Division, National Immunization Program, Centers for Disease Control, 1600 Clifton Road NE, Atlanta, GA 30333. Fax # 404-639-8616**

No.	Document**	Yes/No
1	*Pertussis case investigation form*	
2	*Copy of all patient's vaccination records*	
3	*Admission history and physical (H&P)*	
4	*Discharge summary*	
5	*All medical records, including Emergency Dept notes and lab results****	
6	*Death certificate*	
7	*Autopsy report*	

PATIENT'S VACCINATION INFORMATION

DOSE	Antigen (Circle one)	DATE GIVEN	BRAND/ MANUFACTURER	LOT NUMBER	DATA SOURCE ‡
First	DTP/ DTaP/ DT				
Second	DTP/ DTaP/ DT				
Third	DTP/ DTaP/ DT				
Fourth	DTP/ DTaP/ DT				
Fifth	DTP/ DTaP/ DT				

* Please use the same codes as in the Pertussis Case Report Worksheet
**Please obtain information from each hospital
*** Medical chart/record also includes inpatient progress notes, X-ray reports, echocardiography reports, Doctor's Office notes, vaccination records, lab reports
‡Data Source: Provider Record=1; Parent vaccination card=2; Other baby record (e.g. baby book)=3; Parent's History (no record)=4; Other source=5 (please specify).

DOCTOR'S OFFICE/CLINIC/EMERGENCY DEPARTMENT VISITS

Please list the dates and name of all clinics or doctor's offices/emergency department visits made by the patient for this illness in chronological order.

Date of Visit	**Name and Address of Clinic, Doctor's Office, or Emergency Department visited**	**Telephone No.**

CLINICAL DATA

Was the patient hospitalized? ❑ Yes ❑ No ❑ Unknown

Please list the admission date(s) and discharge dates/transfer dates for this illness in chronological order.

Hospital name	**Date of Admission**	**Date of Discharge / transfer**	**Discharge Diagnosis**

RESPIRATORY SUPPORT:

	Yes/No	**Date Started**
Supplemental O_2 without intubation e.g. mask		
Supplemental O_2 via endotracheal intubation		
Continuous mechanical ventilation		
High Frequency Oscillatory Ventilation		
Extra Corporeal Membrane Oxygenation		

LABORATORY STUDIES: (Including tests obtained 30 days before onset of illness)

Specimen	**Collection Date**	**Culture Result**	**PCR**	**DFA**	**ELISA**
Nasopharyngeal - *B. pertussis*					
-RSV					
-Adenovirus					
-Influenza					
-Parainfluenza					
- Other (specify pathogen)					
Blood					
	Date	**Count**			
Total WBC Count (Initial)			% Lymphocyte		
Highest WBC Count			% Lymphocyte		

OTHER STUDIES

	Yes/No	Date done	Result
Chest X-ray			
Echocardiography			

Was pulmonary hypertension a diagnosis in this patient? ❑ Yes ❑ No ❑ Unknown

Was the patient treated with antibiotics? ❑ Yes ❑ No ❑ Unknown

***If Yes**, please* list all the antibiotics and the dates when given.

Name of Antibiotic Given	Date Started	Date Ended

OTHER MEDICAL AND FAMILY INFORMATION

What is the birth mother's date of birth? [ ] [ ] [ ]

At the time of the patient's birth, did the mother have an immune-suppressed or a chronic underlying medical condition?

❑ Yes ❑ No ❑ Unknown

If yes, what is the name of the condition? [ ]

If the patient was <1 year old, what was the gestational age of the infant at the time of delivery?

[ ] Weeks

What was the weight of the infant at birth? [lb oz] or [kg gm]

Did the patient have underlying or previous medical conditions? ❑ Yes ❑ No ❑ Unknown

If yes, please give details.

In the table below, list everyone who lives in the household, their date of birth, age, sex, the number of doses of pertussis containing vaccine received, and date of the last pertussis vaccine dose, smoking habits at home, and the presence of a cough illness during the 3-week period prior to the cough onset date in the patient. Please indicate if pertussis was the diagnosis for the cough illness, and if so, how pertussis was confirmed.

No.	**Relationship to Patient**	**Date of Birth**	**Age**	**Sex**	**No. doses DTP/ DTaP/DT**	**Date of last dose**	**Smoking habits at home**		**Cough illness in family member during 3-week period prior to cough onset date in case-patient**			
							Current smoker (Yes/No)	**Avg. no. of cigarettes smoked daily**	**Cough (Yes/No)**	**Cough Onset Date**	**Pertussis diagnosis (Yes/No)**	**Confirmation method (Culture/ PCR / DFA/ None)**
1												
2												
3												
4												
5												
6												
7												
8												
9												

During the 3-week period prior to the cough onset, was the patient exposed to anyone **outside of the household** who was known to have a cough illness? ❑ Yes ❑ No ❑ Unknown

If yes, list all persons who had a cough illness and who may have exposed the patient, with the dates of cough onset in the table below.

No.	**Relationship to Patient**	**Date of Birth**	**Age**	**Sex**	**No. doses DTP DTaP/DT vaccine***	**Date of last Dose**	**Cough onset date**	**Date cough stopped**	**Pertussis Diagnosis**	**Confirmation Method (Culture/ PCR/DFA/ None)**
1										
2										
3										
4										
5										

* Indicate type of vaccine if available

Rabies

Rabies (Human or Animal)

Organism: Rabies virus, all mammals are variably susceptible to infection.

Incubation period: Average is 3-8 weeks (range 9 days–7 years); similar for dogs.

Infectious period: In domestic animals, viral shedding can occur 3-7 days before onset of clinical signs, which may include obvious neurological derangement or more subtle signs, such as mild drooling. Once animal is showing signs of rabies, death follows within 10 days (often within 2-3 days).

Transmission route: Virus introduced via animal bite; rarely transmission by non-salivary routes, e.g., corneal transplants.

Treatment: If indicated, rabies post-exposure prophylaxis (PEP) that consists of rabies immune globulin (HRIG) given on a per weight basis at the bite site, and a series of five doses of vaccine (human rabies vaccine or RabAvert®) given over the following 4 weeks on days 0, 3, 7, 14, and 28. If patient was previously vaccinated against rabies, no HRIG is needed and RabAvert® doses are needed only on days 0 and 3.

Information Needed for the Investigation

Verify the Exposure

- Assess likelihood that the animal was rabid:
  - ✓ *Was animal previously vaccinated?*
    Full course is two vaccines 12 months apart, with the first one given after the age of 12 weeks. Once fully vaccinated, dog/cat/ferret is considered protected if 30 days have elapsed since vaccine was given. Vaccine is labeled for 3 years of protection.
  - ✓ *Where in Alaska did the incident occur?*
    Animals from certain geographic areas are more likely to be rabid. Rabies is enzootic and cyclically epizootic in northwestern AK among the fox population. Also ascertain whether animal that bit *originated* from an enzootic area in the recent past.
  - ✓ *Was the bite provoked?*
    Figure out what the human was doing when the bite or exposure occurred. In general, provoked animals are not rabid. Provocation may be overt, e.g., running over a fox with a snowmobile, or subtle, e.g., walking too close to a fearful chained dog.

- ✓ *What kind of animal is involved?*
  Foxes and dogs are highly suspicious in rabies enzootic area; small rodents highly unlikely. Rabies is usually not seen in Alaska bats, except for once in Southeast (Glacier Bay) in the early 1990s.
- ✓ *Is animal available for testing or quarantine?*
  If the animal is readily available to be tested, rabies PEP can be delayed until results are available **if** other circumstances suggest rabies is unlikely.

- Assess the likelihood that a human was exposed:
  - ✓ Rabies is present in saliva and neural tissue. Did an animal bite the person? Handling blood, feces, urine, and/or furs of potentially infected animals are not considered exposures.
  - ✓ Small children for whom reliable exposure histories cannot be obtained and who may have been licked in the eyes or mucous membranes by rabid animals are generally offered PEP. This is a potential, albeit not efficient, means of virus transmission.

Laboratory Specimens

Animals

- Submit intact animal head to Alaska State Virology Laboratory (ASVL) in Fairbanks. Freezing the head does not affect the test result; but is not advisable because it delays processing of the tissues. See ASVL shipping guidelines; notify ASVL before sending.
- Involve animal control or Public Safety officials if needed to obtain or ship the head.

Humans

- For a highly suspicious case one should also consult with CDC's Rabies Branch (404-639-1050).
- Collect brain tissue, nerve tissue from skin at the base of the neck, CSF, saliva, and serum.

Additional treatment considerations

- Emphasize vigorous and thorough cleansing of wound(s).
- Distribute (to provider, CHA, ER, etc.) a treatment schedule for exposed persons.
- Depending on circumstances, (e.g., availability of head for testing, likelihood that animal was rabid, flight schedule), initiate mail-out of PEP before test results are back.
- PEP needs to be initiated ASAP; there is no official cut-off time beyond which treatment is not indicated. CDC recommends proceeding even if the bite occurred up to 30 days before treatment becomes available.
- HRIG is **not** indicated if patient received human rabies vaccine or RabAvert® $\geq$7 days prior to being offered HRIG.

Contact and Control Measures

- All persons who might have handled the animal must be interviewed to determine the extent of their exposure and the need for PEP.
- Involve animal control/VPSO for assistance in determining if any other animals were bitten/came into contact with a rabid animal. (See Rabies Compendium and AAC sections for recommendations regarding quarantine and euthanasia of animals.)

Important Contact Information

State Virology Laboratory…….907-474-7018
Terry Schmidt, Head Virologist……..direct 907-474-6060
……907-269-5520 [pager # 0902 (24/7)]
Anchorage Animal Control …….. 907-343-8118
Mat Su Animal Control …….907-746-5500
Juneau Animal Control……...907-789-0260
Fairbanks Animal Control……..907-459-1451

Important Information

- Sometimes persons traveling through Alaska will be in the middle of a PEP series and were told by their provider to go to an ER for additional vaccines. In the past, we have provided doses for such persons in conjunction with a local Alaska healthcare provider as long as there is documentation from the original provider indicating a series in progress.
- Although CDC guidelines recommend PEP for most persons with exposure to bats, we usually do not recommend PEP for a bat exposure in **Southcentral** Alaska. For example, someone who finds a bat in his or her eaves and chases it around the house in Anchorage. However, because of the one positive bat in **Southeastern** Alaska, although >200 were trapped and tested negative, we will usually recommend PEP for bat exposures in that region of Alaska.

Reporting Requirements

- FTR: Write-up all outbreaks of animal rabies that resulted in significant human exposure(s). Assure that treatment information is given to Louisa Castrodale for her line list of PEP.
- Morbidity Database: Enter all laboratory-confirmed rabid animals and cases of human rabies. Follow instructions on filling out forms for animals; give to Louisa Castrodale.
- CDC Case Definition is used to define confirmed cases of rabies; there is no official CDC definition of a “probable” human case.

STATE OF ALASKA
DEPARTMENT OF HEALTH & SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY
3601 C STREET, SUITE 540
P.O. BOX 240249
ANCHORAGE, ALASKA 99524-0249
FRANK H. MURKOWSKI, GOVERNOR
INFECTIOUS DISEASES
AIDS/STD
TUBERCULOSIS
IMMUNIZATION
CHRONIC DISEASES
DIABETES
INJURY CONTROL
(907) 269-8000
(907) 562-7802

Rabies Pre-Exposure Vaccine Series

Health care provider: _____

Patient Name: _____ Date of Birth: ___/___/_____

A three (3) dose rabies pre-exposure vaccine series has been supplied to me by the Section of Epidemiology, Alaska Division of Public Health, free-of-charge. No charge for this vaccine can be made to the patient. The three doses of vaccine need to be administered to my patient on the recommended schedule of Days 0, 7, and 21 or 28. It is crucial to complete the entire 3-dose series. Patients should receive a Vaccine Information Sheet on rabies vaccine.

Completion of a rabies pre-exposure series does NOT automatically preclude the need for rabies post-exposure prophylaxis (PEP). Persons who have successfully completed a pre-exposure series still may require two (2) additional doses of rabies vaccine on Days 0 and 3 if they have an exposure to a possibly rabid animal.

_____ ___/___/_____
(Healthcare provider signature) (Date)

_____
(Print healthcare provider name)

Patient Name: _____ DOB ___/___/_____

Date 1st dose (Day 0) given: _____ Lot #: _____
2nd dose (Day 7) given: _____ Lot #: _____
3rd dose (Day 21 **or** 28) given: _____ Lot #: _____

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RABIES POST-EXPOSURE PROPHYLAXIS TREATMENT SHEET

Patient name:_____ Date of Birth:_____

1. Post-exposure prophylaxis consists of **both** antibody (Human Rabies Immune Globulin or HRIG) and human rabies vaccine (RabAvert®) with one exception: persons previously immunized require treatment with **only** human rabies vaccine.

2. The dose of HRIG is 20 I.U./kg body weight. HRIG contains 150 I.U./cc. HRIG should be given as soon as possible after the incident; however, HRIG is not indicated if more than 7 days have past since the first dose of human rabies vaccine (RabAvert®) was given. As much as anatomically feasible of the HRIG should be infiltrated into and around the wound or bite. The remainder (if any) should be given by intramuscular injection at an anatomical site distant from vaccine administration.

$$\underset{\textbf{Patient weight}}{_____\ \text{lbs}} \times \frac{0.453\ \text{kg}}{1\ \text{lb}} \times \frac{20\ \text{I.U.}}{1\ \text{kg}} \times \frac{1\ \text{cc}}{150\ \text{I.U.}} = \underset{\textbf{Volume HRIG}}{_____\ \text{cc}}$$

3. For persons without a history of previous immunization with rabies vaccine, five doses of vaccine are required, 1.0 ml each, given intramuscularly in the deltoid region (or anterolateral thigh for infants and small children). The first dose should be given as soon as possible after the exposure. Day 0 is the day that the first dose of human rabies vaccine (RabAvert®) is given. Additional doses should be given on each of days 3, 7, 14, and 28 after the first dose.

   For persons previously immunized, human rabies vaccine (RabAvert®) is required **only** on days 0 and 3.

4. Steroids interfere with the development of active immunity and may increase the likelihood of the development of clinical rabies. Steroids should not be used unless life-threatening complications occur.

5. It is critical that each dose of human rabies vaccine (RabAvert®) be given as scheduled. Healthcare providers must make certain that patients are not lost to follow-up. Consultation and epidemiology assistance can be obtained from the Section of Epidemiology at (907) 269-8000 during business hours or 1-800-478-0084 after hours.

		Date Due	Date Given	Provider
HRIG (day 0)		_____	_____	_____
RabAvert®	**1st dose (day 0)**	_____	_____	_____
	2nd dose (day 3)	_____	_____	_____
	3rd dose (day 7)	_____	_____	_____
	4th dose (day 14)	_____	_____	_____
	5th dose (day 28)	_____	_____	_____

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Indications for Rabies Post-Exposure Prophylaxis (PEP)

Exposure to a potentially rabid animal is considered a public health emergency. Many factors must be considered when evaluating a person for PEP. Rabies is a fatal disease and public health recommendations for PEP will tend to be cautious. Even so, because PEP involves 4 weeks of injections with substantial cost in actual vaccine, personnel time, and travel time for patients, the decision to treat should be based upon **all** of the following criteria.

		Consider PEP	PEP not likely indicated
1. Type of animal:	Dog, fox, etc.	X	
	Rodent, vole, squirrel, etc.		X

Rationale: In Alaska, the fox population is the reservoir for rabies. Although a small rodent theoretically could acquire rabies, they would first have to survive a bite from a rabid animal (a fox or dog)—which is highly unlikely. Rabies among small rodents (an occasional squirrel) has been detected only in areas of the United States where the reservoir population has either been raccoons or skunks because these animals are capable of delivering a potentially non-lethal bite to a small rodent. Unless the exposure to the small rodent occurred outside of Alaska (and even then), PEP is **almost never indicated** for such bites.

2. Geographic location:	Enzootic area	X	
	Non-enzootic area		X

Rationale: Rabies is enzootic among the fox population in the northern and western parts of Alaska, with cyclic epizootics occurring every 3-4 years. Exposures that occur in enzootic areas are more likely to warrant PEP. An Access line list of the locations of all positive animals since 1971 is on the network—N:Inf_apps/Prgstaff/Rabies. Additionally, maps or geographic information about cases in recent years can be found in the Bulletins of the Epidemiology website (http://www.epi.alaska.gov/): Bulletin #5 in 2000, #1 in 2002, and #6 in 2003. Part of the geographic assessment should include the animal's travel history, (e.g., was the animal recently transported from a rabies enzootic area?) A health certificate that includes proof of current rabies vaccination is required for all international flights and international border crossings. Proof of rabies vaccine is also required for public intrastate travel. For exposures that occur in other states, defer the decision to public health authorities in those locations. Contact persons for those states are listed in the same Rabies folder on the N drive.

		Consider PEP	PEP not likely indicated
3. Circumstance of bite:	Unprovoked	X	
	Provoked		X

Rationale: Rabid animals are likely to be disoriented, confused and respond inappropriately to stimuli and therefore tend to bite when unprovoked. Provoking an animal can occur in a variety of different ways. For example, animals on chains or leashes may feel threatened when approached because they are immobilized. Incidents involving small children who poke or prod animals or make quick movements around an animal's head would be classified as provoked.

4. Vaccination status of animal:	None	X	
	Current		X
	Out of date	X	

Rationale: Adequate rabies vaccination of an animal consists of an initial series of two vaccines given 12 months apart beginning no earlier than 12 weeks of age. Thereafter, rabies vaccine must be boostered with a single dose at least every 3 years, or as indicated by the vaccine manufacturer.

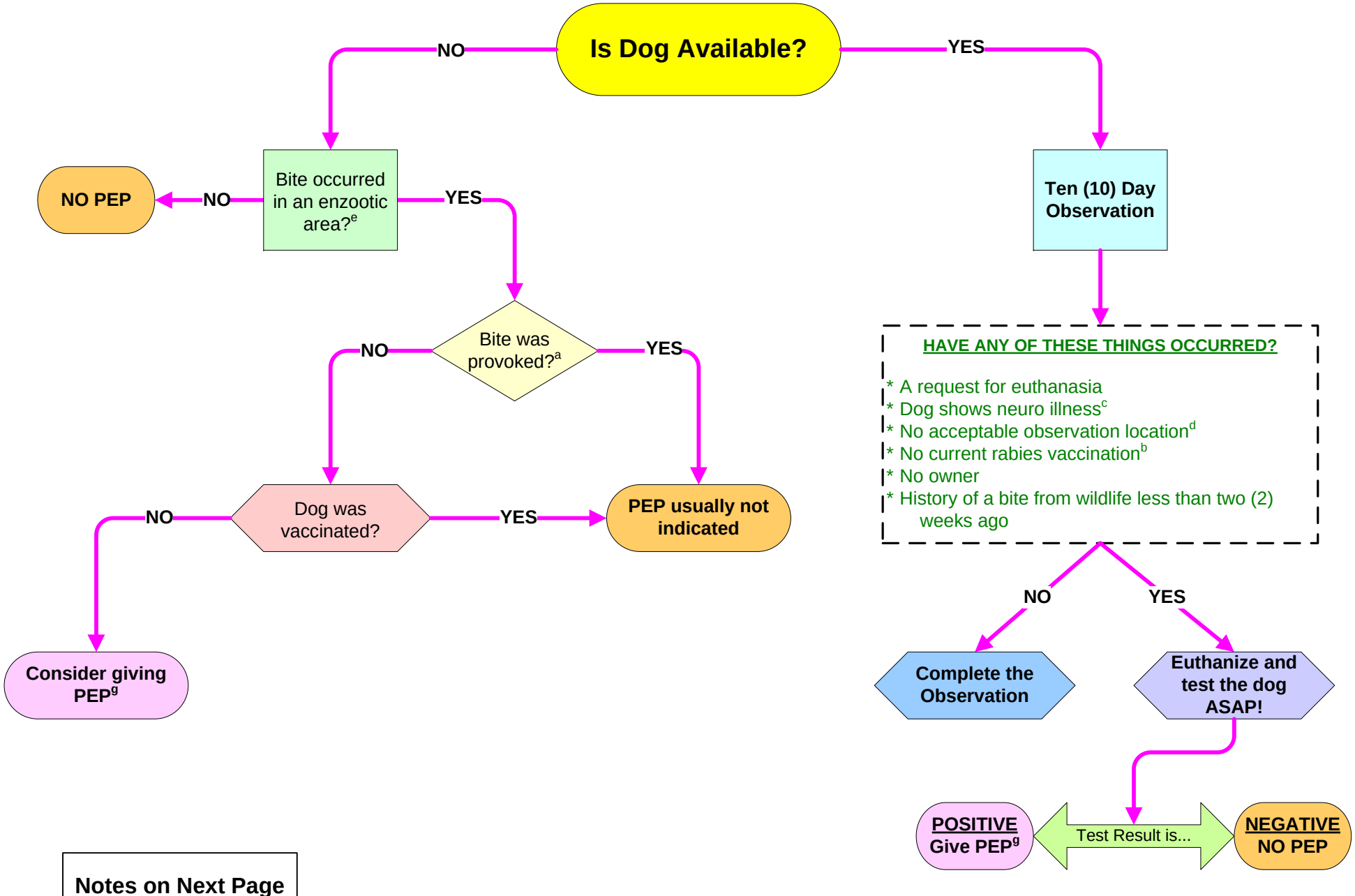
5. Animal available for testing or quarantine:	Yes	X–can wait for results
	No	X

Rationale: If the brain from the animal that bit the patient is available to be tested, PEP can be delayed until test results are available. The Alaska State Virology Laboratory will usually have results available within 24 hours of receiving an animal head. If substantial delays are anticipated or the animal has a high likelihood of being rabid, PEP can be instituted knowing that treatment can be discontinued when results are available. In circumstances where an animal is unlikely to be rabid and is not exhibiting signs of illness, the animal may be placed under quarantine instead of euthanized for testing. The animal is quarantined for 10 days and if alive and healthy at the end of the quarantine period, considered to be free of rabies. Animals must have virus in their saliva to infect another animal/human. Virus appears in the saliva after it has traveled through the central nervous system to the brain. Therefore, when animals are infectious they are days away from death. Ten days is a very generous estimate for how long an animal would survive after the time they began to exhibit clinical signs.

6. Vaccination status of human:	Yes	X
	No	X

Rationale: Even if a human has already been vaccinated against rabies, this would not preclude receiving PEP. However, PEP for vaccinated persons consists of only two doses of vaccine given at days 0 and 3. Persons who have received the pre-exposure series since 1977 (when human diploid cell vaccine became licensed) are considered fully vaccinated.

Risk Assessment for Dog Bites in Alaska



Notes on Next Page

Notes for Animal Bite Risk Assessment

a. Rabies enzootic areas are the northern and western parts of the State for foxes. See N drive for database of all animals tested at ASVL since 1971. There has only ever been one bat positive for rabies and that was in the Glacier Bay region. For the purposes of bat exposures, southeastern Alaska would be considered a higher risk area than the rest of Alaska, although still not technically "enzootic." Per CDC, if a bat is found indoors and there is no history of bat-human contact, rabies post-exposure prophylaxis (PEP) can be considered for persons who were in the *same room* as the bat and who might be unaware that a bite or direct contact had occurred (e.g., a sleeping person awakens to find a bat in the room or an adult witnesses a bat in the room with a previously unattended child, mentally disabled person, or intoxicated person); and rabies cannot be ruled out by testing the bat.

   When determining "enzootic" status, it is also important to ask about the travel history of the animal. For example, a dog that was diagnosed with rabies in Anchorage in 1992 had recently been brought in from Cold Bay. Dogs and cats that travel internationally, interstate via airplane, and intrastate via any public transport, must have proof of a valid rabies vaccine.

b. "Provocation" can occur in numerous ways. Obvious provocation would be reaching into a car window to pet a dog, or pushing/hitting an animal to make it retreat. Subtle acts can also provoke a dog. For example, pedaling a bike might excite a dog to bite at a person's moving feet, or walking too close to a chained dog might make a dog feel threatened enough to lash out and bite.

c. Any animal under a 10-day observation period that shows signs of illness or aberrant behavior should be euthanized IMMEDIATELY and submitted for rabies evaluation.

d. Optimally, observation or quarantine should occur at an official animal control facility; however, these are not widely available. If an animal's owner can adequately confine an animal for the full 10 day-period, this is usually acceptable. Animal control authorities—Village Public Safety Officers or Environmental Health Officers—must make an individual assessment in conjunction with Epidemiology for each situation. For home quarantines, the designated animal control authority must be in regular contact with the owner to ensure that the animal is confined and not showing signs of illness. If acceptable quarantine cannot be arranged, the animal should be euthanized and submitted for testing.

e. To be considered fully vaccinated, an animal must have received a series of two vaccines that have been given at least a year apart; with the first one given after the animal was 12 weeks of age. Although full or partial vaccination prevents rabies in the vast majority of domestic animals, proof of vaccination does not automatically ensure that an animal did not contract the disease. The rabid dog from Cold Bay had actually received one rabies vaccine; however, it was administered at 12 weeks of age while the dog was undergoing treatment for a severe gunshot wound.

f. All rabies testing is conducted at the State Virology Laboratory in Fairbanks. See attached documents regarding protocol for specimen submission. Testing is not always warranted. For example, an unvaccinated dog hit by a car, in a non-enzootic rabies area, that subsequently bites a person trying to touch it, would not generally need to be tested. Epidemiology should be consulted to determine whether it is necessary to test these animals.

g. PEP will only be released to a health care provider after consultation with Epidemiology staff. For instances where health care providers do not agree with the decision reached by the Epidemiology risk assessment, Epidemiology can document its decision in writing and refer the provider to PEP manufacturers to order product on their own. See N drive for template of a letter.

