Vaccine-Preventable Disease Surveillance Guidelines

Bureau of Immunization and Pharmacy Support
Immunization Division
Surveillance and Epidemiology Program
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Section 1: Diphtheria

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

REPORTING
Immediately report suspected cases to the local or regional health department at **(800) 705-8868** or the Texas Department of Health (TDH) Immunization Division at **(800) 252-9152**.

CASE INVESTIGATION
There is no specific case investigation form; however, the TDH Immunization Division will require a detailed written report if a case is confirmed.

CASE CLASSIFICATION
- **Confirmed:** A clinically compatible case that is laboratory confirmed or is epidemiologically linked to a laboratory-confirmed case.
- **Probable:** A clinically compatible case that is not laboratory confirmed and is not epidemiologically linked to a laboratory-confirmed case.

LABORATORY CONFIRMATION
- Isolation of *Corynebacterium diphtheriae* from a clinical specimen.
- Histopathologic diagnosis of diphtheria.

CONTROL MEASURES
- Reports of suspected diphtheria should be investigated **immediately**.
- Identify close contacts.
- Only close contacts of a patient with culture-confirmed or suspected diphtheria should be considered at increased risk for acquiring secondary disease. Such contacts include all household members and other persons with a history of habitual close contact with the patient, as well as those directly exposed to oral secretions of the patient.
- Any patient for whom the decision has been made to treat with diphtheria antitoxin should be considered a suspected case of diphtheria until appropriate laboratory testing confirms or rules out the diagnosis.
- Close contacts should be cultured, receive prompt antimicrobial chemoprophylaxis, and be examined daily for seven days for evidence of disease. Do not wait for culture results before treating contacts.
- Recommended prophylaxis is a 7-10 day course of oral erythromycin (children-40 mg/kg/day, and adults-1 g/day).
- Identified carriers of *C. diphtheriae* should be cultured after they complete antimicrobial therapy. Those who continue to carry the organism should receive an additional 10-day course of oral erythromycin and follow-up cultures.
- All close contacts who have received fewer than three (3) doses of diphtheria toxoid or whose vaccination status is unknown should receive an immediate dose of a diphtheria toxoid-containing preparation appropriate for their age and should complete the primary series according to the recommended schedule.
- Close contacts who have completed a primary series of three or more doses of diphtheria toxoid and who have not been vaccinated with diphtheria toxoid within the previous five years should receive a booster dose appropriate for their age.

- Patient should be kept in strict isolation until two cultures from both throat and nose, taken not less than 24 hours apart, and not less