Rabies, Animal

1997 Case Definition

Laboratory criteria for diagnosis

A positive direct fluorescent antibody test (preferably performed on central nervous system tissue)
Isolation of rabies virus (in cell culture or in a laboratory animal)

Case classification

Confirmed: a case that is laboratory confirmed

Rabies, Human

1997 Case Definition

Clinical description

Rabies is an acute encephalomyelitis that almost always progresses to coma or death within 10 days after the first symptom.

Laboratory criteria for diagnosis

Detection by direct fluorescent antibody of viral antigens in a clinical specimen (preferably the brain or the nerves surrounding hair follicles in the nape of the neck), or
Isolation (in cell culture or in a laboratory animal) of rabies virus from saliva, cerebrospinal fluid (CSF), or central nervous system tissue, or
Identification of a rabies-neutralizing antibody titer greater than or equal to 5 (complete neutralization) in the serum or CSF of an unvaccinated person.

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed

Comment

Laboratory confirmation by all of the above methods is strongly recommended.

ANIMAL BITE INVESTIGATION FORM Date: ___ / ___ / _____

Name of person reporting: _____ Phone: (____) ____ - _____

Name of person bitten/exposed: _____ Phone: (____) ____ - _____

Sex: M F DOB: ___ / ___ / _____ Parent: _____

Where did the incident occur: Geographic location: _____

Descriptive location (e.g., in yard or house, etc.): _____

Date and time of bite/exposure: ___ / ___ / _____

Describe injuries (e.g., body site, puncture vs. scratch, etc.): _____

_____

Did the patient seek medical care? Y N Provider's name and contact info: _____

Describe circumstances of bite/exposure: _____

Animal that bit: Dog Fox Cat Other: _____

Owner's name: _____ Phone: (____) _____ - _____

Date of animal's most recent valid rabies vaccine: ___ / ___ / _____

How was animal behaving prior to the bite? _____

Witnessed by whom? _____ Phone: (____) _____ - _____

NOTE: DECISION FOR PEP SHOULD BE BASED UPON **ALL** CRITERIA LISTED BELOW.

		Consider PEP	PEP not likely indicated
Geographic location:	Enzootic area	X	
	Non-enzootic area		X
Type of animal:	Dog, fox, etc.	X	
	Small rodent, shrew vole squirrel		X
Circumstance of bite:	Provoked		X
	Unprovoked	X	
Rabies vaccine status:	None	X	
	Current		X
	Out of date	X	
Available for testing:	Yes	X +/- wait for results before shipping PEP	
	No	X	

Fax Completed Form to the Section of Epidemiology
Fax Number: (907) 562-7802

STATE OF ALASKA

DEPT. OF HEALTH AND SOCIAL SERVICES

DIVISION of PUBLIC HEALTH

FRANK H. MURKOWSKI, GOVERNOR

ALASKA STATE VIROLOGY LABORATORY
Rm 239 AHB, 901 Koyukuk Dr., South
P.O. BOX 60230
FAIRBANKS, ALASKA 99706-0230
PHONE: (907) 474-7017
FAX: 907-474-4036

RABIES INVESTIGATION REPORT
(Must be Completed and Submitted with Specimen)

PERSON BITTEN/EXPOSED: Please fill out one form for each person exposed. The Section of Epidemiology provides consultation about rabies exposures as a result of animal bites. **IF A PERSON HAS BEEN BITTEN, EPIDEMIOLOGY MUST BE CONTACTED BEFORE A SPECIMEN IS SUBMITTED: (907) 269-8000; after hours (800) 478-0084.**

Name_____ Weight_____ DOB/Age_____ Sex_____

Address_____ Phone #_____

Date bitten or attacked_____ Part of body affected_____

Describe injury_____

Has the person been to the doctor/hospital? (Circle) Yes No If yes, date_____

Dr/healthcare provider name_____ Phone #_____

SPECIMEN:

Animal species_____ Age_____ Sex_____ Weight/size_____ Color_____

If dog/cat, date of last rabies vaccination_____ Who vaccinated animal?_____

Name of animal's owner_____ Phone #_____

How did the attack happen?_____

How did the animal act before and after the attack? _____

Were any other animals bitten by this animal? (Circle) Yes No If yes, how many?_____

Who are their owners and where are they now?_____
(If you have any more information, write on back of this sheet)

Other information about the state of the animal being submitted? (E.g., head been burned, mutilated, presence of porcupine quills, etc.)_____

PERSON SENDING SPECIMEN:

Name_____ Date_____

Address_____ Phone #_____

To whom shall the laboratory report be sent? _____

ASVL PHONE #: **Weekdays: 8:00am to 4:30pm: (907) 474-7017 or 7018**
Weekends, evenings, or holidays: (907) 269-5520, pager # 0902

(Form 06-1272) rev 2/05

STATE OF ALASKA

FRANK H. MURKOWSKI, GOVERNOR

DEPT. OF HEALTH AND SOCIAL SERVICES

DIVISION of PUBLIC HEALTH

ALASKA STATE VIROLOGY LABORATORY
ROOM 239 ARCTIC HEALTH BUILDING
901 KOYUKUK DRIVE
P.O. BOX 60230
FAIRBANKS, ALASKA 99706-0230
PHONE: (907) 474-7017
FAX: 907-474-4036

INSTRUCTIONS FOR RABIES ASSAY SPECIMEN SUBMISSION

Rabies laboratory services are provided through the Alaska State Virology Laboratory (ASVL) in Fairbanks. To ensure accurate and reliable reports, please follow the directions listed below.

1. Specimens will be accepted from physicians and other healthcare providers, veterinarians, environmental health officers, wildlife agents, law officers, or other individuals designated by the Alaska Division of Public Health.

2. Rabies laboratory examinations will be limited to warm-blood animals for which there is a clear or possible history of **human exposure**, or animals deemed necessary by public health or wildlife authorities. **Please contact the Section of Epidemiology for authorization prior to submitting specimens involved in human exposures.** Call (907) 269-8000, or after hours call (800) 478-0084.

3. **Notify ASVL prior to shipping of authorized rabies specimens.** During normal work hours, call (907) 474-7017 or 7018; after-hours call pager (907) 269-5520, pager # 0902.

4. **A completed Rabies Investigation Report (Form 06-1272), must accompany each specimen.**

5. Conditions of shipment:
   a. No **LIVING ANIMAL** will be accepted for rabies diagnostic studies.

   b. **Do NOT shoot the animal in the head** or **mutilate the head in any way.**

   c. Wear gloves when handling the animal. Send head and part of the neck of large animals, such as dogs, foxes, wolves, and lynx. Leave sufficient tissue attached to the head/neck region to ensure inclusion of the salivary glands. No other part of the animal should be submitted.

   d. Small animals, such as mice, voles, and bats may be sent intact if recently dead, **BUT ONLY** after consultation with either ASVL or Section of Epidemiology staff.

   e. Specimens should be kept cold (35-45°F) prior to shipping. Ship specimens with refrigerant packs; **do not use ice.** Frozen specimens are acceptable; freezing will not affect the rabies assay although testing may be delayed until the specimen can be thawed. If there is a chance for the specimen to be delayed in transit to the Laboratory or if ambient temperatures are high, ASVL recommends freezing the specimen to ensure that the tissue remains in satisfactory condition.

6. Packing:
   a. Wear gloves when handling the animal.

   b. Wrap the head in absorbent material and place into **TWO** heavy, watertight plastic bags. Tie the bags tightly to prevent leakage.

c. Place the packaged head in a leak-proof container, packed next to a refrigerant pack.

d. Remove the gloves and either, burn the gloves, or enclose them with the head for disposal. Then wash hands thoroughly with soap.

e. Seal the carton securely with packing tape and include the Rabies Investigation Report.

f. Carcasses of infected animals should preferably be incinerated, or buried.

7. Labeling and shipping:

a. All rabies specimens must bear the following label:

DIAGNOSTIC SPECIMEN
PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650
THIS PACKAGE CONTAINS AN ANIMAL HEAD
REGRIGERATE ON ARRIVAL

b. Address all shipments to:

Alaska State Virology Laboratory
Rm 239 AHB, 901 Koyukuk Drive, South
Or P.O. Box 60230 if sending by mail service
Fairbanks, AK 99706-0230
(907) 474-7017

Ship specimens by **AIR FREIGHT** or **AIR SPECIAL PACKAGE SERVICE**. If mail service must be used, send via **PRIORITY MAIL**, **SPECIAL DELIVERY**, or **EXPRESS MAIL**, if available.

c. Shipments must be **PREPAID** unless prior arrangement has been made with Epidemiology.

d. Contact ASVL and advise on the method of routing and the airway bill number, etc.

e. Specimens may be brought directly to the ASVL office in Fairbanks. Call 474-7018 for directions.

8. Reports:

a. Preliminary fluorescent microscopic report will be called on all **POSITIVE** animal heads, and **ALL HUMAN EXPOSURE** cases within 24-48 hours after specimen receipt and confirmation. Copies of the report will be mailed to the submitter.

b. An interim written report will be forwarded upon the completion of the fluorescent microscopic (FA) examination. When a mouse inoculation test (MI) is performed, this final report will be forwarded subsequent to completion of a 28-day observation period.

FROM:

_____

_____

_____

URGENT EXPEDITE

DIAGNOSTIC SPECIMEN

Packed in Compliance with IATA Packing Instruction 650

This Package Contains an Animal Head

KEEP REFRIGERATED

ALASKA STATE VIROLOGY LABORATORY
239 AHB, 901 KOYUKUK DRIVE
P.O. BOX 60230
FAIRBANKS, AK 99706-0230

Phone: **474-7017 or 474-7018**

STATE OF ALASKA
DEPARTMENT OF HEALTH & SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY
3601 C STREET, SUITE 540
P.O. BOX 240249
ANCHORAGE, ALASKA 99524-0249
FRANK H. MURKOWSKI, GOVERNOR
INFECTIOUS DISEASES
AIDS/STD
TUBERCULOSIS
IMMUNIZATION
CHRONIC DISEASES
DIABETES
INJURY CONTROL
(907) 269-8000
(907) 562-7802

Routing Animal Bite and Possible Rabies Exposure Questions

As many may already know, Don Ritter, Manager at the Alaska State Virology Laboratory (ASVL) in Fairbanks, retired on June 30, 2004, after about **four decades** of state service. He served as a resource all hours of the day and night for questions about rabies distribution in Alaska wildlife, rabies testing of domestic animals, and required or recommended follow-up for humans who were bitten by animals. While many capable professionals continue to work at ASVL, due to staffing changes, ASVL may not always be able to field your questions and especially in cases that involve animal bites to humans, would prefer that calls be routed directly to the Section of Epidemiology. It is always appropriate to refer a person who has been bitten by an animal to their healthcare provider for medical evaluation and rabies risk assessment. Healthcare providers are required to report suspected exposures to rabies to the Section of Epidemiology.

This document is intended to answer some frequently-asked questions and assist you in locating the most appropriate resource for your questions.

Background Information

- All dog bites in and of themselves are **not** reportable to the Section of Epidemiology; however, dog bites **may** be reportable to local animal control authorities depending on the presence of local ordinances.
- By State Regulation 7 AAC 27.005, confirmed rabies cases, but more commonly, suspicion of exposures to rabies, are required to be reported to the Alaska Section of Epidemiology by all healthcare providers.
- By State Regulation 7 AAC 27.020, the Section of Epidemiology adopts the NASPHV Compendium of Animal Rabies Prevention and Control as a guidance document. Specific details for impounding or euthanizing animals for purposes of rabies control and prevention are found in Section (c) of the above-cited regulation.
- By State Regulation 7 AAC 27.030, dogs and cats must be vaccinated against rabies if they are to travel on public **intrastate** transportation.

Frequently Asked Questions or Common Scenarios

1) You would like to have an animal (head) evaluated for rabies (no human has been bitten or otherwise directly exposed to the animal's saliva).

Contact ASVL at (907) 474-7017/7018 during normal working hours. Non-human exposure specimens from rabies enzootic areas are processed as time permits. Contact ASVL for instructions on packing and shipping animal heads, copies of the required forms for submission, and also to inform ASVL of the estimated time of arrival of the package.

2) **Dog/cat has bitten a human and a local animal control agency exists in your area.**
Contact local animal control for assistance on quarantine. Animals with current rabies vaccinations should be placed in a 10-day quarantine. Animals **without** current rabies vaccinations **may** be euthanized immediately and tested for rabies; or placed in a 10-day quarantine after the conclusion of which, they should be vaccinated against rabies. If an animal under quarantine exhibits unusual behavior or illness, it should be euthanized immediately and submitted for rabies testing. Contact the Section of Epidemiology if this occurs, and make arrangements with ASVL as for A1 above for shipment of the head. If any question exists about the need for testing, carcasses can be frozen. Freezing does not affect the results of the rabies assay; however, it may delay processing because the assay must be done on thawed tissue.

3) **Dog/cat has bitten a human; no local animal control agency exists in the area.**
Contact the local public safety authority (e.g., State Trooper or Village Public Safety Officer) or regional Office of Environmental Health (if within a Native health corporation service area). Also contact the Section of Epidemiology for consultation about the exposure and to assist in locating acceptable agencies/personnel for performing animal control functions. Depending on several factors, (e.g., bite scenario, geographic location of incident, vaccination status of animal, etc.), the animal may be euthanized immediately and submitted for rabies testing, or placed under quarantine.

4) **Dog/cat is aggressive/fractious and may cause additional harm while under quarantine; also owners do not want to keep the animal. Under what circumstances can quarantine be bypassed?**
In most cases, animals should be euthanized and submitted to ASVL for rabies evaluation. However, in some circumstances, testing may not be warranted. For example, a healthy animal that is hit by a car, and subsequently bites a human who is trying to handle the injured animal, may sometimes be euthanized immediately and not tested for rabies, especially if this occurs in a rabies non-enzootic area of Alaska. Contact the Section of Epidemiology for more information about rabies distribution in the state and for guidance on managing these scenarios.

5) **What are vaccination and health requirements for pets and/or livestock being imported to, or exported from, Alaska?**
Contact the Office of the State Veterinarian (Dr. Bob Gerlach) at (907) 375-8200 for domestic requirements and for international requirements contact Dr. Mike Philo at (907) 349-0125. Information may also be found at the following web addresses:

Domestic travel http://www.aphis.usda.gov/vs/sregs/
International travel http://www.aphis.usda.gov/vs/ncie/exp-pets.html

Please feel free to contact the Section of Epidemiology or the Alaska State Virology Laboratory at any time if you have additional questions:

- **Section of Epidemiology (907) 269-8000; after-hours (800) 478-0084**
- **ASVL (907) 474-7017/7018; after-hours (907) 269-5520, pager #0902**

Reporting Requirements

- FTR: Write-up all outbreaks of animal rabies that resulted in significant human exposure(s).
- Compile single treatment sheets with case investigation forms and place in the Rabies Folder in the ID Cases Drawer.
- Morbidity database: Enter all laboratory-confirmed rabid animals and humans.

CDC Case Definition is used to define confirmed cases of rabies; there is no official CDC definition of a “probable” human case.

Possible Human Rabies --Patient Information Form

A copy of this form must accompany diagnostic specimens.
Send completed form to:

Rabies Unit
MS G-33
Centers for Disease Control and Prevention
Atlanta, Georgia 30333

FAX: Attn: Rabies EIS Officer
404-639-1564

Please print the following form and fill it out as completely as possible. The first three sections are required (Patient Information, Symptoms, and Laboratory Findings).

Patient Information:

Date (mm/yy/yy)	
Physician's name	
Physician's phone number	
Patient's name	
Gender	☐ **Female** ☐ **Male**
Patient's date of birth	
Occupation	

Symptoms:

Which of the following symptoms have been present? Mark all that apply.

	Yes	**No**	**Unknown**
Fever	☐	☐	☐
Malaise	☐	☐	☐
Headache	☐	☐	☐
Nausea/vomiting	☐	☐	☐
Anxiety	☐	☐	☐
Muscle spasm	☐	☐	☐
Dysphagia	☐	☐	☐
Anorexia	☐	☐	☐
Ataxia	☐	☐	☐
Priapism	☐	☐	☐

Seizures	☐	☐	☐
Aerophobia	☐	☐	☐
Hydrophobia	☐	☐	☐
Localized weakness	☐	☐	☐
Localized pain/paraesthesia	☐	☐	☐
Confusion or delirium	☐	☐	☐
Agitation/combativeness	☐	☐	☐
Autonomic instability	☐	☐	☐
Hyperactivity	☐	☐	☐
Hallucnations	☐	☐	☐
Insomnia	☐	☐	☐
Hypersalivation	☐	☐	☐

Laboratory Findings:

Peripheral WBC (with diff):	**On admission**	**x10^3/µl**
	neutrophils	%
	lymphocytes	%
	monocytes	%
	bands	%
	Highest	x10^3/µl
	neutrophils	%
	lymphocytes	%
	monocytes	%
	bands	%
Chemistry:	**Glucose**, serum	mg/dl
	Total protein, serum	g/dl
	CPK, serum - total	U/l
	Isoenzymes - MM	%
	MB	%
	BB	%

CSF Findings:	**RBC**	/µl
	WBC	/µl
	neutrophils	%
	lymphocytes	%
	monocytes	%
	bands	%
	Glucose	mg/dl
	Protein	mg/dl

Culture Results:

Additional abnormal laboratory values:

Additional pertinent clinical information:

Additional Information:

Location of residence at time of onset:	☐ 1.Urban ☐ 2. Suburban ☐ 3. Rural
City State	
Has the patient traveled to any foreign country in the past six months?	
Country 1	Number of weeks
Country 2	Number of weeks
Any suspicious animal exposures?	☐ Yes ☐ No
Date of exposure (mm/dd/yy):	
Species involved in **most recent exposure**:	☐ Dog
	☐ Cat
	☐ Raccoon
	☐ Skunk
	☐ Fox
	☐ Bat

	☐ Other, specify:
Type of exposure:	☐ Bite
	☐ Nonbite (scratch)
	☐ Nonbite (contact only)
	☐ No known exposure
	☐ Unknown
City and state of most recent exposure:	
Species involved in **previous exposure**:	☐ Dog
	☐ Cat
	☐ Raccoon
	☐ Skunk
	☐ Fox
	☐ Bat
	☐ Other, specify
Date of exposure (mm/dd/yy):	
Type of exposure:	☐ Bite
	☐ Nonbite (scratch)
	☐ Nonbite (contact only)
	☐ No known exposure
	☐ Unknown
City and state of previous exposure:	
First symptoms:	
Date of illness onset:	
Outpatient visit date (mm/dd/yy):	
Outpatient diagnosis:	
Hospitalized?	☐ Yes ☐ No
Date of hospitalization (mm/dd/yy):	
Admitting diagnoses:	

Is /was patient in a coma?	☐ Yes ☐ No
Date of coma onset (mm/dd/yy):	
Has patient expired?	☐ Yes ☐ No
Date of death (mm/dd/yy):	
Current differential diagnosis:	

Rashes

Rashes

Definition: Skin redness or inflammation, a change in the color and texture of the skin.

Considerations:

- Cause of the rash can often be determined from its visible characteristics and other symptoms associated with its occurrence. However, descriptions of rashes are notoriously inconsistent. Request digital photographs of the rash when possible.
- **Epi is interested in rashes of public health importance where investigation will lead to control measures to stop the outbreak and prevent morbidity among contacts.**
- Two rash illnesses are reportable: measles and rubella.
- See **Varicella**
- See **Smallpox (in the Bioterrorism Section)**

Common Causes:

- A simple rash is called dermatitis, i.e. contact dermatitis caused by things your skin touches, such as dyes and chemicals found in clothing; chemicals found in elastic, latex, and rubber products; cosmetics, soaps, and detergents; poison ivy, oak, or sumac.
- Examples of other rashes include: eczema (atopic dermatitis), psoriasis, impetigo, measles, roseola, rubella, fifth disease, hand-foot-mouth disease.
- Medical conditions that cause rashes: lupus erythematosus, rheumatoid arthritis, Kawasaki disease are a few.

Important Questions:

When did the rash begin?
What parts of the body are affected?
Does anything make the rash better? Worse?
Describe the rash: color, size of area affected, raised or flat, size of spots.
Has the person used any new soaps, detergents, lotions, cosmetics?
Has the person been in woods or hiking lately?
Change in medications?
Has the person noticed a tick or insect bite?
Has the person eaten anything unusual lately?
Foreign travel?
What are symptoms? Itching, scaling?
What underlying medical problems does the person have?
Asthma or allergies?

Acute, Generalized Vesicular or Pustular Rash Illness Testing Protocol in the United States

Introduction

This protocol has been developed to illustrate the types of laboratory testing to be undertaken in different situations involving patients with acute, generalized vesicular or pustular rash illness. The protocol is composed of four charts, each illustrating a different set of symptoms or circumstances. It has been designed to correlate with "Evaluating Patients for Smallpox: Acute, Generalized Vesicular or Pustular Rash Illness Protocol" (www.bt.cdc.gov/agent/smallpox/diagnosis/riskalgorithm).

Chart 1 lists the symptoms associated with acute, generalized vesicular or pustular rash illness and categorizes the risk of smallpox according to the patient's signs and symptoms.

Chart 2 presents a flow chart for laboratory testing of specimens from patients presenting with acute generalized vesicular or pustular rash illness. A two-armed algorithm is presented to reduce the time to receive results and to ensure that testing of high-risk specimens is confined to laboratories with appropriate biosafety levels and expertise. The two arms of the testing algorithm are for 1) specimens from individuals with low- and moderate-risk symptoms and 2) specimens from individuals with high-risk symptoms.

Chart 3 presents a testing algorithm that should be used when a smallpox vaccine adverse event or monkeypox infection is suspected.

Chart 4 presents an orthopoxvirus testing algorithm for environmental samples.

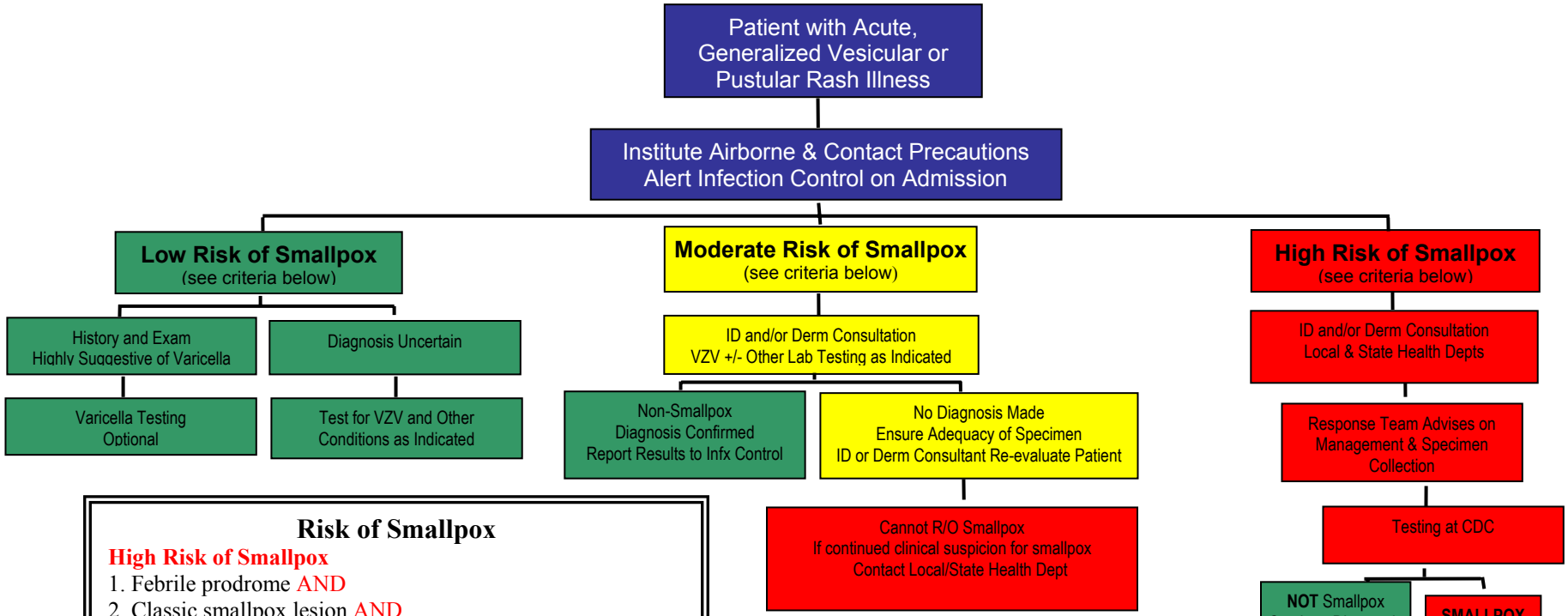
The testing protocols are supported at Laboratory Response Network (LRN) reference laboratories. Details for performance and interpretation of each assay are specified in each LRN procedure.

Details on specimen collection can be found at the following websites:

- Smallpox vaccine: www.bt.cdc.gov/agent/smallpox/vaccination/vaccinia-specimen-collection.asp
- Smallpox: www.bt.cdc.gov/agent/smallpox/response-plan/files/guide-d.pdf
- Monkeypox: www.cdc.gov/ncidod/monkeypox/diagspecimens.htm

Chart 1. Acute, Generalized Vesicular or Pustular Rash Illness Protocol

From the "CDC Protocol for Evaluating Patients for Smallpox" at www.bt.cdc.gov/agent/smallpox/diagnosis/evalposter.asp



Risk of Smallpox

High Risk of Smallpox

1. Febrile prodrome AND
2. Classic smallpox lesion AND
3. Lesions in same stage of development

Moderate Risk of Smallpox

Febrile prodrome AND one other MAJOR smallpox criterion

OR

Febrile prodrome AND ≥4 MINOR smallpox criteria

Low Risk of Smallpox

No febrile prodrome

OR

Febrile prodrome AND <4 MINOR smallpox criteria

Major smallpox criteria:

- Febrile prodrome
  - >101F, 1-4 days prior to rash onset
  - with headache, back ache, or abdominal pain
- Firm, deep seated, well circumscribed vesicles/pustules
- Lesions in the same stage of development in any one area of the body

Minor smallpox criteria:

- Centrifugal distribution
- First lesions in the pharynx, oral mucosa
- Patient appears "toxic"
- Slow evolution of rash
  - 1-2 days each stage: macule, papule, vesicle
- Lesions on the palms and soles

Chart 2. Laboratory Testing for Acute, Generalized Vesicular or Pustular Rash Illness in the United States

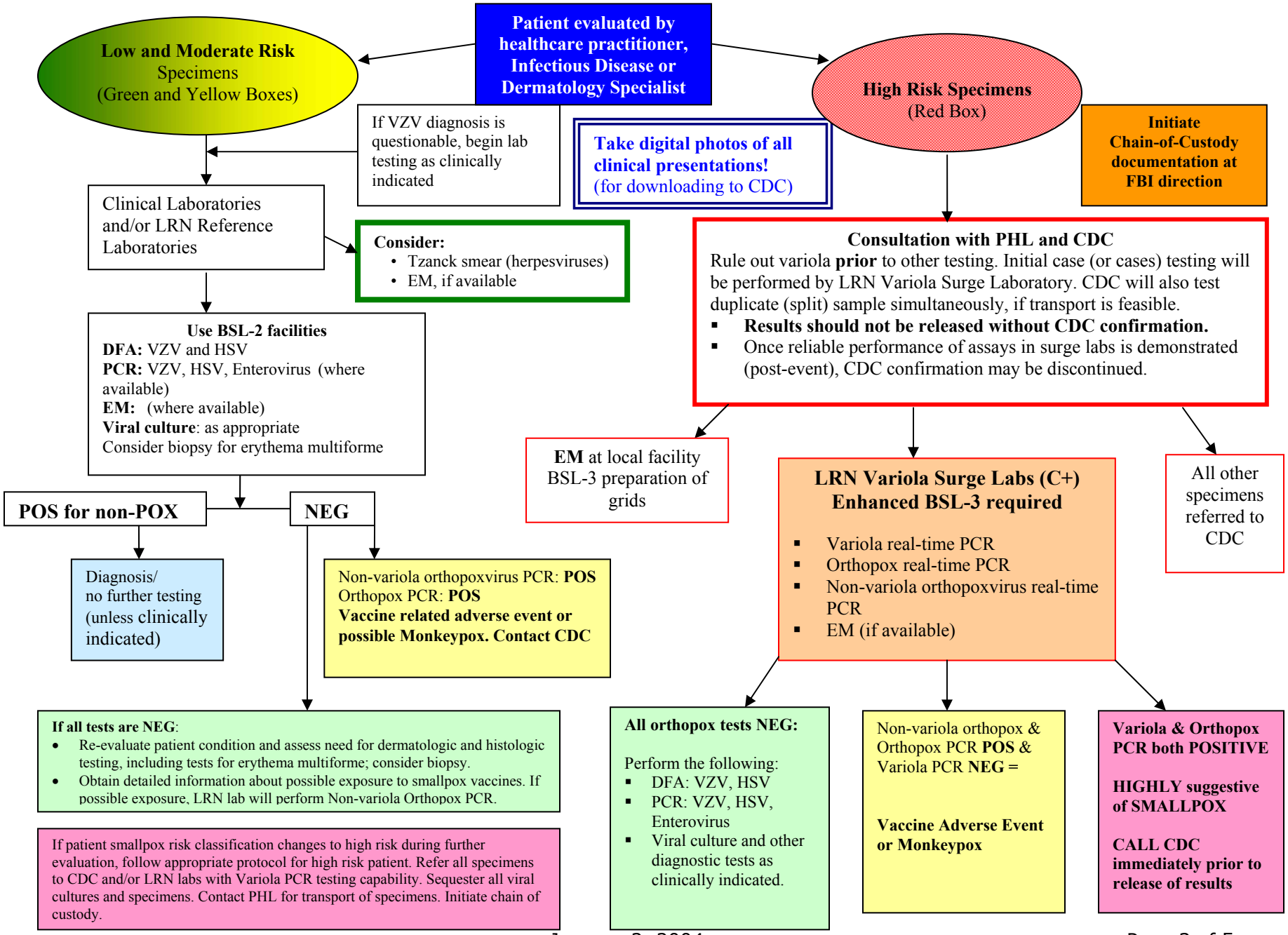


Chart 3. Laboratory Testing for Suspected Smallpox Vaccine (Vaccinia) Adverse Events or Monkeypox in the United States

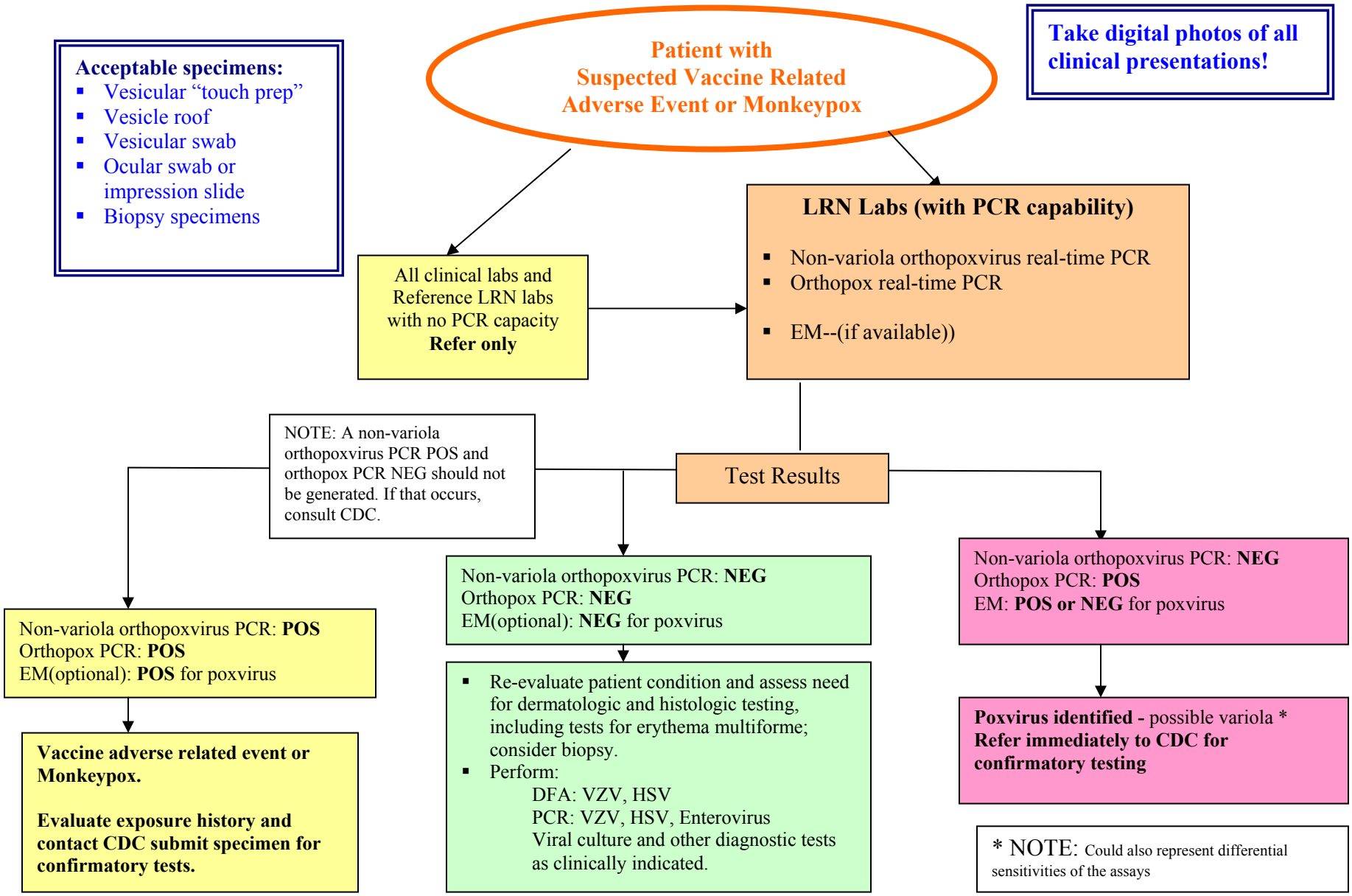
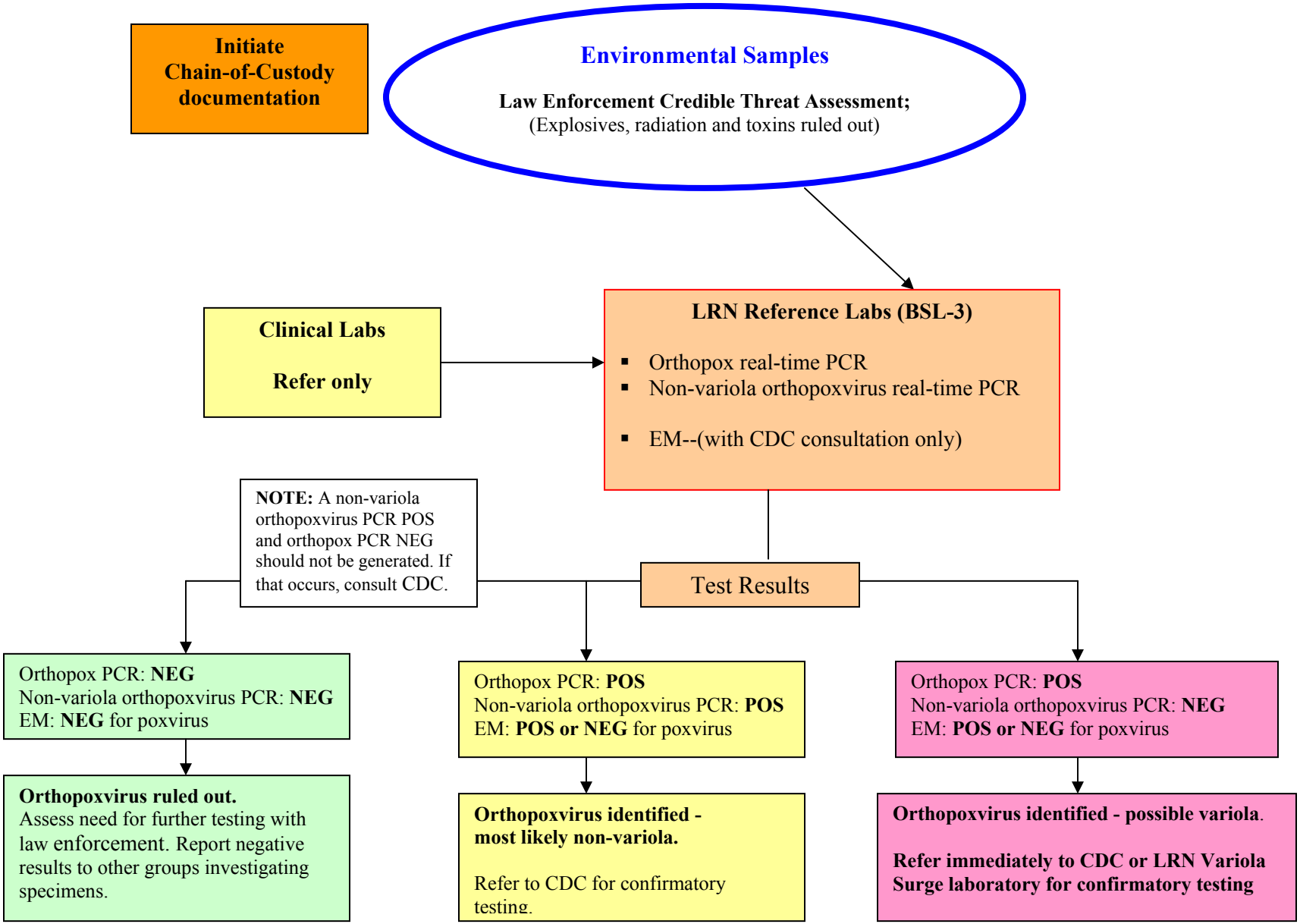


Chart 4. Laboratory Testing for Environmental Samples in the United States



Measles

(Rubeola, red or hard measles)

Organism: RNA virus with 1 serotype, a member of the genus *Morbillivirus* and the Paramyxovirus family**.**

Incubation period: About 10 days, but can be shorter or longer when first symptoms appear, the prodromal period. The rash usually appears 4 days after initial symptoms**.**

Infectious period: From 1 day before the beginning of the prodromal period, which is about 4 days before the rash appears, until 4 days after the appearance of the rash.

Transmission route: Respiratory via direct droplet contact from inhalation of nasopharyngeal secretions. Usually occurs during the late winter and spring. Direct contact with secretions on tissues, drinking glasses, cups, or other surfaces. One of the most highly infectious diseases.

Treatment: Comfort measures. Exclude from childcare, school, work for 4 days prior to rash until 4 days after onset of rash.

Information Needed for the Investigation

Verify the Diagnosis

- Is there a history of prodromal symptoms: temperature of 101°F or higher, cough, coryza, conjunctivitis, and an erythematous maculopapular rash lasting 3 days or more? Are there small spots with white or bluish white centers on an erythematous base on the buccal mucosa (Koplik spots)?

Determine the Extent of Illness

- Complete **Rash Questionnaire**.
  (Note: When interviewing during a measles outbreak, use the more specific **Measles Questionnaire.)**
- Request a digital photo of the rash.
- Determine immunization status, recent travel, or other sites of potential exposure.
- Develop a line list of close contacts and their immunization status.
- Check if patient attends school, childcare, work, and has participated in other social activities. Instruct to stay home until 5th day of rash.
- Notify the Regional Nurse Manager, the local Public Health Nurse, healthcare provider, or infection control person (ICP).

Laboratory Specimens

- Collect 1 tube of blood in serum separator tube or red top tube to test for measles IgG and IgM antibody (2 ml of serum is needed). Repeat draw on day 4 of rash for IgM. Centrifuge and refrigerate; do not freeze.
- Obtain nasopharyngeal and throat swabs (Dacron®) < 5days after rash onset and no later than 5 days after. Put in VTM. Refrigerate; do not freeze. Submit within 48 hours of collection.
- Obtain 50-100 ml of urine <5 days after rash onset and no later than 16 days, for culture. Refrigerate; do not freeze. Submit within 24 hours of collection.
- All specimens should be sent to the State Virology Lab in Fairbanks.
- Measles IgM antibody can usually be detected in serum samples collected one, two, or three days after rash onset. Follow-up samples to initially negative samples are not required unless measles is still suspected.
- Notify the virology lab as soon as possible, preferably when the decision is made to collect samples. (The cell line used to culture measles virus from URT swabs or urine requires several days to prepare from frozen stock.)

Contact and Control Measures

- Contacts born before 1957 are considered immune by disease.
- **Isolate** suspect 4 days prior to rash until 4 days after onset of rash and susceptible contacts on day 5-21 post-exposure.
- Vaccinate those persons who are unvaccinated with 2 doses of MMR, 4 weeks apart. If given within 72 hours of exposure can provide protection.
- Pregnant women and immunocompromised individuals who have been exposed need to be referred to their healthcare provider.
- IG may be used within 6 days of exposure for susceptible household or other high-risk individuals (such as those < 12 months old).
    - Dose is 0.25ml/kg up to maximum of 15 ml for healthy individuals; for immunocompromised dose is 0.50 ml/kg, up to maximum of 15 ml.
- Notify Immunization Program.
- Possible complications of measles include: otitis media, bronchopneumonia, croup, acute encephalitis resulting in permanent brain damage, and subacute sclerosing panencephalitis (SSPE), a rare degenerative nervous system disease that can occur 10-11 years after infection. A person with SSPE is not infectious.

Reporting Requirements

- FTR: write up all confirmed cases.
- Morbidity Database: enter all confirmed and probable cases.
- CDC Case Definition is used to define confirmed and probable cases.

Measles Surveillance Worksheet

APPENDIX 7

NAME (Last, First)				Hospital Record No.
Address (Street and No.)	City	County	Zip	Phone
Reporting Physician/Nurse/Hospital/Clinic/Lab	Address			Phone

---------- DETACH HERE and transmit only lower portion if sent to CDC ----------

Measles Surveillance Worksheet

County | State | Zip

Birth Date (Month Day Year)

Age (Unk = 999)

Age Type
0 = 0-120 years
1 = 0-11 months
2 = 0-52 weeks
3 = 0-28 days
9 = Age unknown

Ethnicity
H = Hispanic
N = Not Hispanic
U = Unknown

Race
N = Native Amer./Alaskan Native
A = Asian/Pacific Islander
B = African American
W = White
O = Other
U = Unknown

Sex
M = Male
F = Female
U = Unknown

Event Date (Month Day Year)

Event Type
1 = Onset Date
2 = Diagnosis Date
3 = Lab Test Done
4 = Reported to County
5 = Reported to State or MMWR Report Date
9 = Unknown

Outbreak Associated (Unk = 999)

Reported (Month Day Year)

Imported
1 = Indigenous
2 = International
3 = Out of State
9 = Unknown

Report Status
1 = Confirmed
2 = Probable
3 = Suspect
9 = Unknown

CLINICAL DATA

Any Rash? Y = Yes, N = No, U = Unknown

Rash Onset (Month Day Year)

Rash Duration 0 - 30 Days, 99 = Unknown

Rash Generalized? Y = Yes, N = No, U = Unknown

Fever? Y = Yes, N = No, U = Unknown

If Recorded, Highest Measured Temp. 36.0 - 110.0 degrees, 999.9 = Unknown

Cough? Y = Yes, N = No, U = Unknown

Coryza? Y = Yes, N = No, U = Unknown

Conjunctivitis? Y = Yes, N = No, U = Unknown

COMPLICATIONS

Otitis? Y = Yes, N = No, U = Unknown

Diarrhea? Y = Yes, N = No, U = Unknown

Pneumonia? Y = Yes, N = No, U = Unknown

Encephalitis? Y = Yes, N = No, U = Unknown

Thrombocytopenia? Y = Yes, N = No, U = Unknown

Death? Y = Yes, N = No, U = Unknown

Other Complications? Y = Yes, N = No, U = Unknown

Hospitalized? Y = Yes, N = No, U = Unknown

Days Hospitalized 0 - 998, 999 - Unknown

If Yes, Please Specify:

LABORATORY

Was Laboratory Testing For Measles Done? Y = Yes, N = No, U = Unknown

Date IgM Specimen Taken (Month Day Year)

Result
P = Positive
N = Negative
I = Indeterminate
E = Pending
X = Not Done
U = Unknown

Date IgG Acute Specimen Taken (Month Day Year)

Date IgG Convalescent Specimen Taken (Month Day Year)

Result
P = Significant Rise in IgG
N = No Significant Rise in IgG
I = Indeterminate
E = Pending
X = Not Done
U = Unknown

Other Lab Result
P = Positive
N = Negative
I = Indeterminate
E = Pending
X = Not Done
U = Unknown

Specify Other Lab Method:

VACCINE HISTORY

Vaccinated? (Received measles-containing vaccine?) Y = Yes, N = No, U = Unknown

If Not Vaccinated, What Was The Reason? (See Reason Codes Below)

Vaccination Date (Month Day Year)	Vaccine Type	Vaccine Manuf	Lot Number

(See Type and Manuf. Codes Below)

Number of doses received BEFORE 1st birthday

Number of doses received ON or AFTER 1st birthday

If vaccinated BEFORE 1st birthday, but no doses given ON or AFTER 1st birthday, what was the reason?

If received one dose after 1st birthday, but never received 2nd dose after 1st birthday, what was the reason?

Reason Codes
1 = Religious Exemption
2 = Medical Contraindication
3 = Philosophical Objection
4 = Lab. Evidence of Previous Disease
5 = MD Diagnosis of Previous Disease
6 = Under Age For Vaccination
7 = Parental Refusal
8 = Other
9 = Unknown

Vaccine Type Codes
A = MMR
B = Measles
O = Other
U = Unknown

Vaccine Manuf. Codes
M = Merck
O = Other
U = Unknown

EPIDEMIOLOGIC INFORMATION

Date First Reported to a Health Department (Month Day Year)

Date Case Investigation Started (Month Day Year)

Transmission Setting (Where did this case acquire measles?)
1 = Day Care
2 = School
3 = Doctor's Office
4 = Hospital Ward
5 = Hospital ER
6 = Hospital Outpatient Clinic
7 = Home
8 = Work
9 = Unknown
10 = College
11 = Military
12 = Correctional Facility
13 = Church
14 = International Travel
15 = Other

Outbreak Related? Y = Yes, N = No, U = Unknown

If Yes, Outbreak Name

Source of Exposure For Current Case (Enter State ID if source was an in-state case; enter Country if source was out of US; enter State if source was out-of-state)

Were Age and Setting Verified? (Is age appropriate for setting, i.e. aged 49 years and in day care, etc.) Y = Yes, N = No, U = Unknown

If Transmission Setting Not Among Those Listed And Known, What Was The Transmission Setting?

Epi-Linked to Another Confirmed or Probable Case? Y = Yes, N = No, U = Unknown

Is Case Traceable Within 2 Generations to an International Import? Y = Yes, N = No, U = Unknown

Indicates epidemiologically important items not yet on NETSS screen

Contact Information: (For statistical health department use)

Mother's Name	Father's Name
Phone	

---------- DETACH HERE ----------

The information below is epidemiologically important, but not included on NETSS screens

Activity History For 18 Days Before Rash Onset and 7 Days After Rash Onset
Day -18
Day -17
Day -16
Day -15
Day -14
Day -13
Day -12
Day -11
Day -10
Day -9
Day -8
Day -7
Day -6
Day -5
Day -4
Day -3
Day -2
Day -1
Day 0 (Rash Onset)
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Clinical Case Definition*: A generalized rash lasting ≥ 3 days, a temperature ≥ 101.0° F (≥38.3° C), and cough, coryza, or conjunctivitis.
Case Classification*: Suspected: Any febrile illness accompanied by rash. Probable: A case that meets the clinical case definition, has noncontributory or no serologic or virologic testing, and is not epidemiologically linked to a confirmed case. Confirmed: A case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically-linked to a confirmed case. A laboratory-confirmed case does not need to meet the clinical case definition.

STATE OF ALASKA
DEPARTMENT OF HEALTH & SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY
3601 C STREET, SUITE 540
P.O. BOX 240249
ANCHORAGE, ALASKA 99524-0249
FRANK H. MURKOWSKI, GOVERNOR
INFECTIOUS DISEASES
AIDS/STD
TUBERCULOSIS
IMMUNIZATION
CHRONIC DISEASES
DIABETES
INJURY CONTROL
(907) 269-8000
(907) 562-7802

Measles Fact Sheet

(rubeola, red or hard measles)

What is measles?
Measles is a highly contagious rash illness caused by a virus of the genus *Morbillivirus* in the *Paramyxovirus* family. Complications from measles such as ear infections, pneumonia, croup, encephalitis, seizures, and death can occur.

How do you get it?
Anyone who has not had measles previously or who has not received the vaccine can get measles. Direct exposure to secretions from the nose or throat of a person with the disease can cause measles. Transmission occurs when a person with measles coughs or sneezes and airborne droplets are in the air for another person to breathe. Airborne transmission can occur for up to 2 hours after a person with measles has been in a closed area. It spreads rapidly and easily.

What are the symptoms of measles?
The symptoms usually occur in 2 stages. The first stage commonly begins with a runny nose, red watery eyes, fever, and cough. A red blotchy rash appears in the second stage, starting on the face and spreading down the body to the arms and legs and usually lasts for about 4-6 days.

When do symptoms start?
The fever, runny nose, and cough usually appear 10 days after exposure, but can appear as late as 18 days after exposure. The rash appears 3 to 7 days after the onset of the first symptoms.

When and for how long is a person able to spread measles?
Measles can be spread from one day before the onset of cold-like symptoms through the fourth day of the rash.

What is the treatment for measles?
There is no specific treatment for measles. Rest and symptomatic treatment is best for uncomplicated cases.

Should a person with measles be excluded from work or school?
Yes, for 4 days after the onset of the rash.

If you get measles once, can you get it again?
No. Adults born before 1957 are usually immune because they had measles as a child.

How can you keep from getting it?
Measles vaccine (in the form of MMR or MR or measles only vaccines) can prevent measles.

Measles (Rubeola)

1990 Case Definition

Clinical case definition

An illness characterized by all of the following clinical features:

a generalized rash lasting greater than or equal to 3 days
a temperature greater than or equal to 38.3°C (101°F)
cough, or coryza, or conjunctivitis

Laboratory criteria for diagnosis

Isolation of measles virus from a clinical specimen, or
Significant rise in measles antibody level by any standard serologic assay, or
Positive serologic test for measles IgM antibody

Case classification

Suspect: any rash illness with fever

Probable: meets the clinical case definition, has no or noncontributory serologic or virologic testing, and is not epidemiologically linked to a probable or confirmed case

Confirmed: a case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically linked to a confirmed or probable case. A laboratory-confirmed case does not need to meet the clinical case definition.

Comment

Two probable cases that are epidemiologically linked would be considered confirmed, even in the absence of laboratory confirmation. Only confirmed cases should be reported to the NNDSS.

Rubella
(German measles, 3 Day Measles)

Organism: Togavirus of the genus *Rubivirus.*

Incubation period: 16 to 18 days.

Infectious period: 7 days before and 7 days after the onset of the rash.

Transmission route: Respiratory via direct droplet contact from inhalation of nasopharyngeal secretions. Fomite transmission from touching tissues or sharing drinking glass, cup, bottle used by someone with rubella.

Treatment: Comfort measures. Children must be excluded from childcare or school for 7 days after the onset of rash. Infants born with congenital rubella syndrome (CRS) should be considered contagious until they are at least 1 year old, unless nasopharyngeal and urine cultures are repeatedly negative for rubella virus.

Information Needed for the Investigation

Verify the Diagnosis

- Was there an acute onset of generalized maculopapular rash, a temperature of > 99 F (37.2 C) together with arthralgia/arthritis, lymphadenopathy (postauricular lymph nodes) or conjunctivitis? Was there an exposure to a confirmed case? Rash may be very faint, fine, or lacy.

Determine the Extent of Illness

- Complete **Rash Questionnaire**.
- Request a digital photo of the rash.
- Determine immunization status, recent travel, and potential exposure.
- Develop a line list of close contacts and their immunization status.
- Check if patient attends school, childcare, work, and has participated in other social activities. Instruct patient to stay home for 7 days after onset of rash.
- Contact the Regional Nurse Manager, the local Public Health Nurse, healthcare provider, infection control person (ICP).

Laboratory Specimens

- Collect red top or serum separator tube (SST) of blood to test for rubella IgG & IgM as soon as possible, within 7-10 days after onset of illness and again 14-21 days later.
- The best acute serum specimen to rule rubella in or out is a sample drawn at least four days after rash onset for rubella IgM.
- Obtain nasopharyngeal and throat swabs (Dacron®) 7 days before to 14 days after rash onset. Put in VTM. Refrigerate; do not freeze. Submit within 48 hours.

- Obtain 50-100 ml of urine in sterile cup, seal with Parafilm®. Refrigerate; do not freeze. Submit within 24 hours of collection. Maximum viral shedding occurs up to day 4 after rash onset.
- All specimens should be sent to the State Virology Lab in Fairbanks.

Contact and Control Measures

- Exclude persons from school, work, and childcare for 7 days after the onset of rash.
- Define at-risk population and vaccinate with MMR if unvaccinated and not contraindicated.
- Draw serum on any pregnant woman whose rubella status is unknown and who is a contact. Repeat in 2-3 weeks to check for rise in antibody titer. Refer to Obstetrician.
- Infants born with congenital rubella syndrome (CRS) should be considered contagious until they are at least 1 year old, unless NP and urine cultures are repeatedly negative for rubella virus.
- Notify Immunization Program.
- Rubella is dangerous because of its ability to damage an unborn baby, causing CRS, which may include: deafness, cataracts, heart defects, liver and spleen damage and mental retardation.

Reporting Requirements

- FTR: write up outbreak cases.
- Morbidity Database: enter all confirmed and probable cases.
- Complete Rash Questionnaire and place in file folder.
- CDC Case Definition is used to define confirmed and probable cases.

STATE OF ALASKA
DEPARTMENT OF HEALTH & SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY
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DIABETES
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(907) 269-8000
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Rubella Fact Sheet

(German Measles)

What is rubella?
Rubella is a fever-producing, rash illness caused by a virus of the *Rubivirus* genus. The illness is usually mild, but if it occurs during the first 3 months of pregnancy, it can cause serious defects in the unborn child. Rubella occurs more often in the winter and spring months.

How do you get it?
You get rubella by exposure to airborne droplets from the nose or throat from a person infected with rubella virus. Rubella can also be transmitted by direct contact.

What are the symptoms of rubella?
The symptoms include rash, low-grade fever, body and joint aches, headache, runny nose and reddened eyes. Painful swelling of the lymph nodes at the back of the neck often precedes development of the skin rash. The rash, which lasts for 3 days or less, usually starts on the face and spreads from head to foot. Up to 50 percent of individuals who get the disease do not develop a rash. Many persons with rubella may have few or no symptoms.

When do symptoms start?
The symptoms usually start 16 to 18 days following exposure to the rubella virus, but the onset can range from 14 to 23 days.

For how long is a person contagious?
A person is contagious from 7 days before, to 7 days after, the onset of rash.

If you get rubella once, can you get it again?
No. Having the disease once protects you against repeated infection.

Is there a vaccine for rubella?
Yes. Rubella vaccine is usually given in a combination measles-mumps-rubella (MMR) vaccine at 1 year old.

What happens if you get rubella?
The disease is most serious if a woman is infected in the first 3 months of pregnancy because it can cause complications to the unborn baby. These complications, called congenital rubella syndrome (CRS), can include deafness, mental retardation, heart defects, cataracts, or death.

Should a person with rubella be excluded from school or work?
Yes, for 7 days after onset of rash.

How can you keep from getting it?
Get vaccinated. All women of childbearing age should be vaccinated for rubella before getting pregnant.

Rubella (German measles)

1996 Case Definition

Clinical case definition

An illness that has all the following characteristics:

Acute onset of generalized maculopapular rash
Temperature greater than 99.0 F (greater than 37.2 C), if measured
Arthralgia/arthritis, lymphadenopathy, or conjunctivitis

Laboratory criteria for diagnosis

Isolation of rubella virus, or
Significant rise between acute- and convalescent-phase titers in serum rubella immunoglobulin G antibody level by any standard serologic assay, or
Positive serologic test for rubella immunoglobulin M (IgM) antibody

Case classification

Suspected: any generalized rash illness of acute onset

Probable: a case that meets the clinical case definition, has no or noncontributory serologic or virologic testing, and is not epidemiologically linked to a laboratory-confirmed case

Confirmed: a case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically linked to a laboratory-confirmed case

Comments

Serum rubella IgM test results that are false positives have been reported in persons with other viral infections (e.g., acute infection with Epstein-Barr virus [infectious mononucleosis], recent cytomegalovirus infection, and parvovirus infection) or in the presence of rheumatoid factor. Patients who have laboratory evidence of recent measles infection are excluded.

Rubella, Congenital Syndrome

1999 Case Definition

Clinical description

Presence of any defect(s) or laboratory data consistent with congenital rubella infection. Infants with congenital rubella syndrome usually present with more than one sign or symptom consistent with congenital rubella infection. However, infants may present with a single defect. Deafness is most common single defect.

Laboratory criteria for diagnosis

Isolation of rubella virus, or
Demonstration of rubella-specific immunoglobulin M (IgM) antibody, or
Infant rubella antibody level that persists at a higher level and for a longer period than expected from passive transfer of maternal antibody (i.e., rubella titer that does not drop at the expected rate of a twofold dilution per month).
PCR positive rubella virus

Clinical case definition

An illness, usually manifesting in infancy, resulting from rubella infection *in utero* and characterized by signs or symptoms from the following categories:
a) Cataracts/congenital glaucoma, congenital heart disease (most commonly patent ductus arteriosus or peripheral pulmonary artery stenosis), hearing impairment, pigmentary retinopathy.
b) Purpura, hepatosplenomegaly, jaundice, microcephaly, developmental delay, meningoencephalitis, radiolucent bone disease.

Case classification

Suspected: A case with some compatible clinical findings but not meeting the criteria for a probable case.

Probable: A case that is not laboratory confirmed and that has any two complications listed in paragraph “a” of the clinical case definition or one complication from paragraph “a” and one from paragraph “b”, and lacks evidence of any other etiology.

Confirmed: A clinically consistent case that is laboratory confirmed.

Infection only: A case that demonstrates laboratory evidence of infection, but without any clinical symptoms or signs.

Note

In probable cases, either or both of the eye-related findings (cataracts and congenital glaucoma) count as a single complication. In cases classified as infection only, if any compatible signs or symptoms (e.g., hearing loss) are identified later, the case is reclassified as confirmed.

Alaska Note

The Alaska State Virology Lab does not have the ability to isolate rubella virus.

Rubella Surveillance Worksheet

NAME (Last, First)				Hospital Record No.
Address (Street and No.)	City	County	Zip	Phone
Reporting Physician/Nurse/Hospital/Clinic/Lab	Address			Phone

---------- DETACH HERE and transmit only lower portion if sent to CDC ----------

Rubella Surveillance Worksheet

County	State	Zip	Country of Birth

Birth Date (Month Day Year)

Age (Unk = 999)

Age Type
0 = 0-120 years
1 = 0-11 months
2 = 0-52 weeks
3 = 0- 28 days
9 = Age unknown

Ethnicity
H = Hispanic
N = Not Hispanic
U = Unknown

Race
N = Native Amer./Alaskan Native
A = Asian/Pacific Islander
B = African American
W = White
O = Other
U = Unknown

Sex
M = Male
F = Female
U = Unknown

Event Date (Month Day Year)

Event Type
1 = Onset Date
2 = Diagnosis Date
3 = Lab Test Date
4 = Reported to County
5 = Reported to State or MMWR Report Date
9 = Unknown

Outbreak Associated (Unk = 999)

Reported (Month Day Year)

Imported
1 = Indigenous
2 = International
3 = Out of State
9 = Unknown

Report Status
1 = Confirmed
2 = Probable
3 = Suspect
9 = Unknown

CLINICAL DATA

Any Rash? Y = Yes, N = No, U = Unknown

Rash Onset (Month Day Year)

Rash Duration 0 - 30 Days, 99 = Unknown

Fever? Y = Yes, N = No, U = Unknown

If Recorded, Highest Measured Temp. 36.0 - 110.0 Degrees, 999.9 = Unknown

Arthralgia/ Arthritis? Y = Yes, N = No, U = Unknown

Lymphadenopathy? Y = Yes, N = No, U = Unknown

Conjunctivitis? Y = Yes, N = No, U = Unknown

COMPLICATIONS

Encephalitis? Y = Yes, N = No, U = Unknown

Arthralgia/Arthritis? Y = Yes, N = No, U = Unknown

Thrombocytopenia? Y = Yes, N = No, U = Unknown

Death? Y = Yes, N = No, U = Unknown

Other Complications? Y = Yes, N = No, U = Unknown

If Yes, Please Specify:

Hospitalized? Y = Yes, N = No, U = Unknown

Days Hospitalized 0 - 998, 999 - Unknown

LABORATORY

Was Laboratory Testing For Rubella Done? Y = Yes, N = No, U = Unknown

Date IgM Specimen Taken (Month Day Year)

Result
P = Positive E = Pending
N = Negative X = Not Done
I = Indeterminate
U = Unknown

Date IgG Acute Specimen Taken (Month Day Year)

Date IgG Convalescent Specimen Taken (Month Day Year)

Result
P = Significant Rise in IgG
N = No Significant Rise in IgG
I = Indeterminate
E = Pending
X = Not Done
U = Unknown

Other Lab Result
P = Significant Rise in IgG
N = No Significant Rise in IgG
I = Indeterminate
X = Not Done
E = Pending
U = Unknown

Specify Other Lab Method:

VACCINE HISTORY

Vaccinated? (Received rubella-containing vaccine?) Y = Yes, N = No, U = Unknown

Vaccination Date (Month Day Year)	Vaccine	Vaccine Type	Manuf.	Lot Number

Vaccine Type Codes
A = MMR
B = Rubella
O = Other
U = Unknown

Vaccine Manufacturer Codes
M = Merck
O = Other
U = Unknown

Number of doses received ON or AFTER 1st birthday

If Not Vaccinated, What Was The Reason?
1 = Religious Exemption
2 = Medical Contraindication
3 = Philosophical Objection
4 = Lab. Evidence of Previous Disease
5 = MD Diagnosis of Previous Disease
6 = Under Age For Vaccination
7 = Parental Refusal
8 = Other
9 = Unknown

EPIDEMIOLOGIC

Date First Reported to a Health Department (Month Day Year)

Date Case Investigation Started (Month Day Year)

Outbreak Related? Y = Yes, N = No, U = Unknown

If Yes, Outbreak Name

Transmission Setting (Where did this case acquire rubella?)
1 = Day Care
2 = School
3 = Doctor's Office
4 = Hospital Ward
5 = Hospital ER
6 = Hospital Outpatient Clinic
7 = Home
8 = Work
9 = Unknown
10 = College
11 = Military
12 = Correctional Facility
13 = Church
14 = International Travel
15 = Other

If Other, Specify Transmission Setting:_____

Were Age and Setting Verified? (Is age appropriate for setting, i.e. aged 49 years and in day care, etc.) Y = Yes, N = No, U = Unknown

Source of Exposure For Current Case (Enter State ID if source was an in-state case; enter Country if source was out of U.S.; enter State if source was out-of-state)

Epi-Linked to Another Confirmed or Probable Case? Y = Yes, N = No, U = Unknown

Indicates epidemiologically important items not yet on NETSS screen

---------- DETACH HERE and transmit only lower portion if sent to CDC ----------

PREGNANT WOMEN

Was The Case Pregnant?

☐ Y = Yes
N = No
U = Unknown

Number of Weeks Gestation (or Trimester) at Onset of Illness ☐☐☐

1st = First Trimester
2nd = Second Trimester
3rd = Trimester

Or

1 = 1 Week
2 = 2 Weeks
3 = 3 Weeks
Etc. – continue up to 45 weeks

Prior Evidence of Serological Immunity?

☐ Y = Yes
N = No
U = Unknown

Year of Test ☐☐☐☐

OR

Age of Patient at Time of Test ☐☐

0 -50
99 - Unknown

Was Previous Rubella Serologically Confirmed?

☐ Y = Yes
N = No
U = Unknown

Year of Disease ☐☐☐☐

OR

Age of Patient at Time of Disease ☐☐

0 -50
99 - Unknown

The information below is epidemiologically important but not included on NETSS screens

Exposure Period — **Period of Communicability**

21 Days — 14 Days — 7 Days — Rash Onset — 7 Days

Month	Day	Year	Month	Day	Year	Month	Day	Year	Month	Day	Year	Month	Day	Year
☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐

Contacts to case in case's infectious period (7 days before to 7 days after rash onset) who are in 1st 5 months of pregnancy

Name	Address/Phone	Documented Prior Rubella Immunization?	If Yes, Date	Documented Rubella Seropositivity Before Or Within 7 Days After First Exposed	If No or Unknown, Action Taken – Rubella Serology, etc.
		☐ Y = Yes N = No U = Unknown	Month ☐☐ Day ☐☐ Year ☐☐	☐ Y = Yes N = No U = Unknown	
		☐ Y = Yes N = No U = Unknown	Month ☐☐ Day ☐☐ Year ☐☐	☐ Y = Yes N = No U = Unknown	
		☐ Y = Yes N = No U = Unknown	Month ☐☐ Day ☐☐ Year ☐☐	☐ Y = Yes N = No U = Unknown	

Group contacts to case in case's infectious period (7 days before to 7 days after rash onset), i.e., households, child care center, school, college, workplace, jail/prison, physician's office/clinic/hospital/emergency room, etc.

Name of Group/Site	Address/Phone	Notes

Clinical Case Definition:
An illness that has all of the following characteristics: acute onset of generalized maculopapular rash, temperature > 99° F (> 37° C), if measured, and arthralgia/arthritis, lymphadenopathy, or conjunctivitis.

Case Classification:
***Suspected*: any generalized rash illness of acute onset**
***Probable*: a case that meets the clinical case definition, has no or noncontributory serologic or virologic testing, and is not epidemiologically linked to a laboratory-confirmed case**
***Confirmed*: a case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically linked to a laboratory-confirmed case**

The **Congenital Rubella Syndrome Case Report Form** in PDF format is available at this website:

http://www.cdc.gov/niP/publications/surv-manual/app17_rub_case_rpt.pdf

It has been copy-protected and could not be included in this manual.

SARS

Severe Acute Respiratory Syndrome (SARS)

Organism: SARS coronavirus (SARS-CoV)

Incubation period: 2 to 10 days, median 4 to 6

Infectious period: Believed to begin with the onset of symptoms and continue for 10 days after resolution of fever and clinical improvement.

Transmission route: Primarily droplet. Airborne transmission has been reported from aerosolization of respiratory secretions and stool. Fomites and animal vectors may be involved in transmission.

Treatment: Supportive.

Information Needed for Investigation

Important – Before responding to questions about SARS or SARS-CoV testing, review the current situation report at http://www.cdc.gov/ncidod/sars/index.htm.

Is investigation indicated?
The early symptoms of SARS are non-specific. Illness usually begins with fever, headache, and myalgias. Cough and dyspnea develop within 2 to 7 days of the onset of illness. By day 7 to 10, most people with SARS have radiographic evidence of pneumonia. No test exists to reliably detect SARS-CoV early in the course of the illness.

In the absence of documented person to person transmission of SARS anywhere in the world, surveillance is limited to **adults** who:

1. Require hospitalization for radiologically confirmed pneumonia or acute respiratory distress syndrome without identifiable etiology **AND**
2. Have one of the following risk factors in the 10 days before the onset of illness
    a. Travel to mainland China, Hong Kong, or Taiwan, or close contact with an ill person with a history of recent travel to one of these areas **OR**
    b. Employment in an occupation associated with a risk for SARS-CoV exposure (e.g., health care worker with direct patient contact; worker in a laboratory that contains live SARS-CoV), **OR**
    c. Part of a cluster of cases of atypical pneumonia without an alternative diagnosis.

Initiate the DHSS-DPH Communication Plan (see Annex ? in the DPH Emergency Operations Plan) whenever a SARS investigation is begun.

Evaluate Public Health Impact

- Obtain a full travel history for the 10 days before the onset of symptoms. Include flight numbers, airports, contact numbers for tour groups, hotel room numbers, and other details.
- Evaluate family members and close contacts for similar symptoms of illness. Consider hospitalization or voluntary home isolation of symptomatic contacts.
- Prepare a line listing of contacts after the onset of symptoms.

Laboratory Specimens

- See attached "Guidelines for collecting specimens form potential SARS patients" available online at http://www.cdc.gov/ncidod/sars/guidance/f/app4.htm
- Obtain informed consent for SARS-CoV testing as described in the attached "The consent process for SARS-CoV RT-PCR and EIA testing at CDC and public health laboratories" available online at http://www.cdc.gov/ncidod/sars/guidance/f/app3.htm
- Consult with the CDC about the appropriate specimen submission form.

Contact and Control Measures

- See infection control and isolation measures for various settings at http://www.cdc.gov/ncidod/sars/ic.htm
- SARS control activities are authorized under AS18.15.350.
- See also "SARS preparedness for rural health care facilities", available online at http://www.akepi.org/bulletins/catlist.jsp?cattype=SARS

Reporting requirements

- Immediate phone report to CDC when SARS is suspected.
- FTR: for all SARS investigations.

References

CDC Health Update: Update on SARS and Avian Influenza. June 10, 2004.

State of Alaska Epidemiology

Bulletin

Department of Health and Social Services
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Division of Public Health
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Bulletin No. 15 June 11, 2003

SARS Preparedness for Rural Health Care Facilities

Introduction

On April 7, 2003, the Alaska Section of Epidemiology worked with an Anchorage hospital to evaluate an individual reported as a possible case of Severe Acute Respiratory Syndrome (SARS).[1] On the same day, three other possible cases of SARS were ruled out based on the Centers for Disease Control and Prevention (CDC) case definition.[1] Since that time, the Section of Epidemiology has consulted with several health care providers to evaluate potential cases. To date, no laboratory confirmed cases of SARS have been identified in Alaska; however; two individuals meeting the CDC SARS case definition have been cared for at hospitals, one in Anchorage and one in Juneau.

Influenza, community acquired pneumonia, respiratory syncytial virus (RSV), and tuberculosis (TB) are common causes of fever and cough in Alaska. Evaluation for these conditions should be conducted before considering a SARS diagnosis. Although the risk of SARS in an Alaskan resident or tourist presenting with a cough and fever is currently low, all rural hospitals and clinics in Alaska should assure that systems are in place for evaluating and caring for an individual with possible SARS.

Policy development

Education: Rural health care providers should have access to up-to-date information about:

- The current SARS case definition,
- http://www.cdc.gov/ncidod/sars/casedefinition.htm
- The clinical presentation SARS, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5212a5.htm
- Geography of current SARS-affected areas, http://www.cdc.gov/ncidod/sars/travel.htm
- The use of contact and airborne precautions in the hospital, outpatient, and community setting, http://www.cdc.gov/ncidod/sars/ic.htm
- Additional training materials, including publications, Internet webcasts and slides can be found at: http://www.cdc.gov/ncidod/sars/training.htm

Infection Control: Rural health care facilities have limited resources to implement full SARS infection control precautions. However, the provider should implement precautions to the extent possible when caring for a possible SARS case. For example, 1) if a negative airflow room is not available, use a private room with the door closed and limited traffic in and out of the room; or 2) if providers do not have fit tested N95 personal respirators, a surgical mask is a backup option.

Information access: If a facility does not have Internet access, or if low speed access makes it difficult to use the CDC website, the organization may wish to designate one individual to fax or mail document updates to healthcare providers when they are revised.

Communication plan: Health care organizations may want to prepare a communication plan for notifying key people (including local health authorities, tribal health administrators, and medical directors) and employees designated to work with the media for SARS and other potentially newsworthy conditions.

Recommendations

1. Supplies and equipment

- Fit test health care providers who may provide direct care to a SARS patient using a N-95 respirator or higher.
- Stock adequate supplies of personal protective equipment (N-95 respirators, disposable gloves, gowns, and eye protection) for all health care providers who may provide direct patient care to a SARS patient.
- Consider stocking supplies for SARS specimen collection, including dacron or rayon swabs, viral transport media, sterile vials, whole blood in a serum separator tubes, and purple top EDTA blood collection tubes. Refer to http://www.cdc.gov/ncidod/sars/lab.htm for details on specimen collection. The Section of Epidemiology will assist with specimen collection and transport of specimens.

2. Patient with fever and cough

- Provide the patient with a surgical mask if this can be tolerated. If the patient is unable to wear the mask, provide tissues and ask the patient to cover the nose and mouth while coughing.
- If possible, bring the patient to a single room as soon as possible. Close the door and turn off any fan or air circulation system that moves air from the room throughout the building.
- Take an initial history that includes a travel history for the 10 days before the onset of symptoms, including any airports the patient was in. Question the patient about contact with others with similar symptoms. If symptoms and history are consistent with SARS, consult with the clinical supervisor or medical director and review the SARS case definition.

3. Patient meeting SARS case definition

- Contact the Section of Epidemiology at 907-269-8000 or 1-800-478-0084 (after hours) if a patient meets the current SARS case definition.
- If the patient is being transported to a hub hospital or larger facility for evaluation, notify the receiving facility about the possible diagnosis of SARS prior to transport. When possible, the patient may travel by private automobile. If a medivac or ambulance transport is necessary, notify the transport crew and receiving facility that SARS is suspected.
- Transport by commercial aircraft or ferry is not recommended for persons with possible SARS. Consult with the Section of Epidemiology prior to travel.
- Patients with mild illness or who are in the recovery phase of SARS can be isolated at home or in some other outpatient setting, using CDC guidelines: http://www.cdc.gov/ncidod/sars/closecontacts.htm. Facilities with dormitories or bunkhouses should designate a place, such as an isolated room with an outdoor entrance or a private home, where people with respiratory illnesses can stay to reduce the risk of transmission to others. Consult the Section of Epidemiology about daily follow-up for patients on self-isolation.

Reference:
1. Severe Acute Respiratory Syndrome: Evaluation and Diagnosis. *Bulletin* No. 7, April 21, 2003. Section of Epidemiology, Division of Public Health, Department of Health and Social Services, State of Alaska, Anchorage, AK.

(Submitted by Susan Keady, RN, MS and Sue Anne Jenkerson, RNC, MSN, FNP, Alaska Section of Epidemiology.)

Supplement F: Laboratory Guidance

Appendix F3

Guidelines for Clinicians: The Consent Process for SARS-CoV RT-PCR and EIA Testing at CDC and Public Health Laboratories

Key Messages

- A consent form is recommended when submitting specimens for SARS-CoV reverse-transcription polymerase chain reaction (RT-PCR) or enzyme immunoassay (EIA) testing.
- Due to important public health concerns, if SARS-CoV testing is indicated, specimens will be tested even if a consent form is NOT received.
- A patient information sheet, informing patients about the tests and requesting permission for long-term storage of their specimen remainders, will be sent to the physician with the patient's test results. The physician should provide this document to the patient and return a signed copy to the local or state health department if consent for long-term specimen storage is obtained.

CDC has distributed a SARS-CoV RT-PCR assay (www.cdc.gov/ncidod/sars/lab/rtpcr/) under an FDA investigational device exemption (IDE) and an EIA assay (www.cdc.gov/ncidod/sars/lab/eia/) to state and local public health laboratories to test specimens for SARS-CoV. These tests are used to evaluate persons suspected of having SARS-CoV disease. The RT-PCR assay is used to test for SARS-CoV viral RNA in respiratory samples, stool, plasma, or serum. The EIA test is used to detect SARS-CoV antibodies in blood or serum specimens. A signed consent form for performance of each test is recommended because neither test has been licensed by the FDA and the RT-PCR test is being used under an FDA-approved IDE. A signed consent form is also required for storage of specimen remainders for future investigations.

To submit specimens for SARS-CoV RT-PCR or EIA testing, healthcare providers should follow these steps:

1. **Consult the state or local health department** to determine if SARS-CoV testing is indicated.
2. **Seek informed consent** from the patient for testing.
   The RT-PCR consent form can be found at:
   http://www.cdc.gov/ncidod/sars/lab/rtpcr/consent.htm.
   The EIA consent form can be found at:
   http://www.cdc.gov/ncidod/sars/lab/eia/consent.htm.
3. **Collect specimens** for testing. Guidelines for specimen collection are provided in Appendix F4.
4. **Submit specimens**, with a signed consent form and completed specimen submission form, to the state or local public health laboratory.

Guidelines for Clinicians: The Consent Process for SARS-CoV RT-PCR and EIA Testing at CDC and Public Health Laboratories

(continued from previous page)

Specimens will be tested at the reference public health laboratory. Final results will be reported to you through the state or local health department. Information on interpreting these test results is provided in Appendix F7.

5. **Deliver test results** to the patient. Provide a patient information sheet/consent for long-term specimen storage to the patient along with the test results. Specimen remainders stored long term may be used for future investigations.

   The RT-PCR patient information sheet/consent for long-term specimen storage can be found at: http://www.cdc.gov/ncidod/sars/lab/rtpcr/participant.htm.
   The EIA patient information sheet/consent for long-term specimen storage can be found at: http://www.cdc.gov/ncidod/sars/lab/eia/participant.htm.

6. **If a signed patient information sheet/consent for long-term storage is obtained, fax it** to the state or local public health department. Contact information is provided at http://www.cdc.gov/other.htm#states.

Frequently Asked Questions

Where can I find information on how to report a possible SARS case and submit specimens for SARS-CoV testing?
This information is available through the state or local health department. Contact information is provided at: http://www.cdc.gov/other.htm#states.

Why is a signed informed consent form recommended for SARS-CoV testing?
A signed consent form is recommended because neither the RT-PCR test nor the EIA test has been licensed by FDA and the RT-PCR test is being used under an FDA-approved investigational device exemption (IDE). In addition, consent is required to store specimen remainders for future investigations.

Why are there two different consent forms, one for RT-PCR and one for EIA?
Two forms are required because of differing IRB review requirements; CDC's IRB reviewed and approved two separate protocols.

What happens if I submit specimens for testing without a signed consent form?
Because of the potentially serious public health impact of SARS-CoV transmission, specimens that are received by a state or local public health laboratory without a signed consent form will still be tested.

What is the patient information sheet, and when do I use it?
The patient information sheet/consent for long-term specimen storage will be sent to the physician along with the patient's test results. The physician should provide this document to the patient. It explains to the patient why SARS-CoV testing was performed on their specimens, explains what the results mean, and asks the patient for permission to store specimen remainders for future investigations.

Why should a signed patient information sheet be returned?
The patient information sheet asks the patient for permission to store specimen remainders for future investigations. If a signed consent form is not received before testing, it is necessary to receive the signed patient information sheet to store any specimen remainders. Specimens without a signed informed consent or signed patient information sheet allowing long-term specimen storage must be destroyed.

For more information, visit www.cdc.gov/ncidod/sars or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

Supplement F: Laboratory Guidance

Appendix F4

Guidelines for Collecting Specimens from Potential SARS Patients

This document updates and replaces the guidelines for specimen collection posted previously on CDC's SARS website, to reflect the most recent information on laboratory diagnostics for SARS-CoV. The main changes are as follows:[1]

- Addition of stool, serum, and plasma to the list of specimens for RT-PCR testing
- Addition of information on the optimal timing of specimen collection and testing by specimen type
- Recommendation to collect multiple specimens for RT-PCR testing

[1] Pending IRB approval.

Key Messages

- Consult the state or local health department to determine the appropriateness and details of SARS testing.
- If possible, collect multiple specimens from different body sites and at different times during illness.
- A signed consent form is recommended when collecting specimens for SARS-CoV RT-PCR or antibody testing.

Before collecting and shipping specimens for SARS-CoV testing, consult with the state health department/state epidemiologist to determine whether the patient meets the SARS case definition. Health department contact information is available at: www.cste.org/members/state_and_territorial_epi.asp.

When possible, collect multiple respiratory specimens for testing. For example, collect specimens from two different sites on the same day (e.g., one nasopharyngeal swab and a stool specimen or another respiratory specimen) or from two different times during the illness. The chart on the last page specifies recommended specimen types for SARS-CoV diagnostics by stage of illness, including postmortem specimen collection.

A signed consent form is recommended when collecting specimens for SARS-CoV RT-PCR or antibody testing. Information on the consent process for collection of respiratory specimens, blood or stool for RT-PCR testing is provided at: www.cdc.gov/ncidod/sars/lab/rtpcr/index.htm. Information on the consent

(continued from previous page)

process for the collection of blood/serum for antibody testing is provided at: www.cdc.gov/ncidod/sars/lab/eia/index.htm.

RT-PCR Diagnostics

Although studies to date have not definitively determined the best specimens for SARS RT-PCR diagnostics, it is reasonable to collect:

During the first week of illness:	Nasophyaryngeal (NP) swab plus oropharyngeal (OP) swab and a serum or plasma specimen
After the first week of illness:	NP swab plus OP swab and a stool specimen

Serologic Diagnostics

Serum specimens for SARS-CoV antibody testing should be collected when the diagnosis is first suspected and at later times if indicated. An antibody response is occasionally detected during the first week of illness, likely to be detected by the end of the second week of illness, and sometimes may not be detected until >28 days after onset of symptoms.

I. Collecting Respiratory Specimens

Eight types of respiratory specimens may be collected for viral and/or bacterial diagnostics: 1) nasopharyngeal wash/aspirates, 2) nasopharyngeal swabs, 3) oropharyngeal swabs, 4) broncheoalveolar lavage, 5) tracheal aspirate, 6) pleural fluid tap, 7) sputum; and 8) post-mortem tissue. Nasopharyngeal wash/aspirates are the specimen of choice for detection of most respiratory viruses and are the preferred specimen type for children under age 2 years.

In contrast to most respiratory pathogens for which respiratory specimens are optimally collected within 72 hours after the onset of symptoms, levels of SARS-CoV may be higher later in the course of the illness.

Before collecting specimens, review the infection control precautions in Supplement I.

A. Collecting specimens from the upper respiratory tract

1. Nasopharyngeal wash/aspirate

Have the patient sit with head tilted slightly backward. Instill 1 ml-1.5 ml of nonbacteriostatic saline (pH 7.0) into one nostril. Flush a plastic catheter or tubing with 2 ml-3 ml of saline. Insert the tubing into the nostril parallel to the palate. Aspirate nasopharyngeal secretions. Repeat this procedure for the other nostril. Collect the specimens in sterile vials. Label each specimen container with the patient's ID number and the date collected. If shipping domestically, use cold packs to keep the sample at 4°C. If shipping internationally, pack in dry ice.

2. Nasopharyngeal or oropharyngeal swabs

Use only sterile dacron or rayon swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inactivate some viruses and inhibit PCR testing.

(continued from previous page)

Nasopharyngeal swabs -- Insert a swab into the nostril parallel to the palate. Leave the swab in place for a few seconds to absorb secretions. Swab both nostrils.
Oropharyngeal swabs -- Swab the posterior pharynx and tonsillar areas, avoiding the tongue.

Place the swabs immediately into sterile vials containing 2 ml of viral transport media. Break the applicator sticks off near the tip to permit tightening of the cap. Label each specimen container with the patient's ID number and the date the sample was collected. If shipping domestically, use cold packs to keep sample at 4°C. If shipping internationally, pack in dry ice.

B. Collecting specimens from the lower respiratory tract

1. Broncheoalveolar lavage, tracheal aspirate, pleural fluid tap

Centrifuge half of the specimen, and fix the cell pellet in formalin. Place the remaining unspun fluid in sterile vials with external caps and internal O-ring seals. If there is no internal O-ring seal, then seal tightly with the available cap and secure with Parafilm®. Label each specimen container with the patient's ID number and the date the sample was collected. If shipping domestically, use cold packs to keep sample at 4°C. If shipping internationally, ship fixed cells at room temperature and unfixed cells frozen.

2. Sputum

Educate the patient about the difference between sputum and oral secretions. Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile screw-cap sputum collection cup or sterile dry container. If shipping domestically, use cold packs to keep sample at 4°C. If shipping internationally, pack in dry ice.

II. Collecting Blood Components

Serum and blood (plasma) should be collected early in the illness for RT-PCR testing. The reliability of RT-PCR testing performed on blood specimens decreases as the illness progresses.

Both acute and convalescent serum specimens should be collected for antibody testing. To confirm or rule out SARS-CoV infection, it is important to collect convalescent serum specimens >28 days after the onset of illness.

A. Collecting serum for antibody or RT-PCR testing

Collect 5 ml-10 ml of whole blood in a serum separator tube. Allow the blood to clot, centrifuge briefly, and collect all resulting sera in vials with external caps and internal O-ring seals. If there is no internal O-ring seal, then seal tightly with the available cap and secure with Parafilm®. The minimum amount of serum preferred for each test is 200 microliters, which can easily be obtained from 5 mL of whole blood.

A minimum of 1 cc of whole blood is needed for testing of pediatric patients. If possible, collect 1 cc in an EDTA tube and in a clotting tube. If only 1cc can be obtained, use a clotting tube.

Label each specimen container with the patient's ID number and the date the specimen was collected. If unfrozen and transported domestically, ship with cold packs to keep the sample at 4°C. If frozen or transported internationally, ship on dry ice.

Guidelines for Collecting Specimens from Potential SARS Patients
(continued from previous page)

B. Collecting EDTA blood (plasma) for RT-PCR

Collect 5 ml-10 ml of blood in an EDTA (purple-top) tube. Transfer to vials with external caps and internal O-ring seals. If there is no internal O-ring seal, then seal tightly with the available cap and secure with Parafilm®. Label each specimen container with patient's ID number and date of collection. Store and ship blood specimens with cold packs to keep the sample at 4°C.

III. Collecting Stool Specimens for PCR

Begin collecting stool specimens as soon as possible in the course of the illness. Although collecting earlier specimens is ideal, SARS-CoV has been detected in stool as late as one month after the onset of symptoms.

Place each stool specimen -- as large a quantity as can be obtained (at least 10 cc) -- in a leak-proof, clean, dry container, and refrigerate at 4°C. Patients may drape plastic kitchen wrap across the back half of the toilet, under the toilet seat, to facilitate collection of stool specimens.

IMPORTANT: Refrigerate or freeze tubes after specimens are placed in them. If specimens will be examined within 48 hours after collection, they can be refrigerated. If specimens must be held longer than 48 hours, freeze them as soon as possible after collection. Although storage in an ultra-low freezer (-70°C) is preferable, storage in a home-type freezer (if properly set at -20°C) is acceptable for short periods.

Specimens from possible and known SARS cases must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations at (www.iata.org/dangerousgoods/index) and US DOT 49 CFR Parts 171-180 (hazmat.dot.gov/rules.htm). Step-by-step instructions on appropriate packaging and labeling are available at: www.cdc.gov/ncidod/sars/pdf/packingspecimens-sars.pdf.

Guidelines for Collecting Specimens from Potential SARS Patients
(continued from previous page)

Recommended specimens for evaluation of potential cases of SARS

Outpatient

Upper Respiratory
- Nasopharyngeal wash/ aspirate
- Nasopharyngeal and oropharyngeal swabs

Lower Respiratory
- Sputum

Blood
- Serum -- acute and convalescent (>28 days post onset)
- Blood (plasma)

Stool

Inpatient

Upper Respiratory
- Nasopharyngeal wash/aspirate
- Nasopharyngeal and oropharyngeal swabs

Lower Respiratory
- Broncheoalveolar lavage, tracheal aspirate, or pleural fluid tap
- Sputum

Blood
- Serum -- acute and convalescent (>28 days post onset)
- Blood (plasma)

Stool

Fatal

Tissue
- Fixed tissue from all major organs (e.g., lung, heart, spleen, liver, brain, kidney, adrenals)
- Frozen tissue from lung and upper airway (e.g., trachea, bronchus)

Upper Respiratory
- Nasopharyngeal wash/ aspirate
- Nasopharyngeal and oropharyngeal swabs

Lower Respiratory
- Broncheoalveolar lavage, tracheal aspirate or pleural fluid tap

Blood
- Serum
- Blood (plasma)

Stool

Guidelines for Collecting Specimens from Potential SARS Patients
(continued from previous page)

Specimens for SARS-CoV Testing:
Priority Specimens and Timing for Collection

The likelihood of detecting infection is increased if multiple specimens, e.g., stool, serum, and respiratory tract specimens, are collected during the course of illness.

Specimen, by test type	**<1 week after symptom onset**	**1-3 weeks after symptom onset**	**>3 weeks after symptom onset**
RT-PCR[1] for viral RNA detection			
Sputum[2]	√[3]	√√	√
Bronchoalveolar lavage, tracheal aspirate, or pleural fluid tap[4]	√	√√	√
Nasopharyngeal wash/aspirate	√	√√	√
Nasopharyngeal and oropharyngeal swabs	√	√√	√
Serum (serum separator tube)	√√	√	not recommended
Blood (plasma) (EDTA/purple top tube for plasma)	√√	√	not recommended
Stool (minimum 10 cc specimen)	√	√√	√√
EIA[1] for antibody detection			
Serum[5] (serum separator tube)	√√	√√	√√

[1] Because of the investigational nature of both the SARS RT-PCR (reverse transcription-polymerase chain reaction) and the SARS EIA (enzyme immunoassay), it is recommended that the clinician obtain a signed informed consent form from the patient. The consent form for the RT-PCR test can be found at: www.cdc.gov/ncidod/sars/lab/rtpcr/consent.htm. The consent form for the EIA test can be found at: www.cdc.gov/ncidod/sars/lab/eia/consent.htm.

[2] A sputum specimen is preferred if the patient has a productive cough.

[3] The more checks, the better the results from a particular specimen at a specific point in the illness.

[4] Consider these specimen types if sputum is not available.

[5] Also collect a convalescent specimen >28 days post onset.

For more information, visit www.cdc.gov/ncidod/sars or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

Form Approved
OMB NO. 0920-0596
Exp. Date _____

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

Version 3-27-03 12:00

International SARS Case Report Form

1. Name/affiliation of person filling out form		Patient ID # (***if any***)					
Date of Report:	MM	DD	2003	**Time of Report:**	:	AM PM	

2. Followup Contact Information	Last Name:	First Name:	**Country:**			
Phone: ( )	Email:	Other ( )	☐ Phone ☐ Fax	Other ( )	☐ Phone ☐ Fax	

3. Reporter or Clinician Contact	Last Name:	First Name:			
Hospital or Clinic Name:			City:		
Country	Province:				
Phone: ( )	Email:	Other ( )	☐ Phone ☐ Fax	Other ( )	☐ Phone ☐ Fax

4. Patient Information	Last Name:	First Name:				
City of residence:	Province of residence:	Country of Residence:	Nationality: _____			
Date of Birth: MM	DD	YYYY	Age _____	☐ Years ☐ Months	Sex	☐ Male ☐ Female

5. Occupation	Healthcare worker? ☐ Yes ☐ No	***If yes, specify*** ☐ Physician ☐ Nurse/PA ☐ Laboratory ☐ **Other:** _____
If not a healthcare worker, list occupation:		

6. Signs and Symptoms	Date of symptom onset	MM	DD	YYYY

Check all signs and symptoms that apply

☐ Temperature > 38°C (100.4°F)	Highest Temperature _____	☐°C ☐°F	☐ Cough	☐ Shortness of breath/ difficulty breathing
☐ Pneumonia ☐ Radiographic evidence of Pneum.		☐ Respiratory Distress Syndrome—(ARDS)		
☐ Other symptoms or relevant findings, ***List:***				

7. Clinical status at the time of report	☐ Outpatient ☐ Discharged ☐ Inpatient ☐ Died ☐ Unknown						
Was Patient Hospitalized?	☐ Yes ☐ No ☐ Unknown	Was patient placed on mechanical ventilation?	☐ Yes ☐ No ☐ Unknown	Is patient currently on mechanical ventilator?	☐ Yes ☐ No ☐ Unknown		
Date of Hospitalization:	MM	DD	YY	**Date of Discharge or Death**	MM	DD	YY
Name of Hospital:		**City:**		**Country:**	**Phone number:**		

Public reporting burden of this collection of information is estimated to average X minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX).

If patient died: Was an autopsy performed?	☐ Yes ☐ No ☐ Unk	Was pathology consistent with Respiratory Distress Syndrome?	☐ Yes ☐ No ☐ Unk

Was pathology consistent with Respiratory Distress Syndrome?

What was the cause of death based on autopsy? _____ ☐ Unknown

8. Diagnostic evaluation:	Has an etiology for patient's illness been determined? ☐ Yes ***If yes***: list: _____ ☐ No

Please fill in results of any tests that have been performed at this time:

☐ Blood culture(s) ☐ Positive ☐ Negative ☐ Pending **Comment/Result:**_____

☐ Sputum gram stain ☐ Positive ☐ Negative ☐ Pending **Comment/Result:**_____

☐ Rapid Influenza test ☐ Positive ☐ Negative ☐ Pending **Comment/Result:**_____

☐ Resp Sync Virus ☐ Positive ☐ Negative ☐ Pending **Comment/Result:**_____

9. Other pertinent clinical information and laboratory tests:

☐ Lowest **WBC** Count: _____ ☐ Lowest **Platelet** Count:_____

☐ Highest **CPK** : _____ ☐ Lowest Absolute lymphoctye count : _____

☐ Highest **AST** : _____

☐ Highest **ALT** : _____

Needed Supplemental Oxygen? ☐ Yes ☐ No

10. Travel History	Did patient travel to any the following destinations within 10 days of symptom onset? ☐ Yes, ***specify below*** ☐ No ☐ Unknown travel history

☐ Hong Kong
☐ Guangdong Province, People's Rep. of China
☐ Hanoi, Vietnam
☐ Singapore
☐ Toronto, Canada
☐ Other _____ City/State/Country

11. Exposure History	Indicate if the patient was one or more of the following :	☐ Health Care worker ☐ Household Contact of SARS Case ☐ Friend of SARS Case ☐ Guest at a hotel where other SARS patients stayed ☐ Other ☐ Unknown

Notes: (Dates of contact with SARS patients if known)

12. FOR CDC use only : Meets Suspect Case Definition: ☐ Yes ☐ No **CDC ID#**

Completed forms should be faxed to the CDC Emergency Operations Center at 1-770-488-7107.

Trichinosis

Trichinosis (Trichinellosis)

Organism: *Trichinella nativa*, an arctic (cold-resistant) nematode.

Incubation period: Larvae become adults in 1-3 days in the small intestine and may evoke gastrointestinal symptoms. Adults shed eggs that grow to larvae, which migrate throughout striated muscle over the following 6+ weeks and will evoke intense myalgias, fever, and marked eosinophilia.

Infectious period: Persons are not infectious. Uncooked meat with larvae should be considered contaminated and can remain infectious for very long periods of times.

Transmission routes: Ingestion.

Treatment: Mainly symptomatic treatment. Providers may want to give an anthelminthic (albendazole or mebendazole, both approved for usage by FDA, but considered investigational drugs for this purpose); this may or may not help patient. If there is larval migration in vessels or CNS, corticosteroids are indicated.

	Dosages for both adult and pediatric patients
Mebendazole	200-400 mg tid x 3d; then 400-500 mg tid x 10d
Albendazole (alternative)	400 mg bid x 8-14d

Reference: **Medical Letter** (www.medletter.org) as recommended by CDC.

Information Needed for the Investigation

Verify the Diagnosis

- Is there a history of eating raw, dried, or undercooked meat (usually bear, walrus, or other carnivorous mammal)?
- Does patient have a clinically compatible history?

Determine the Extent of Illness

- Determine all other persons that may have shared the meat; get the details of food preparation if meat was consumed at different times.
- Refer symptomatic persons to their healthcare providers. We do not routinely recommend serologies on asymptomatic persons.
- Obtain a sample of the suspected meat if possible.

Laboratory Specimens

- Serum from patients can be sent to CDC via ASPHL for total trichinella antibody.
- Marked eosinophilia on a CBC (along with exposure history) is highly suggestive of acute trichinellosis. During outbreak investigation, may wish to do eosinophil counts on others exposed.
- Meat may be submitted for evaluation. Contact the Section of Epidemiology for details.

Contact and Control Measures

- Goal is to identify other persons who may have consumed raw meat and educate them about the risks of consuming inadequately cooked infected meat.
- Because most meat is not commercially produced, there is no requirement to inform USDA or DEC for individual cases. However, if meat was ground or processed at a local meat market, alert DEC to the potential for other product that could have been contaminated if equipment was not properly sanitized.

Reporting Requirements

- FTR: write up confirmed or probable cases that are part of a larger outbreak. (Not necessary to write an FTR for each individual case.)
- Morbidity database: enter all laboratory-confirmed and epidemiologically-linked cases.
- File case report form (in case report files). Fill out trichinosis form and fax to CDC. CDC Case Definition is used to define confirmed cases of trichinosis.

STATE OF ALASKA
DEPARTMENT OF HEALTH & SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY
3601 C STREET, SUITE 540
P.O. BOX 240249
ANCHORAGE, ALASKA 99524-0249
FRANK H. MURKOWSKI, GOVERNOR
INFECTIOUS DISEASES
AIDS/STD
TUBERCULOSIS
IMMUNIZATION
CHRONIC DISEASES
DIABETES
INJURY CONTROL
(907) 269-8000
(907) 562-7802

Trichinellosis (Trichinosis) Fact Sheet

(Source: CDC: http://www.cdc.gov/ncidod/dpd/parasites/trichinosis/factsht_trichinosis.htm)

What is Trichinellosis, also called trichinosis?
Trichinellosis, also called trichinosis, is caused by eating raw or undercooked pork and wild game products infected with the larvae of a species of worm called *Trichinella*. Infection occurs worldwide. In Alaska, trichinosis is mainly associated with eating undercooked meat from bears, walruses, or seals.

What are the symptoms of a trichinellosis infection?
Nausea, diarrhea, vomiting, fatigue, fever, and abdominal discomfort are the first symptoms of trichinellosis. Headaches, fevers, chills, cough, eye swelling, aching joints and muscle pains, itchy skin, diarrhea, or constipation follow the first symptoms. If the infection is heavy, patients may experience difficulty coordinating movements, and have heart and breathing problems. In severe cases, death can occur. For mild to moderate infections, most symptoms subside within a few months. Fatigue, weakness, and diarrhea may last for months.

How soon after infection will symptoms appear?
Abdominal symptoms can occur 1-2 days after infection. Further symptoms usually start 2-8 weeks after eating contaminated meat. Symptoms may range from very mild to severe and relate to the number of infectious worms consumed in meat. Often, mild cases of trichinellosis are never specifically diagnosed and are assumed to be common illnesses.

How does infection occur in humans and animals?
When a human or animal eats meat that contains infective *Trichinella* cysts, the acid in the stomach dissolves the hard covering of the cyst and releases the worms. The worms pass into the small intestine and, in 1-2 days, become mature. After mating, adult females lay eggs. Eggs develop into immature worms, travel through the arteries, and are transported to muscles. Within the muscles, the worms curl into a ball and encyst (become enclosed in a capsule). Infection occurs when these encysted worms are consumed in meat.

Am I at risk for trichinellosis?
If you eat raw or undercooked meats, particularly pork, bear, wild feline (such as a cougar), fox, dog, wolf, horse, seal, or walrus, you are at risk for trichinellosis.

Can I spread trichinellosis to others?
No. Infection can only occur by eating raw or undercooked meat containing *Trichinella* worms.

What should I do if I think I have trichinellosis?
See your healthcare provider who can order tests and treat symptoms of trichinellosis infection. You should tell your health care provider if you have eaten raw or undercooked meat.

How is trichinellosis infection diagnosed?
A blood test or muscle biopsy can show if you have trichinellosis.

How is trichinellosis infection treated?
Several safe and effective prescription drugs are available to treat trichinellosis. Persons should discuss treatment decisions with their healthcare provider.

Is trichinellosis common in the United States?
Infection was once very common; however, infection is now relatively rare. From 1991-1996, an annual average of 38 cases per year were reported. The number of cases has decreased because of legislation prohibiting the feeding of raw meat garbage to hogs, commercial and home freezing of pork, and the public awareness of the danger of eating raw or undercooked pork products. Cases are less commonly associated with pork products and more often associated with eating raw or undercooked wild game meats.

How can I prevent trichinellosis?

- Cook meats until the juices run clear or to an internal temperature of 170 º F.
- Freeze pork less than 6 inches thick for 20 days at 5 º F to kill any worms.
- Cook wild game meat thoroughly. Freezing wild game meats, unlike freezing pork products, even for long periods of time, will not effectively kill all worms.
- Cook all meat fed to pigs or other wild animals.
- Clean meat grinders thoroughly if you prepare your own ground meats.
- Curing (salting), drying, smoking, or microwaving meat does not consistently kill infective worms.

For more information:

1. Centers for Disease Control. Trichinosis Surveillance, United States, 1987-1990, MMWR 1991;40:(SS-3)35-42.

2. Moorehead A, Grunenwald PE, Dietz VJ, Schantz PM, Trichinellosis in the United States, 1991-1996: Declining but not gone. Am J Trop Med Hyg 1999; 60:66-69.

Trichinellosis *(Trichinella spp.)* (Trichinosis)

1996 Case Definition

Clinical description

A disease caused by ingestion of *Trichinella* larvae. The disease has variable clinical manifestations. Common signs and symptoms among symptomatic persons include eosinophilia, fever, myalgia, and periorbital edema.

Laboratory criteria for diagnosis

Demonstration of *Trichinella* larvae in tissue obtained by muscle biopsy, or
Positive serologic test for *Trichinella*

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed

Comment

In an outbreak setting, at least one case must be laboratory confirmed. Associated cases should be reported as confirmed if the patient shared an epidemiologically implicated meal or ate an epidemiologically implicated meat product and has either a positive serologic test for trichinosis or a clinically compatible illness.

Trichinosis Case Investigation Report Form

Date of report_____ Name of investigator_____

Patient name_____ Phone ( )_____

DOB___/___/_____ Race_____ Parents' names(for a child)_____

Residence_____

Date of symptom onset___/___/_____

Describe symptoms_____

_____

Eosinophil count_____ Date blood drawn___/___/_____

Muscle biopsy performed? **Y N** Date___/___/_____ Result_____

ELISA result for total antibody_____ Date blood drawn___/___/___ Result_____

Number of other persons who also consumed meal_____ Is anyone else ill? **Y N**

NAME	PHONE

Implicated or suspected food_____ Date food was consumed___/___/_____

Where did the food/meat come from?_____

Narrative (When meal was prepared? How was food prepared, stored ?)_____
_____
_____
_____
_____

Was the meat tested? **Y N** Larval cysts/gram muscle_____

Does anyone else have portions of the meat? **Y N**

NAME	PHONE

The **Trichinosis Surveillance Case Report Form** in PDF format is available at this website:

http://health.utah.gov/epi/forms/trichinosis.pdf

It has been copy-protected and could not be included in this manual.

Varicella

Varicella (Chickenpox, Shingles)

Organism: Varicella-zoster virus, a herpesvirus.

Incubation period: 14 to 16 days, range 10 to 21 (longer after VZIG or in immuno-suppressed people).

Infectious period: 1 to 2 days before rash onset (occasionally as long as 5 days) until all lesions are crusted (usually 5 days), longer in immune deficiencies. Zoster is communicable by direct contact in the first week after lesions appear. Susceptible, exposed individuals should be considered infectious 10 to 21 days after exposure.

Transmission route: Droplet or airborne spread through respiratory secretions, direct contact with fluid from vesicles.

Treatment: None indicated (but often prescribed) for healthy children with chickenpox. Acyclovir for those at higher risk of complications of chickenpox—adolescents, adults, pregnant women, chronic skin or lung disease, aspirin therapy, short term or low dose corticosteroids. IV acyclovir for immune-suppressed children and adults. Famcyclovir and valacyclovir for zoster.

Information Needed for the Investigation

Verify the Diagnosis

- Usually made clinically.
- History of varicella vaccination does not rule out current disease.
- In unusual presentations (such as a febrile prodrome or a cluster of acute rash illness in adults) follow the CDC's "Acute, generalized vesicular or pustular rash illness testing protocol," available in **Bioterrorism.**
- Serology can identify individuals immune because of natural disease, but most commercial tests are not sensitive enough to demonstrate vaccine-induced antibody response. Special test available at CDC for vaccine-induced antibody for investigational purposes only.
- Digital photo of rash.

Evaluate the Public Health Impact

- Infection in pregnancy can lead to congenital varicella syndrome.
- Pregnant women with varicella are at high risk for pneumonia.
- Neonates who develop chickenpox between 5 and 10 days, and those whose mothers have chickenpox 5 days before or within 2 days after delivery are at risk for severe generalized varicella.
- Immunosuppressed persons are at risk for disseminated disease and death.
- Special guidelines exist for clusters in schools, daycare centers and unvaccinated populations.

Laboratory Specimens

- Blood, 5 cc red top for serum.
- Vesicular fluid, or vesicular scrapings.

Contact and Control Measures

- Most adults who do not have a history of chickenpox are immune.
- Consider varicella vaccine for susceptible children within 72 to 120 hours of exposure.
- VZIG is recommended as soon as possible or within 96 hours after significant exposure to varicella for:
    - Immuno-compromised children.
    - Susceptible pregnant women.
    - Newborn infant when mother had onset of chickenpox within 5 days of delivery or within 48 hours after delivery.
    - Hospitalized preterm infants.
        - >= 28 weeks gestation if mother does not have history of chickenpox or serological evidence of immunity.
        - < 28 weeks regardless of mother's status.
- Special guidelines exist for evaluation of clusters in childcare center schools and unvaccinated populations.
- Obtaining Varicella-Zoster Immune Globulin (VZIG).
    - American Red Cross Blood Services Regional Distribution Centers no longer offer this product in most parts of the U.S. The sole source for California purchasers of VZIG is FFF Enterprises, 41093 County Center Drive, Temecula, CA 92591. Telephone: (800) 843-7477. FFF ships VZIG orders out promptly on an overnight delivery basis. The cost is approximately $560 for the 625-unit vial (the usual adult dose), and $123 for the 125-unit vial. It is important to assess the varicella immunity status of pregnant women. If a pregnant woman is susceptible, she should be evaluated for VZIG.

Reporting Requirements

- FTR and CDC report for varicella **deaths** only.
- FTR for outbreaks.
- Not reportable in Alaska; not entered into morbidity database.

References

Control of Communicable Diseases Manual (17th Edition), 2002.
Red Book (26th Edition), 2003.
Varicella FAQs may be found at http://www.cdc.gov/.

VARICELLA REPORT FORM

PATIENT INFORMATION		
Name:	**Birthdate:**	**Date:**
Address:	**Phone:**	**Sex: M☐ F☐**
City:	**State:**	**Zip:**
Race:	**Hispanic ☐**	**Non-Hispanic ☐**

REPORT SOURCE		
Name:	**Agency/Site:**	**Phone:**
School ☐ Pre-School/Childcare ☐ Health Care Provider ☐ Health Department ☐ Laboratory ☐		

CLINICAL INFORMATION		
Onset of Rash: / / -OR- First day absent due to Chickenpox: / /		
Severity of Rash:		
<50 Lesions (Mild) ☐		
50 – 500 Lesions (Average) ☐		
>500 Lesions (Severe) ☐		
Vaccinated for Varicella: Yes ☐ No ☐ Unknown ☐		
If yes, fill in the following:		
Varicella (VZV) Dose 1 / /	**Lot Number:**	**Agency/Office:**
Varicella (VZV) Dose 2 / /	**Lot Number:**	**Agency/Office:**
Diagnosed by: Parent ☐ HCP ☐ School Personnel ☐ Self ☐ Other ☐		
Hospitalized: Yes ☐ No ☐ Unknown☐	**If yes, outcome: Alive ☐ Deceased ☐ Unknown ☐**	

LAB TEST INFORMATION		
Lab:	**Collection Date: / /**	
Specimen:	**Test type:**	**Result:**

Varicella Surveillance Worksheet

NAME (Last, First)				Hospital Record No.
Address (Street and No.)	City	County	Zip	Phone
Reporting Physician/Nurse/Hospital/Clinic/Lab	Address			Phone

---------- DETACH HERE and transmit only lower portion if sent to CDC ----------

Varicella Surveillance Worksheet

County | State | Zip

Birth Date (Month Day Year)

Age (Unk = 999)

Age Type
0 = 0-120 years
1 = 0-11 months
2 = 0-52 weeks
3 = 0-28 days
9 = Age unknown

Ethnicity
H = Hispanic
N = Not Hispanic
U = Unknown

Race
N = Native Amer./Alaskan Native
A = Asian/Pacific Islander
B = African American
W = White
O = Other
U = Unknown

Sex
M = Male
F = Female
U = Unknown

Event Date (Month Day Year)

Event Type
1 = Onset Date
2 = Diagnosis Date
3 = Lab Test Done
4 = Reported to County
5 = Reported to State or MMWR Report Date
9 = Unknown

Outbreak Associated (Unk = 999)

Reported (Month Day Year)

Imported
1 = Indigenous
2 = International
3 = Out of State
9 = Unknown

Report Status
1 = Confirmed
2 = Probable
3 = Suspect
9 = Unknown

CLINICAL DATA

Any Rash? Y = Yes, N = No, U = Unknown

Rash Onset (Month Day Year)

Rash Duration 0 - 30 Days, 99 = Unknown

Rash Type G = Generalized, L = Localized/dermatomal, U = Unknown

Immunocompromised? Y = Yes, N = No, U = Unknown

Lesion Severity
1 = Mild: few scattered lesions on the body
2 = Moderate: number of lesions between mild and severe
3 = Severe: lesions numerous enough to almost touch, or normal skin is difficult to see between lesions

Fever? Y = Yes, N = No, U = Unknown

If Recorded, Highest Measured Temp. 36.0 - 110.0 degrees, 999.9 = Unknown

Fever Duration 0 - 30 Days, 99 = Unknown

COMPLICATIONS

Pneumonia? Y = Yes, N = No, U = Unknown

Encephalitis? Y = Yes, N = No, U = Unknown

Cerebellar Ataxia? Y = Yes, N = No, U = Unknown

Skin Infection? Y = Yes, N = No, U = Unknown

Other Secondary Infection? Y = Yes, N = No, U = Unknown

Thrombocytopenia? Y = Yes, N = No, U = Unknown

Other Complications? Y = Yes, N = No, U = Unknown

If Yes, Please Specify: _____

Hospitalized? Y = Yes, N = No, U = Unknown

Days Hospitalized 0 - 998, 999 - Unknown

Outpatient Care for Varicella? Y = Yes, N = No, U = Unknown

Death? Y = Yes, N = No, U = Unknown

Date of Death (Month Day Year)

Autopsy Performed? Y = Yes, N = No, U = Unknown

Cause of Death:

LABORATORY

Was Laboratory Testing For Varicella Done? Y = Yes, N = No, U = Unknown

Date IgM Specimen Taken* (Month Day Year)

Result
P = Positive
N = Negative
I = Indeterminate
E = Pending
X = Not Done
U = Unknown

* Not currently recommended for case investigation

	Date IgG Specimen Taken (Month Day Year)	Result
Acute		
Convalescent		

Specify Other Lab Method: _____

Other Lab Result

Result Codes
P = Significant Rise in IgG
N = No Significant Rise in IgG
I = Indeterminate
E = Pending
X = Not Done
U = Unknown

VACCINE HISTORY

Vaccinated? (Received varicella-containing vaccine?) Y = Yes, N = No, U = Unknown

Number of doses received ON or AFTER 1st birthday

Vaccination Date (Month Day Year)	Vaccine Type*	Vaccine Manuf**	Lot Number

* Vaccine Type Codes
A = MMR
B = Varicella
O = Other
U = Unknown

**Vaccine Manuf. Codes
M = Merck
O = Other
U = Unknown

If Not Vaccinated, What Was The Reason?

Reason Codes
1 = Religious Exemption
2 = Medical Contraindication
3 = Philosophical Objection
4 = Lab. Evidence of Previous Disease
5 = MD Diagnosis of Previous Disease
6 = Under Age For Vaccination
7 = Parental Refusal
8 = Other
9 = Unknown

EPIDEMIOLOGIC INFORMATION

Date First Reported to a Health Department (Month Day Year)

Date Case Investigation Started (Month Day Year)

Transmission Setting (Where did this case acquire measles?)
1 = Day Care
2 = School
3 = Doctor's Office
4 = Hospital Ward
5 = Hospital ER
6 = Hospital Outpatient Clinic
7 = Home
8 = Work
9 = Unknown
10 = College
11 = Military
12 = Correctional Facility
13 = Church
14 = International Travel
15 = Other

Outbreak Related? Y = Yes, N = No, U = Unknown

If Yes, Outbreak Name

Source of Exposure For Current Case (Enter State ID if source was an in-state case; enter Country if source was out of US; enter State if source was out-of-state)

Were Age and Setting Verified? (Is age appropriate for setting, i.e. aged 49 years and in day care, etc.) Y = Yes, N = No, U = Unknown

If Transmission Setting Not Among Those Listed And Known, What Was The Transmission Setting? _____

Epi-Linked to Another Confirmed or Probable Case? Y = Yes, N = No, U = Unknown

Contact Information: (For state/local health department use)

Mother's Name	Father's Name
Phone	

---------- DETACH HERE ----------

The information below is epidemiologically important, but not included on NETSS screens

PREGNANT WOMEN

If the case was female, was she pregnant?

☐ Y = Yes
N = No
U = Unknown

Number of Weeks Gestation (or Trimester) at Onset of Illness

☐☐☐

1st= First Trimester
2nd=Second Trimester
3rd=Third Trimester

Prior Evidence of Serological Immunity?

☐ Y = Yes
N = No
U = Unknown

Year of Test ☐☐☐☐ **OR** **Age of Patient at Time of Test** ☐☐

Was Previous Varicella Serologically Confirmed?

☐ Y = Yes
N = No
U = Unknown

Year of Disease ☐☐☐☐ **OR** **Age of Patient at Time of Disease** ☐☐

Notes/Comments:

Varicella (Chickenpox)

1999 Case Definition

Clinical case definition

An illness with acute onset of diffuse (generalized) maculo-papulovesicular rash without other apparent cause.

Laboratory criteria for diagnosis

Isolation of varicella virus from a clinical specimen, or
Direct fluorescent antibody (DFA), or
Polymerase chain reaction (PCR), or
Significant rise in serum varicella immunoglobulin G (IgG) antibody level by any standard serologic assay

Case classification

Probable: a case that meets the clinical case definition, is not laboratory confirmed, and is not epidemiologically linked to another probable or confirmed case

Confirmed: a case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically linked to a confirmed or probable case

Notes

Two probable cases that are epidemiologically linked would be considered confirmed, even in the absence of laboratory confirmation.

In vaccinated persons who develop varicella more than 42 days after vaccination (breakthrough disease), the disease is almost always mild with fewer than 50 skin lesions and shorter duration of illness. The rash may also be atypical in appearance (maculopapular with few or no vesicles).

Laboratory confirmation of cases of varicella is not routinely recommended; laboratory confirmation is recommended for fatal cases and in other special circumstances.

West Nile Virus

2006 West Nile Virus Surveillance Documents

A. 2006 Guidelines for WNV Surveillance Bulletin.
B. Human case report form.[1,2]
C. Copy of ASVL human specimen submission form.[1]
D. Human extended case report/questionnaire form.[1,2]
E. Avian WNV Surveillance Form.[2]
F. Avian WNV Surveillance Form instructions.[2]
G. Instructions for shipping avian carcasses.[2]

8 AM - 5 PM

Humans:

1. If patient meets clinical criteria listed in Bulletin (Document A); fill out Case Report Form (Document B).
2. Ask healthcare provider to collect at least 0.5 ml serum; fill in ASVL submission form (Document C). Work with provider to arrange shipment of specimen and form to ASVL. Please let Jayme/Terry know specimen is coming (907 474-7017).
3. Inform Epi team; if we have numerous suspects can create a T:drive linelist.
4. Further investigation maybe needed, e.g., pregnant patient, h/o organ transplant, etc.; Document D is an extended case form.

Dead birds:

1. Start filling out a WNV Surveillance Form for birds (Document E); use instructions from Document F, and then G if the carcass will be shipped.
2. After completing Document E, please give Form to LC to track.

AFTER HOURS

Humans:

1. WNV is not a public health emergency.
2. If patient meets clinical criteria listed in Bulletin (Document A); ask healthcare provider to collect and set aside at least 0.5 ml serum. Specimens should be stored in refrigerator at 4°C (NOT FROZEN). Arrange to contact provider the next work day to give details on shipping instructions, and to obtain more details on case history.
3. There is no specific tx regimen for WNV; tx is mainly supportive.

Dead birds:

1. Dead birds are also not a public health emergency.
2. If the dead bird meets the criteria outlined in the Bulletin (Document A; using Documents E and F to help decide), and the caller has the ability to freeze the carcass; arrange to contact the caller the next work day to work out shipping instructions. Please make sure that you recommend wearing gloves/bags when handling dead birds; and that the carcasses are double bagged before freezing.
3. Please remind caller that collecting dead birds is a convenience surveillance sample. Our goal is not to test every dead bird that meets the criteria. We need to ensure that the samples ASVL receives are fresh and thereby do not compromise test results. Birds will only be shipped on certain days to ensure quality of specimens. Thank them for calling if their bird does not meet the criteria; please make sure that they dispose of carcass according to Bulletin (Document A) procedure.

[1]2006 version same as 2003.
[2]Document stored on N drive in Prgstff/WNV folder.

State of Alaska Epidemiology

Bulletin

Department of Health and Social Services
Karleen Jackson, Commissioner

Division of Public Health
Richard Mandsager, MD, Director

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3601 C Street, Suite 540, PO Box 240249, Anchorage, Alaska 99524-0249 (907) 269-8000
24-Hour Emergency Number 1-800-478-0084 http://www.epi.Alaska.gov

Bulletin No. 13 May 22, 2006

Summary of 2005 West Nile Virus Surveillance in Alaska and What's New for 2006

Introduction

Almost 3,000 human cases of West Nile virus (WNV) were reported in the United States in 2005.[1] Since 1999, when WNV was first detected in New York, the epicenter of disease has shifted ever westward in the United States during each subsequent season. Alaska and Hawaii remain the only two states in the nation that have not recorded local WNV infection in birds, mosquitoes, or humans.

WNV Testing in Alaska

In 2003, the Alaska State Virology Laboratory (ASVL) developed WNV laboratory capacity for both human and avian specimens. Human sera and cerebrospinal fluid can be evaluated for IgM antibodies using IgM antibody capture ELISA, and avian brain tissue can be evaluated for WNV RNA using real time polymerase chain reaction (PCR) methods.

Human Testing Results

In 2005, ASVL evaluated one serum sample from a suspect case of human WNV infection. The patient, a 22-month-old infant hospitalized with meningoencephalitis, tested negative for WNV IgM antibodies. Of 25,929 units of blood donated through the Blood Bank of Alaska, WNV was detected in none by nucleic acid amplification tests. To date, no cases of WNV infection acquired in Alaska have been identified.

Avian Testing Results

Of the 34 dead birds collected in 2005 and tested at ASVL (Table 1), none were positive for WNV by PCR.

Table 1. Dead Birds Tested for WNV by ASVL, 2005

Species of bird	Location in Alaska (# of birds tested)
Crow, Northwestern	Anchor Point Skagway Soldotna
Eagle, Bald	King Salmon
Goshawk, Northern	Fairbanks
Hawk, Red-Tailed	Minto Village
Hawk, Rough-legged	Fairbanks
Jay, Steller's	Juneau
Kestrel, American	Fairbanks (2)
Magpie, Black-billed	Anchorage
Merlin	North Pole Kenai
Owl, Boreal	Fairbanks (2)
Owl, Great Gray	Fairbanks
Owl, Great-Horned	Salcha Fairbanks (2) Galena
Owl, Northern Hawk	Fairbanks
Owl, Not specified	Fairbanks (2)
Owl, Short-Eared	Richardson Hwy
Raven, Common	Elliot Hwy Fairbanks (7) North Pole Kotzebue

WNV Testing for Humans

Healthcare providers who suspect cases of WNV should contact the Section of Epidemiology at 907-269-8000 (8AM-5PM) or 800-478-0084 (after hours) for consultation regarding the diagnosis and for information regarding the transport of diagnostic specimens to ASVL.

Specimens are indicated for WNV testing for patients hospitalized with clinical diagnoses indicative of neuroinvasive WNV infection, such as:

- Viral encephalitis
- Viral meningoencephalitis
- Guillain-Barré Syndrome
- Acute flaccid paralysis

A minimum of 0.5 ml of serum is needed for testing; serum should be collected ≥ 8 days after illness onset. Specimens must be kept cool (4°C) prior to and during shipment.

Reporting Dead Birds

To report dead or sick birds with no obvious cause, call the Alaska Interagency Bird Reporting hotline at 1-866-5-BRDFLU (1-866-527-3358).
Do not handle birds found sick or dead!

Testing for WNV

Reports of clusters of ill or dead birds will be reviewed by wildlife authorities and investigations will be performed, if warranted. For single dead birds, as in previous years, only certain species will be evaluated for WNV. These include common ravens, northwestern or American crows, black-billed magpies, Steller's or gray jays, and any species of owl, hawk, eagle or falcon.

Carcasses must be fresh to detect virus by PCR. Therefore, dead birds will only be tested if they are free of maggots and foul odors, their bodies are intact and not scavenged, and they are thought to have been dead less than 24 hours.

Method of Carcass Disposal

Once you have reported a dead bird to the Hotline and a wildlife authority has determined it will not be tested, use disposable gloves or put your hand inside of a plastic bag to handle the carcass if it needs to be moved. Double bag the carcass and dispose of it in the garbage; then wash your hands thoroughly with soap and water.

Acknowledgments

The Section of Epidemiology would like to thank the Alaska WNV working group and all persons who assisted with collecting and testing dead birds.

Reference

[1] CDC West Nile Virus Statistics, Surveillance, and Control. Available at: http://www.cdc.gov/ncidod/dvbid/westnile/surv&controlCaseCount05_detailed.htm. Accessed on May 11, 2006.

(Prepared by Louisa Castrodale, DVM, MPH, Alaska Section of Epidemiology.)

Initial Case and Laboratory Submission Report for Suspected West Nile Virus Encephalitis/Meningitis
ALASKA SECTION OF EPIDEMIOLOGY

For Epi Use Only: AKEpi ID# _____
Initials of Epi staff _____
Testing approved: Yes No DateRcvd_____

Date of Report: ____/____/____

1. IDENTIFYING PATIENT INFORMATION

Last name |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
First name |__|__|__|__|__|__|__|__|__|__| Middle name |__|__|__|__|__|__|__|__|
Date of Birth____/____/____ (if not available, Age_____ years/ months/ weeks) Sex: Male Female
Address_____
State (country) of residency:_____
Tel. H (____)____-_____ W (____)____-_____ Race: W AN/AI B Asian Other Ethnicity: Hisp. Non-Hisp.

2. CLINICAL INFORMATION

Current diagnosis: encephalitis meningitis GBS other (Specify_____)
Hospitalized? Yes No Hospital name_____
Medical record # _____ Date of admission____/____/____ Date of discharge____/____/____

Date of first symptoms____/____/____

Fever (≥ 38°C or 100°F)	Yes	No	Unknown	Altered mental status	Yes	No	Unknown
Muscle weakness	Yes	No	Unknown	Stiff neck/meningeal signs	Yes	No	Unknown
Headache	Yes	No	Unknown	Seizures	Yes	No	Unknown
Rash	Yes	No	Unknown	Muscle pain	Yes	No	Unknown
Joint pain	Yes	No	Unknown	Other neurologic signs	Yes	No	Unknown

Outcome: Recovered Still ill Died (date of death____/____/____) Unknown

3. LABORATORY AND RADIOLOGY TEST RESULTS

CSF obtained: Yes (date____/____/____) No Pending/planned
Glu_____ Prot_____ RBC_____ WBC_____ Diff: Segs_____% Lymphs_____%
Gram stain_____ Bacterial culture_____ Fungal/parasitic tests_____
Viral test results (Culture/Serology/PCR)_____
CBC Date____/____/____ WBC_____ Diff: Segs_____% Bands_____% Lymphs_____%
MRI Date____/____/____ Result_____
CT Date____/____/____ Result_____

4. SPECIMENS BEING SUBMITTED TO ASVL FOR WEST NILE VIRUS TESTING

Specimen No.	Type: Specify CSF or Serum	**DATE OF COLLECTION *****Required*******	FOR Epi USE ONLY ASVL Accession No.
1.			
2.			

Note: CSF should be kept frozen, preferably at -70° F; sera should be kept refrigerated, not frozen.

5. REPORTED BY:

Last name_____ First name_____ Title (ICP, Resident, Attending)_____
Work address_____ City_____ State____ Zip Code_____
Telephone (_____)_____-_____ Pager (_____)_____-_____

All suspected cases of WNV should be reported to the Section of Epidemiology at 907-269-8000 during business hours or at 800-478-0084 after hours.

STATE OF ALASKA
Alaska State Virology Laboratory - Fairbanks
Division of Public Health
P.O. Box 60230, Fairbanks, Alaska 99706-0230
Voice (907)-474-7017 // Fax (907)-474-4036

WEST NILE VIRUS SEROLOGY REQUEST FORM

Accession # _____

SUBMITTER INFORMATION	**Patient Information**
PHYSICIAN NAME:	PATIENT REFERRAL #_____
FACILITY:	LAST NAME _____
ADDRESS:	FIRST NAME _____ INIT _____
	DOB _____/ _____ / _____ (MONTH DAY YEAR)
CITY/ZIP:	SEX ____
PHONE #:	SPECIMEN COLLECTION DATE _____/ _____ / _____ (MONTH DAY YEAR)

SPECIMEN	**Immunization Status**	**Travel History :** _____
_____ SERUM	Yellow Fever: Y ❑ N ❑	_____
_____ OTHER _____	Japanese B: Y ❑ N ❑	

Brief Clinical History:
_____

Illness Onset Date: _____

Dengue/DHF Infection: Y ❑ N ❑

SHADED AREA FOR LABORATORY USE ONLY

DATE RECEIVED:	**RECEIVED BY:**	**CONDITION OF SPECIMEN:**	**REMARKS:**

Apr. 10, 2003

ALASKA SECTION OF EPIDEMIOLOGY: West Nile Encephalitis Extended Case Investigation Form

ID Number:_____ **Date case reported to Epi**:___/___/___ **Date of patient/proxy interview**:___/___/___

Date of chart review:___/___/___ **Name of person who reviewed chart**:_____

I. PATIENT INFORMATION:

1. First name:_____ **Last name**:_____ **Middle**:_____

2. Address:_____

3. Home phone #:____-_____-_____ **Work/Other #**:____-_____-_____
Other contact information: _____

4. Age:_____ **or Date of Birth**:___/___/____ **5. Parents' name if <18 yrs old**:_____

6. State (country) of residency: _____ **7. Sex:** Male Female

8. Race: White AK Native Black Asian Other
Ethnicity: Hispanic Nonhispanic Unknown

9. Attending healthcare provider information:
Name:_____ Hospital affiliation:_____
Office phone #:_____ Pager #:_____ Fax #:_____

10. Reporting provider information (if different than above).
Name:_____ Hospital affiliation:_____
Office phone #:_____ Pager #:_____ Fax #:_____

II. HOSPITAL INFORMATION:

1. Hospital: _____ **2. Medical record #:**_____

3. Date of admission: ___/___/___ **4. Date of discharge:** ___/___/___

5. Admission diagnoses: **a)**_____ **ICD9 Code** _____
b)_____ **ICD9 Code** _____
c)_____ **ICD9 Code** _____

Discharge diagnoses **a)**_____ **ICD9 Code** _____
b)_____ **ICD9 Code** _____
c)_____ **ICD9 Code** _____

6. Chief complaint:_____ **7. Date of onset:**___/___/___

8. Symptoms on presentation:

Fever: Yes (**Maximum temp reported:**_____C / F) No Unknown
Headache: Yes No Unknown
Stiff neck: Yes No Unknown
Photophobia: Yes No Unknown
Fatigue: Yes No Unknown
Swollen glands: Yes No Unknown
Joint pains: Yes No Unknown
Muscle pains: Yes No Unknown
Muscle weakness: Yes No Unknown
(**Specify which muscles:** Upper extremities Lower extremities Both)
Describe in detail any subjective complaints of motor weakness:_____
Rash: Yes No Unknown
Nausea: Yes No Unknown

Diarrhea: Yes No Unknown
Vomiting: Yes No Unknown
Abdominal pain: Yes No Unknown
Urinary sx: Yes (**Specify:**_____) No Unknown
Chest pain: Yes No Unknown
Shortness of breath: Yes No Unknown
Cough: Yes No Unknown
Conjunctivitis: Yes No Unknown
Altered mental status: Yes (**Specify:**_____) No Unknown
Unconscious: Yes No Unknown
Confusion: Yes No Unknown
Seizures: Yes (**Specify:** generalized focal status epilepticus) No Unknown

9. Past medical history:
Hypertension: Yes No Unknown
Diabetes: Yes (**Specify:** IDDM NIDDM) No Unknown
Cardiac disease: Yes (**Specify:**_____) No Unknown
Lung disease: Yes (**Specify:**_____) No Unknown
Hepatitis: Yes (**Specify:** Hep A Hep B Hep C Other) No Unknown
Pancreatitis: Yes No Unknown
Seizures: Yes (**Specify:**_____) No Unknown
Cancer: Yes (**Specify:**_____) No Unknown
(**Currently on tx:** Yes No Unknown)
Status 1/Status 2: Yes (**Last CD4 count:**_____ **Date:**___/___/___) No Unknown
Other immunocompromising diseases: Yes (**Specify:**_____) No Unknown
West Nile Encephalitis: Yes (**Year dx:**_____) No Unknown
St. Louis Encephalitis: Yes (**Year dx:**_____) No Unknown
Dengue Fever: Yes (**Year dx:**_____) No Unknown
Japanese Encephalitis: Yes (**Year dx:**_____) No Unknown
Other flavivirus: Yes (**Year dx:**_____) No Unknown
(**Specify:**_____)

10. Vaccination history:
Vaccination against yellow fever: Yes (**Date:**___/___/___) No Unknown
Name of provider who administered:_____ **Phone #:**____-____-_____

Vaccination against Japanese Encephalitis virus: Yes (**Date:**___/___/___) No Unknown
Name of provider who administered:_____ **Phone #:**____-____-_____

Vaccination against tickborne encephalitis: Yes (**Date:**___/___/___) No Unknown
Name of provider who administered:_____ **Phone #:**____-____-_____

11. Physical exam on admission:
a. Vitals: Temp:____(**Oral** **Rectal**) **HR:**_____ **Resp Rate:**_____ **BP:**____/____
Duration of fever (consecutive days since admission with T>100.4 F)_____

b. Mental Status on presentation to the ED or as noted on admission note:
Level of alertness (circle one): Alert Somnolent Lethargic Stuporous Comatose

Oriented to (circle all that apply): Person Place Time
Responds to verbal stimuli: Yes No Unknown
Responds to painful stimuli: Yes No Unknown

Describe other mental status abnormalities on presentation:_____

c. Motor exam as noted on ED or admission H&P:_____

d. Head and neck exam:
Stiff neck: Present Absent Not noted
Brudzinski: Present Absent Not noted
Kernig: Present Absent Not noted

Photophobia: Present Absent Not noted
Conjunctivitis: Present Absent Not noted

e. Other:
Lymphadenopathy: Present Absent Not noted
Skin: Normal Abnormal (**Specify type of rash and location:**_____) Not noted
Abdomen: Normal Abnormal (**Specify type and location:**_____) Not noted
Heart Exam: Normal Abnormal (**Specify type and location:**_____) Not noted

f. Other significant positive findings (describe): _____

12. Initial laboratory studies:

a. Urinalysis: Yes (**Date:**___/___/___) No Unknown
General:_____ **Color:**_____ **WBCs:**_____ **Protein:**_____

b. CBC: **Date:**__/__/__ **HGB:**___ **HCT:**___ **Platelets:**____ **Total WBC:**____
% Gran:___ **% Bands:**____ **%Lymphs:**_____ **%Monos:**_____ **Absolute Gran:**____

c. T cell studies: Yes (**Date:**__/__/__) No Unknown
CD4:_____ **CD8:**_____ **%CD4:**_____

d. Chemistry: **Date:**__/__/___ **Na:**____ **K:**____ **Cl:**____ **CO2:**____ **BUN:**____ **Cr:**____**Glu:**____

e. CPK: **1st date:**__/__/__ **2nd date:**__/__/__ **3rd date:**__/__/__
Total:___ **MB:**___ **Index:**___ **Total:**___ **MB:**___ **Index:**___ **Total:**___ **MB:**___ **Index:**___

f. LFTs: **Date:**__/__/__ AST:___ ALT:____ T.bili:____ Indirect .bili:____ ALP:____ GGT:____

g. Amylase:____ **Date:**__/__/__ **h. Lipase:**____ **Date:**__/__/__ **i. LDH:**____ **Date:**__/__/__

j. Spinal tap done? Yes No Unknown
1st CSF date:__/__/__ **Protein:**____ **WBC ct:**_____ **% Polys**___ **% Segs**___ **% Lymphs**____
Gram stain: Positive (**Specify:**_____) Negative Unknown
Bacterial culture: Positive (**Specify:**_____) Negative Unknown
Herpes PCR: Positive Negative Unknown
Other:_____

2nd CSF date:__/__/__ **Protein:**____ **WBC ct:**_____ **% Polys**___ **% Segs**___ **% Lymphs**____
Gram stain: Positive (**Specify:**_____) Negative Unknown
Bacterial culture: Positive (**Specify:**_____) Negative Unknown
Herpes PCR: Positive Negative Unknown
Other:_____

13. Radiological and diagnostic studies: (Final reports ONLY).
EKG (__/__/__): _____

CXR (__/__/__): _____

EMG (__/__/__): _____

MRI of head (__/__/__): _____

CT of head (__/__/__): _____

14. Neurology examination:
Was neurology consulted? Yes No Unknown **Date of exam:**__/__/__
Name of neurologist:_____ **Phone #** ( )_____ - _____ **Pager #** ( )_____ - _____

If no neurologist consulted, please list provider who conducted the exam used to complete this section:
Name of provider:_____ **Phone #** ( ) _____ - _____ **Pager #** ( ) _____ - _____

Mental status: Normal Abnormal Not noted
(**If abnormal, level of alertness:** Alert Somnolent Lethargic Stupor Coma Other _____)

Oriented to (circle all that apply): Person Place Time
Attention/concentration: Normal Abnormal Not noted
Agitation: Present Absent Not noted
Cranial nerve function: Normal Abnormal Not noted
Describe abnormality and location:_____

Motor exam: Normal Abnormal Not noted (Note abnormalities using 0/5–5/5 scale.)
a.. Left arm__ Right arm__ Left leg__ Right leg__
b. Pattern of weakness identified: Ascending__ Descending__ Unknown__
c. Describe weakness in more detail:_____

Reflexes: Normal Abnormal Not noted (Note abnormalities using 0/5–5/5 scale.)
Left Arm__ Right Arm__ Left Leg__ Right Leg__

Cerebellar Function: Normal Abnormal Not noted
Describe abnormality and location:_____

Diagnostic impressions of neurology consultant (circle all that apply)?
Meningitis Encephalitis Guillain-Barre syndrome None
Other _____
Other _____

15. Infectious disease consult:
ID consult obtained? Yes (**Date:**__/__/__) No Unknown
Name of consultant:_____ **Phone #** ( ) _____ - _____ **Pager #** ( )_____ - _____

Was West Nile encephalitis mentioned as a possible dx? Yes No Unknown

Was West Nile testing recommended? Yes (**Date recommended:**____/____/___) No Unknown

Were other diagnostic tests/laboratory studies recommended? Yes No Unknown
(**Specify:**_____)

What was diagnostic impression of ID consultant (circle all that apply)?
Meningitis Encephalitis Guillain-Barre syndrome None
Other:_____
Other:_____

Was an etiologic agent(s) mentioned by the ID consultant? Yes (**Please list below**) No
_____

16. Hospital course:
Initial treatment: a. antibiotics? Yes (**Specify:**_____) No Unknown
b. acyclovir? Yes No Unknown

Did patient require intensive care? Yes No Unknown
Date admitted to ICU:____/____/____ **Date left ICU:**____/____/____ **# days stayed:**_____

Was patient on mechanical ventilation? Yes No Unknown
Did patient have physical therapy and or consult? Yes No Unknown
Did patient have speech therapy and or consult? Yes No Unknown
Did patient have occupational therapy and or consult? Yes No Unknown

Who mentioned WNV as a possible dx in the chart first?_____ **Date:**___/___/___ **Specialty:**_____

17. Disposition:
Patient's discharge status: Recovered Died Still in hospital Improved but not to baseline Other_____

Discharged to: Home Long-term care facility Still in hospital Other_____

Condition on discharge:
a) Ambulation:
Fully ambulatory Ambulatory with assistance Wheel chair Bedridden Other Unknown
b) Activities of daily living:
Unchanged from admission Impaired from admission Requires total assistance Unknown

III. RISK EXPOSURE HISTORY

(The time frame for all questions below should be the three weeks prior to illness onset: ___/___/___ to ___/___/___)

1. Person interviewed: Patient **Other: name of person:**_____
Relationship:_____ **Phone #** (_____) - _____- _____

2. Did the patient travel outside the USA in the three weeks before illness onset? Yes No Unknown
Countries visited:_____
Date departed from US:___/___/___ **Date returned to US:**___/___/___

3. Did the patient travel outside Alaska during the three weeks before illness onset? Yes No Unknown
Places visited _____
Date departed from AK:___/___/___ **Date returned to AK:**___/___/___

4. (For persons born in US only)
Has the patient <u>ever</u> traveled outside the United States? Yes No Unknown
(If patient has traveled extensively, pls focus on areas in African, Middle East and Asia.)

Country(ies) visited	**Date departed US**	**Date returned to US**
_____	____/____/____	____/____/____
_____	____/____/____	____/____/____
_____	____/____/____	____/____/____

5. Is patient employed? Yes (**Occupation:**_____) No Unknown
Where does he/she work?_____

6. Please ask if patient spent time outdoors in any of the following areas during the 3 weeks before illness onset?

Beach: Yes (**Specify location:**_____) No Unknown
Zoo: Yes (**Specify location:**_____) No Unknown
Public garden/park: Yes (**Specify location:**_____) No Unknown
Cemetery: Yes (**Specify location:**_____) No Unknown
Outdoors sport field/stadium: Yes (**Specify location:**_____) No Unknown

Ask patient/proxy to list all OTHER places patient likely spent time outdoors in the three weeks before illness onset:
_____

Does patient recall being bitten by mosquitoes during the 3 weeks before illness onset? Yes No Unknown
If yes: Often Sometimes Rarely **Where?**_____

7. Did the patient see dead birds in the 3 weeks before illness onset? Yes No Unknown
Where?_____

8. Did patient have direct contact with dead bird (touching bird with bare hands)? Yes No Unknown

9. Does patient have air conditioning in their home? Yes No Unknown

10. Did patient leave windows open at home w/o screens during the 3 weeks before illness onset? Yes No Unknown

2006 WEST NILE VIRUS SURVEILLANCE FORM—ALASKA

ALASKA STATE VIROLOGY LABORATORY, ALASKA DIVISION OF PUBLIC HEALTH
239 ARCTIC HEALTH BUILDING, 901 KOYUKUK DRIVE SOUTH
PO BOX 60230, FAIRBANKS, AK 99706-0230
TEL: 907.474.7017 FAX: 907.474.4036

SPECIES/TYPE OF BIRD *(Indicate # of each)*

___ **RAVEN** – LARGE (21" FROM TAIL TO BEAK), SOLID BLACK FEATHERS, EYES, BEAK, AND LEGS

___ **CROW** – MEDIUM (15"), SOLID BLACK FEATHERS, EYES, BEAK, AND LEGS

___ **MAGPIE** – MEDIUM (14"), BLACK AND WHITE BODY WITH LONG, BLUE-GREEN METALLIC TAIL

___ **JAY** – SMALL (10"), BLUE OR GRAY BODY

___ **EAGLE** – VERY LARGE (32"), HOOKED BILL AND STRONG TALONS

___ **HAWK OR FALCON** – SMALL TO LARGE (9-20"), HOOKED BILL AND STRONG TALONS

___ **OWL** – SMALL TO LARGE (7-22"), HOOKED BILL AND STRONG TALONS

*******ONLY THESE SPECIES WILL BE ACCEPTED FOR TESTING.*******

___ **OTHER** (*Species if known*)_____

DATES

SICK /DEAD BIRD(S) OBSERVED:_____

SPECIMEN(S) COLLECTED:_____

CONDITION/FRESHNESS

	YES	NO
MAGGOTS OR EGGS PRESENT	☐	☐
FOUL ODOR OR LIQUID EMANATING FROM BODY	☐	☐
OBSERVED DEAD >24 HRS.	☐	☐
BODY SCAVENGED/VISCERA ABSENT	☐	☐

*******BIRD WILL ONLY BE ACCEPTED IF ANSWERS TO ALL QUESTIONS ARE NO.*******

FOUND BY:

NAME:_____
MAILING ADDRESS:_____
_____
_____
EMAIL:_____
TEL (HOME):_____
TEL (WORK):_____

SUBMITTED BY *(If different)*:

NAME:_____
MAILING ADDRESS:_____
_____
_____
EMAIL:_____
TEL (HOME):_____
TEL (WORK):_____

LOCATION WHERE BIRD WAS FOUND: *(Please be as precise as possible)*

STREET ADDRESS: _____
CITY / ZIP:_____GPS LAT/LONG:_____
DIRECTIONS AND DISTANCE FROM NEAREST TOWN OR DISTINGUISHING LANDMARK: _____
_____
_____

DETAILS OR COMMENTS: *(Use back of form if needed)*

_____
_____

SPECIES	# SICK/DEAD	# DISPOSED OF	# SUBMITTED FOR EXAM	ASVL ACC. #

REPORT RECEIVED BY_____ **DATE**_____ **AGENCY CODE**_____ - _____ - _____

2006 West Nile Virus Surveillance Form Instructions

IF BIRD IS ALIVE:

Refer caller in Anchorage to Bird TLC, 907 562-4852.
Refer caller in Fairbanks to AK Bird Observatory, 907 451-7159.

IF BIRD IS DEAD:

1. Record info about caller/contact numbers and location on WNV Surveillance form.
2. Does bird meet species criteria (on form)?
    a. Yes; continue to #3.
    b. No; skip to #8.
    c. If unsure, continue to #3.
3. Does bird meet freshness criteria (on form)?
    a. Yes; continue to #4.
    b. No; skip to #9.
    c. If unsure, continue to #4.
4. Is it obvious that bird died from suspicious circumstances (i.e., shot, electrocuted, etc.)?
    a. Yes; refer caller to USFWS Enforcement (800-858-7621, or 271-2828 in Anchorage); then skip to #9.
    b. No; continue to #5.
    c. If unsure, continue to #5.
5. Thank caller for reporting bird; tell them that if someone is not in touch with them within 24 hours, to dispose of bird according to Bulletin procedure: with gloves on (or hands in bags) double bag bird and throw in regular garbage. Continue to #6.
6. Arrange for pickup and transfer of bird; call regional Wildlife Contact (WC) to relay info about caller to them so they can coordinate details of carcass pick-up. Also obtain fax number and fax form to WC so they can have form to include in shipment.
    a. Juneau/Southeast, call Karen Blewas, (907) 465-4148; continue to #7.
    b. Fairbanks, call Kimberlee Beckmen, (907) 459-7206; continue to #7.
    c. Anchorage, try and meet caller to obtain bird and ship off to Goldstreak. If caller is from a wildlife agency, have them ship to ASVL themselves. Additional Anchorage contacts are Tom Rothe (267-2206) or Colleen Handel (USGS) 786-3418. Continue to #7.
7. Please remind WC of a few things (on the Shipping Instructions sheet).
    a. Wear gloves (or plastic bags over hands) when handling bird carcass.
    b. Double-bagged bird should be put in a box, along with identifying information or surveillance form in a separate plastic bag, and packed with ice packs to send to ASVL. Birds can be frozen.
    c. If needed, give out Epi Goldstreak number (27449001785) for package.
    d. Call Jayme Leonard (907 474-7017) with ETA of package. Continue to #10.
8. Request that the caller report their bird to 866-527-3358 (5BRDFLU). Explain that Epi is the contact for only certain species associated with WNV; we share reports with wildlife authorities as part of their larger project to track all dead birds. Continue to #10.
9. Fax form to the Bird Hotline staff (271-2744; attn: Cathy Tracy); continue to #10.
10. Please give form to LC to log; continue to #11.
11. THANKS!!

2006 WEST NILE VIRUS SURVEILLANCE—ALASKA

Alaska State Virology Laboratory (ASVL)
Alaska Division of Public Health
Phone: 907.474.7017; Fax: 907.474.4036

INSTRUCTIONS FOR COLLECTION AND SHIPMENT OF AVIAN CARCASSES

1. Use rubber gloves when picking up sick or dead birds. If you do not have gloves, insert your hand into a plastic bag. Place one bird in a plastic bag, tie shut, then place inside a second bag and tie shut (more then one individually bagged bird can be placed in the second bag). If you cannot ship the carcass within 24 hours of finding the dead bird, freeze the carcass until it can be shipped. **Carcasses should only be shipped Mon-Wed, so that they do not arrive at ASVL on the weekend.**

2. Ship all fresh or frozen birds in a hard-sided plastic cooler or a styrofoam cooler placed in a cardboard box. A shipping container can be made by lining a cardboard box with at least 1-inch thick pieces of styrofoam. Line either type of cooler with a large plastic bag and pack the individually bagged animal(s) in the cooler with enough ice packs to keep carcasses cold. Place crumpled newspaper or similar absorbent material in the cooler with the bagged carcasses to fill unused space, keep ice in contact with carcasses, provide insulation, and absorb any liquids. Tape cooler or box shut with strapping tape.

3. Place a copy of the original form in an envelope protected by a plastic bag, and tape to the outside of the shipping container.

4. Ship package via Alaska Airlines Goldstreak Service. May need to get creative if GS service doesn't exist in the specific location. Once package has been shipped, contact Jayme/Terry (907 474-7017 or jayme_leonard@health.state.ak.us ; terry_schmidt@health.state.ak.us), to inform them of the estimated arrival time.

5. Label package as DIAGNOSTIC SPECIMEN: WILDLIFE, with address:

Alaska State Virology Laboratory (ASVL)
Alaska Division of Public Health
239 Arctic Health Building
901 Koyukuk Drive South
Fairbanks, AK 99706

ATTENTION: Terry Schmidt or Jayme Leonard

Laboratories

Laboratories

State Lab-Anchorage
4500 Boniface Pkwy
Anchorage AK 99507
907-334-2100 Fax 907-334-2161
Bernd Jilly (24 hours) cell 351-2649

- Stool for enterics and O&P
- Nasopharyngeal swabs for *Bordetella pertussis*
- Foods from foodborne outbreaks
- Bacterial isolates for ID, serotyping
- Sputums for TB
- Viral transport media
- Forwards to State Lab-Fairbanks, CDC labs, private labs

State Lab-Fairbanks
901 Koyukuk Drive, South
Fairbanks, AK 99775
907-474-7018 Fax: 907-474-4036
Terry Schmidt, Manager
Direct Line: 907-474-6060
After hours call 269-5520
Pager # 0902

Specimens for viral isolation
- Serum for viral testing
- Animal heads for rabies
- Viral transport media

DEC Laboratory
5251 Hinkle Road
Anchorage, AK 99507
PHONE: (907) 375-8200
FAX: (907) 929-7335
Thomas K. Hathaway, PhD
Chief, Laboratory Services

- Shellfish for PSP, *Vibrio parahaemolyticus*
- Meats for *Trichinella*
- Water in special circumstances

Spider Information and Possible Identification

AK Co-op Extension
Anchorage 907-786-6300

Entomologist
Rod Crawford 206-543-9853
Burke Museum
University of Washington
Box 353010
Seattle, WA 98195
tiso@uwashington.edu

Entomologist
Jim Kruse 907-451-2701
U.S. Forest Service
Fairbanks

The form on the following page can be used to order requisition forms and other supplies from the Alaska State Public Health Laboratory.

Alaska State Public Health Laboratory
4500 Boniface Pkwy
Anchorage AK 99507
Phone: 907-334-2100
Fax: 907-334-2161

http://www.hss.state.ak.us/dph/labs/publications/publications.htm

Supply Request

State Public Health Laboratory-Anchorage
P O Box 196093 99519-6093
4500 Boniface Pkwy, Anchorage Alaska 99507
Voice: 907-334-2100 Fax: 907-334-2161

Please indicate the quantity of each item requested.

FORMS

_____ Miscellaneous Examination
_____ Enteric Examination
_____ Gonorrhea Culture
_____ Parasitology
_____ Region X Chlamydia/Gonorrhea
_____ Syphilis Serology
_____ Tuberculosis
_____ other-specify
_____ other-specify

TRANSPORT MEDIA

_____ Chlamydia/Gonorrhea DNA probe (Aptima Combo 2)
_____ Swabs (unisex)
_____ Urine
_____ Enteric (Carey Blair)
_____ Fungal (Sabouraud & Mycosel)
_____ Ova & Parasite (10% formalin & zinc)
_____ Pertussis culture (Regan Lowe medium & nasopharyngeal calcium alginate tipped swab)
_____ Pertussis slides (FA slides)
_____ Tuberculosis
_____ Collection tubes with sodium carbonate preservative for **sputum**
_____ Collection tubes **WITHOUT** preservative
_____ other-specify
_____ other-specify

SHIPPING SUPPLIES

_____ Diagnostic specimen shipping container-Ambient complete
_____ Infectious specimen shipping container-Ambient complete

SHIP TO: _____
ATTN: _____
_____
_____
_____

DATE REQUESTED: _____ **REQUESTED BY:** _____

DATE MAILED: _____

☐ 1st Class ☐ 3rd Class/Parcel post ☐ Call Pickup ☐ Overnight

Alaska State Public Health Laboratories
Chain-of-Custody Specimen Tracking Form

Accession No. SECC No. _____

Specimen: _____
(e.g. blood, urine, tissue, other material, with approximate amount)

_____

Specimen Identifier: _____
(patient name & DOB, OR chart number, OR other number assigned by collector)

Collection Site: _____
(name of hospital/clinic, building,OR other geographic location at which collection was done)

Collected by: _____
(name & institution)

Collection Date: _____ Time of Collection: _____ am / pm
(mm/dd/yyyy) *(circle am/pm)*

Reason for Collection: _____

Prescreened for ☐ Radiologicals ☐ Chemicals ☐ Explosives

☐ Other _____ ☐ Not warranted by circumstances

Received from: _____
(name & institution) *(signature)*

Received by: _____
(name & institution) *(signature)*

Date: _____ Time: _____

Reason for transfer:

Received by: _____
(name & institution) *(signature)*

Date: _____ Time: _____

Reason for transfer:

Alaska State Public Health Laboratories
Chain-of-Custody Specimen Tracking Form

Received by: _____
(name & institution) *(signature)*

Date: _____ Time: _____

Reason for transfer:

Received by: _____
(name & institution) *(signature)*

Date: _____ Time: _____

Reason for transfer:

Received by: _____
(name & institution) *(signature)*

Date: _____ Time: _____

Reason for transfer:

Received by: _____
(name & institution) *(signature)*

Date: _____ Time: _____

Reason for transfer:

Received by: _____
(name & institution) *(signature)*

Date: _____ Time: _____

Reason for transfer:

The form on the following page can be used to order requisition forms (examples on following pages) and other supplies from the Alaska State Virology Laboratory.

Alaska State Virology Lab
901 Koyukuk Drive, South
Fairbanks, AK 99775
Phone: 907-474-7018
Fax: 907-474-4036

http://www.hss.state.ak.us/dph/labs/publications/publications.htm

Supply Request

State Public Health Laboratory-Fairbanks
PO Box 60230, Fairbanks, Alaska 99706-0230
901 Koyukuk Avenue South SHB 239 99775
Voice: 888-474-7017 Fax: 907-474-4036

Please indicate the quantity of each item requested.

FORMS

_____ Hepatitis
_____ HIV
_____ Miscellaneous Viral Serology
_____ Rubella Serology
_____ Virology Culture

TRANSPORT MEDIA

_____ Viral transport medium

SHIPPING SUPPLIES

_____ Diagnostic specimen shipping container-Ambient complete
_____ Infectious specimen shipping container-Ambient complete

Please ship the requested items **DIRECTLY** to the name and address shown below. Thank you.

SHIP TO: _____
ATTN: _____
_____
_____
_____

DATE REQUESTED: _____ **REQUESTED BY:** _____

☐ 1st Class ☐ 3rd Class/Parcel post ☐ Call Pickup ☐ Overnight

Alaska State Virology Laboratory - Fairbanks
Division of Public Health
P.O. Box 60230
Fairbanks, Alaska 99706-0230
Phone (907)474-7017 FAX (907)474-4036

STATE OF ALASKA
HEPATITIS REQUEST FORM

PLEASE PRINT LEGIBLY

EXEMPTION # _____

INS/MEDICAID # _____

ACCESSION # _____

PATIENT INFORMATION

_____
LAST NAME FIRST NAME M.I.

OTHER PATIENT ID # _____

DATE OF BIRTH ____/____/____
month day year

*RACE _____ SEX _____ *RISK _____

SPECIMEN COLLECTION DATE ____/____/____
month day year

*SEE BACK OF FORM FOR RACE AND RISK CODES

PROVIDER INFORMATION

NAME

FACILITY

ADDRESS

PHONE #

FAX #

REMARKS _____

_____

TEST REQUESTED

- [ ] HEPATITIS A
- [ ] HEPATITIS B
- [ ] HEPATITIS C

REASON FOR TEST

- [ ] SCREEN
- [ ] PRENATAL
- [ ] POST VACCINE — # OF VACCINES _____
- [ ] SYMPTOMATIC — DATE OF ONSET mo ____ day ____ year ____
- [ ] PREVIOUS SURFACE ANTIGEN POSITIVE

DATE RECEIVED	RECEIVED BY
CONDITION/COMMENTS	

STATE OF ALASKA
Alaska State Virology Laboratory - Fairbanks
Division of Public Health
P.O. Box 60230, Fairbanks, Alaska 99706-0230
Voice (907)-474-7017 // Fax (907)-474-4036

NOROVIRUS PCR REQUEST.FORM

Accession # _____

SUBMITTER INFORMATION	**Patient Information**
PHYSICIAN NAME:	PATIENT REFERRAL # _____
FACILITY:	LAST NAME _____
ADDRESS:	FIRST NAME _____ INIT _____
	DOB _____/ _____/ _____ MONTH DAY YEAR
CITY/ZIP:	SEX ____
PHONE #:	SPECIMEN COLLECTION DATE _____/ _____/ _____ MONTH DAY YEAR

SPECIMEN	**Immunization Status**	**Travel History** : _____
_____ STOOL _____ OTHER _____		

Brief Clinical History: _____

Illness Onset Date: _____

SHADED AREA FOR LABORATORY USE ONLY

DATE RECEIVED:	RECEIVED BY:	CONDITION OF SPECIMEN:	REMARKS:

VIROLOGY CULTURE REQUEST FORM

STATE OF ALASKA
Alaska State Virology Laboratory - Fairbanks
Division of Public Health
P.O. Box 60230, Fairbanks, Alaska 99706-02230
Phone (907)474-7017 FAX (907)474-4036

PLEASE PRINT LEGIBLY

EXEMPTION # _____

INSURANCE/MEDICAID # _____

SUBMITTER INFORMATION	PATIENT INFORMATION
PHYSICIAN NAME:	PATIENT REFERRAL # _____
FACILITY:	LAST NAME _____
ADDRESS:	FIRST NAME _____ INIT _____
	DOB _____ / _____ / _____ (MONTH DAY YEAR)
CITY/ZIP:	RACE* _____ SEX _____ RISK* _____ *SEE BACK OF FORM FOR RACE AND RISK CODES
PHONE #:	SPECIMEN COLLECTION DATE _____ / _____ / _____ (MONTH DAY YEAR)

Please check any of the following that apply:

TYPE:	CLINICAL DIAGNOSIS (Specific viral etiology):	SIGNS & SYMPTOMS:	Illness onset date:
___ Nasopharyngeal ___ CSF ___ Throat ___ Genital ___ Stool ___ Other_____	___ Adenovirus ___ *Rotavirus* ___ *Herpes simplex* ___ Enterovirus ___ RSV ___ Influenza ___ Other_____	___ *Respiratory* ___ *Neurologic* ___ Gastrointestinal ___ Skin/membranes ___ Other_____	Immunization status:

Brief clinical summary: _____

SHADED AREA FOR LABORATORY USE ONLY	DATE REC'D:	REC'D BY:	CONDITION OF SPECIMEN:	ACCESSION #

STATE OF ALASKA
Alaska State Virology Laboratory - Fairbanks
Division of Public Health
P.O. Box 60230, Fairbanks, Alaska 99706-0230
Voice (907)-474-7017 // Fax (907)-474-4036

WEST NILE VIRUS SEROLOGY REQUEST FORM

Accession # _____

SUBMITTER INFORMATION	**Patient Information**
PHYSICIAN NAME:	PATIENT REFERRAL #_____
FACILITY:	LAST NAME _____
ADDRESS:	FIRST NAME _____ INIT _____
	DOB _____/ _____ / _____ MONTH DAY YEAR
CITY/ZIP:	SEX ____
PHONE #:	SPECIMEN COLLECTION DATE _____/ _____ / _____ MONTH DAY YEAR

SPECIMEN	**Immunization Status**	**Travel History** : _____
_____ SERUM	Yellow Fever: Y ❑ N ❑	_____
_____ OTHER _____	Japanese B: Y ❑ N ❑	

Brief Clinical History:
_____

Illness Onset Date: _____

Dengue/DHF Infection: Y ❑ N ❑

SHADED AREA FOR LABORATORY USE ONLY

DATE RECEIVED:	**RECEIVED BY:**	**CONDITION OF SPECIMEN:**	**REMARKS:**

MISCELLANEOUS VIRAL SEROLOGY REQUEST FORM

STATE OF ALASKA
Alaska State Virology Laboratory - Fairbanks
Division of Public Health
P.O. Box 60230, Fairbanks, Alaska 99706-02230
Phone (907)474-7017 FAX (907)474-4036

PLEASE PRINT LEGIBLY

EXEMPTION # _____

INSURANCE/MEDICAID # _____

SUBMITTER INFORMATION	PATIENT INFORMATION
PHYSICIAN NAME:	PT REFERRAL # _____
FACILITY:	LAST NAME _____
ADDRESS:	FIRST NAME _____ INIT _____
	DOB _____ / _____ / _____ (MONTH DAY YEAR)
CITY/ZIP:	RACE* _____ SEX _____ RISK* _____
	*SEE BACK OF FORM FOR RACE AND RISK CODES
PHONE #:	SPECIMEN COLLECTION DATE _____ / _____ / _____ (MONTH DAY YEAR)

TEST REQUESTED

- ☐ RUBELLA
- ☐ RUBEOLA
- ☐ MUMPS
- ☐ VARICELLA ZOSTER
- ☐ CYTOMEGALOVIRUS
- ☐ HERPES SIMPLEX
- ☐ EPSTEIN-BARR VIRUS
- ☐ TOXOPLASMOSIS
- ☐ OTHER (PLEASE SPECIFY) _____

REASON FOR TEST

- ☐ SCREEN
- ☐ SYMPTOMATIC

DATE OF ONSET _____ / _____ / _____ (MONTH DAY YEAR)

(SHADED AREA FOR LAB USE ONLY) REMARKS: _____

DATE RECEIVED:	RECEIVED BY:	CONDITION OF SPECIMEN:	ACCESSION #

Stool Collection

Stool Culture for Enteric Pathogens (ETM)

Collection Instructions:

1. Collect feces in to a clean container or on plastic wrap stretched across the toilet. Do not use toilet paper to collect stool. Toilet paper may contain inhibitors for some fecal pathogens.
2. Never collect specimens from a toilet bowl. Contamination with urine or water from toilet bowl renders the specimen unsatisfactory.
3. The specimen **should not** contain barium, antibiotics, mineral oil or any drugs. Delay specimen collection for a minimum of 5 days after administration of these agents.
4. Samples must be placed in to Enteric Transport Media within **ONE hour** of collection for recovery of organisms.

Materials

1. Collection container
2. Enteric Transport Media (ETM) or Carey-Blair Rectal Swab
3. Enteric Requisition Form

ETM collection procedures:

1. Collect stool in clean dry container or on plastic wrap stretched across toilet.
2. Stool must be placed into ETM within one hour of sample collection.
3. Carefully open ETM, use scoop mounted in lid to place approximately a walnut size amount of stool in to transport. Add only the amount of stool needed to fill exactly to **red fill line.** Do not overfill.
4. Clearly label specimens with patient name, collection date, and date of birth or patient number.
5. Fill-out Enteric Requisition Form completely, with patient and submitter information.

Carey-Blair Transport Swabs for Rectal Collection:

- Carey-Blair Transport Swabs are available from ASPHL for rectal collections.
- A stool collection is the preferred sample, but is not always possible to collect.
- Do not use expired swab for collection.
- Store and ship swabs at room temperature.

Packaging & Shipment:

1. Do not allow specimen or media to freeze.
2. Package appropriately for current shipping regulations.
3. Ship at room temperature.
4. Send to the State Public Health Laboratory in Anchorage.

Test Interpretation:

- Enteric specimens will be screened for the common pathogens including: *Salmonella, Shigella, Campylobacter*, and *E. coli 0157*. All positive *Salmonella* & *Shigella* species will be serotyped.
- Negative and preliminary results will be available in two working days from receipt of sample.
- Pulse-field Gel Electrophoresis (PFGE) is performed on all *Salmonella, Shigella, Campylobacter*, and *E. coli 0157* as specimen volume and time allows. If expedited PFGE results are needed, please call Dr. Jilly (Chief) or Shellie Smith (Lab Manager) at the ASPHL to request.
- Examination for *Yersinia entercolitica* and *Vibrio* species (including *V. cholera*) will be performed upon request and should be noted clearly on the requisition slip.
- Multiple specimens must not be collected on the same day. Collect 24-48 hours apart.

Specimen Collection in an Outbreak of Foodborne Illness

Confirmation of an Outbreak:
Two or more people having similar symptoms after consuming a common food or consumption of different food in a common place.[1]

Confirm Diagnosis (when possible):
Collect specimens from cases and, if possible and indicated, collect samples of the implicated food.

Possibly Bacterial:
Average incubation: 1–7 days
Diarrhea
Abdominal cramps
Fever/headache/muscle aches
Possibly vomiting

Associated Vehicles:
Beef/fish/pork
Chicken/eggs, seafood, shellfish
Unpasteurized milk, juices
Manure fertilized fruits & vegetables

Possible Bacterial Organisms:
Campylobacter jejuni 2-5 D
E. coli O157:H7/ETEC/EHEC 1-8 D
Listeria monocytogenes 9-48 hr
Salmonella spp.; Shigella spp. 1-3 D
Vibrio spp. 1-7 D
Yersinia enterocolytica 24-48 hr

Enteric Culture Collection Kit*:
Amies or other suitable transport media
Instructions
Requisition (lab) form
Diagnostic shipper (if applicable)

Possibly Viral:
Average incubation: 1–2 days
Vomiting/abdominal cramps
Muscle aches
Diarrhea
Fever/headache

Associated Vehicles:
Shellfish
Uncooked foods
Salads
Food handled by ill person

Possible Viral Organisms:
Norwalk-like virus 12-72 hr
Rotavirus 1-3 D
Hepatitis A[2] 15-50 D

Stool Collection Kit*:
Specimen collection cup
Instructions
Requisition (lab) form
Diagnostic shipper (if applicable)

Possibly Toxin:
Average incubation: 0.5 to 20 hrs
Diarrhea/abdominal cramping
Nausea/vomiting
Flushing
Fever/headache
Paresthesia/neurologic Sx

Associated Vehicles:
Shellfish/tuna/mahi mahi
Raw produce, meat, stew, gravy
Home-canned foods, rice

Possible Toxins:
Staphylococcus aureus[3] (<1-4 h)
Bacillus cereus[4] (<1-6 or 6-24h)
Clostridium perfringens (6-20h)
Clostridium botulinum[4] (12-36h)
Scombroid[5] (<1-3h)

Stool Collection Kit*:
Specimen collection cup
Instructions
Requisition (lab) form
Diagnostic shipper (if applicable)

Possibly Parasitic:
Average incubation: 7 days
Diarrhea
Abdominal cramps
Vomiting
Fever/headache
Nausea
Fatigue

Associated Vehicles:
Fecally contaminated water
Food handled by ill person

Possible Parasitic Organisms:
Cryptosporidium parvum 7 Days
Giardia lamblia 1–4 Weeks
Cyclospora cayentanensis 1 Week

Parasitic Collection Kit*:
Ova and Parasite kit
-1 PVA, 1 formalin
Instructions
Requisition (lab) form
Diagnostic shipper (if applicable)

1. One case of botulism or scombroid toxicity is considered an outbreak.
2. Serum specimens are necessary for these infections.
3. & 4. Stool, vomitus, and food can be tested for toxin.
5. Must test for histamine in fish tissue.

* Outbreaks of unknown etiology may require specimen collection by using more than one kit.

Enteric Bacteria Specimen Submission for Outbreak Investigations

Specimens are collected and submitted on patients associated with a suspected outbreak and/or complaining of gastrointestinal symptoms including diarrhea, abdominal cramping, nausea, and vomiting. All specimens should be accompanied with a lab requisition form containing the patient's name, address, phone number, a brief symptom history, and the suspected organism(s).

Collection

1. **Carey-Blair or other suitable transport media**
   - ✓ The cotton or Dacron swab must be completely soiled with feces.
   - ✓ If a case is unable to pass a stool, a rectal swab can be taken.
2. **Collection Instructions**
   - ✓ See stool collection form.
3. **Requisition Form**
4. **Diagnostic Shipper**
   - ✓ Diagnostic shipper should be pre-addressed with the mailing label provided and affixed with a clinical specimen sticker. Apply postage and ship to:

State Public Health Laboratory
P.O. 196093
Anchorage, AK 99519-6093
-or-
4500 Boniface Parkway
Anchorage, AK 99707

Precautions

1. Instruct patients to wash hands before and after collecting a stool specimen.
2. Instruct patients to avoid contact of feces with urine or stool water.
3. If a patient has begun an antibiotic regimen, specimens may not be accepted for testing.

Storage and Shipping

Be certain that each specimen tube has a requisition form properly completed. Make sure the caps on the collection tubes are tightly sealed. **See the page detailing diagnostic and infectious agent shipping instructions.**

Patient Instruction Sheet for Stool Collection

Instructions for collecting a stool specimen (viral and bacterial pathogens)

1. Place a piece of saran wrap over the toilet bowl between the seat and the base.
2. Defecate on the saran wrap.
3. With gloves on, place a generous quantity of stool or diarrhea into the specimen cup.
4. Unscrew the black cap from the glass bottle with the blue gelatinous media.
5. Taking a Q-tip, scoop up some stool with the cotton end of the Q-tip and place stool-coated Q-tip into the glass bottle.
6. Push the tip of the Q-tip all the way to the bottom of the blue media and then break off enough of the remaining wooden end so that you can screw the black cap tightly back onto the glass bottle.
7. Wrap any remaining stool in the saran wrap and dispose of in the trash.
8. Remove gloves and wash hands well.

Instructions for collecting a stool specimen (parasitic pathogens)

1. From the specimen cup or from the remaining stool on the saran wrap, place enough stool into the plastic containers with yellow and blue tops to raise the liquid level to the appropriate point. More detailed instructions accompany this kit. Please follow those directions carefully.

Parasitic Specimen Collection for Outbreak Investigations

Specimens are collected and submitted on patients associated with a suspected outbreak and/or complaining of gastrointestinal symptoms including diarrhea, abdominal cramping, and nausea. All specimens should be accompanied with a lab requisition form containing the patient's name, address, phone number, a brief symptom history, and the suspected organism(s).

Collect feces into a clean container or in a sheet of plastic wrap stretched across the toilet. Never collect specimens from the toilet bowl. Collect a total of two specimens, one every 48 hours.

Collection Kit

1. **Ova and Parasite Kit**
   - 1 vial containing 10% formalin.
   - 1 vial containing polyvinyl alcohol fixative.
   - A scoop spoon is attached to the lid of each vial for ease of transferring feces to the vials.
   - Add specimen to collection system kit provided by the APHL. Add sufficient specimen to the indicated fill level. Do not over fill. Mix thoroughly.
2. **Collection Instructions**
   - To increase the probability of collecting a viable specimen, thoroughly explain the collection instructions included in the collection kit. An improperly collected specimen may render it not testable at the Lab, thus making confirmation of a diagnosis impossible
   - DO NOT freeze specimens.
3. **Requisition Form:** Parasitology
   - Examination for Cryptosporidium or Cyclospora sp. will be performed upon request.
4. **Diagnostic Shipper**
   - Diagnostic shipper should be pre-addressed with the mailing label provided and affixed with a clinical specimen sticker. Apply postage and send via United States Postal Service to:

State Public Health Laboratory PO Box 196093 Anchorage, AK 99519-6093	State Public Health Laboratory 4500 Boniface Parkway Anchorage, AK 99507

Precautions

1. Instruct patients to wash hands before and after collecting a stool specimen.
2. Instruct patients to avoid contact of feces with urine or stool water.

Storage and Shipping

Each case should submit two Ova and Parasite (O&P) kits consisting of two vials. Be certain that each O&P kit is clearly labeled (name on each vial) and has a requisition form properly completed. Make sure the caps on the collection vials are tightly sealed. **The lab must receive specimens within three days of collection.** The lab may take 5 working days to provide results.

Stool Specimen Collection for Outbreak Investigations of Viral Agents or Bacterial Toxins

Specimens are collected and submitted on patients associated with a suspected outbreak and/or complaining of gastrointestinal symptoms including diarrhea, abdominal cramping, and nausea. All specimens should be accompanied with a lab requisition form containing patient name, address, phone number, a brief symptom history, and the suspected organism(s).

Collection Kit

1. **Sterile Collection Receptacle**
   - Screw capped, wide mouth container; inform patient not to fill the container more than half full.
2. **Collection Instructions**
   - To increase the probability of collecting a viable specimen, thoroughly explain the collection instructions included in the collection kit. An improperly collected specimen may render it not testable at the Lab, thus making confirmation of a diagnosis impossible.
3. **Refrigerant packs**
   - All whole stool specimens must be shipped with refrigerant packs.
4. **Requisition Form**
5. **Diagnostic Shipper**
   - Diagnostic shippers should be pre-addressed with the mailing label provided and affixed with a clinical specimen sticker. If out of mailing labels, please address the diagnostic shipper before distributing it to a case to:

Alaska State Virology Laboratory
901 Koyukuk Dr. South
Fairbanks, AK 99775
(907-474-7017).

Precautions

1. Instruct patients to wash hands before and after collecting a stool specimen.
2. Instruct patients to avoid contact of feces with urine or stool water.

Storage and Shipping

Send bulk, unpreserved stool specimens in an insulated box containing refrigerant packs and absorbent material to contain any leakage that may occur. Be certain that each specimen receptacle is tightly sealed and has a requisition form properly completed and attached to the respective receptacle with a rubber band. All shipments need to be shipped as a diagnostic sample with a clinical specimen notice attached to the box. **The lab must receive specimens within three days of collection.**

Food Specimen Collection Kit for Outbreak Investigations

Specimens are collected and submitted on patients associated with a suspected outbreak and/or complaining of gastrointestinal symptoms including diarrhea, abdominal cramping, nausea, and vomiting. All specimens should be accompanied with a lab requisition form containing the patient's name, address, phone number, a brief symptom history, and the suspected organism(s).

Collection Kit

1. **Sample containers**
   - Use sterile zip-top or whirlpak bags for solid samples.
   - Use sterile plastic cups with screw tops for liquids.
2. **Collection implements**
   - Spoons, scoops, spatula, swabs
3. **Refrigerant packs**
4. **Requisition Form**
5. **Diagnostic Shipper**

Collection of Environmental Samples

Ideal environmental samples include food consumed from the suspect meal; samples obtained from the food preparation area; and, samples of food prepared in a similar manner as the suspect food. When canned or packaged food is suspected, collect unopened samples. Also, if appropriate, swab surfaces of suspect utensils and food preparation areas.
In general, food samples should be less than three days old.

1. Be sure to clearly mark the container and attach the accompanying lab requisition form.
   - Include on the requisition form:
     - type of sample
     - where collected
     - date of sample
     - outbreak name or code
2. Be sure that containers are tightly sealed to prevent leakage.
3. Collect an adequate amount of sample—approximately 200g (1/3 to 1/2 lb).

Storage and Shipping

Send all environmental samples from one outbreak in a single shipment with an identifier. All samples should be accompanied with a lab requisition form. Environmental samples should be shipped as follows: frozen foods should be shipped on dry ice; perishable or cold foods should be shipped on ice or with refrigerant packs; canned or low moisture foods can be shipped at ambient temperature. Samples should be sent in an insulated box to:

State Public Health Laboratory PO Box 196093 Anchorage, AK 99519-6093	State Public Health Laboratory 4500 Boniface Parkway Anchorage, AK 99507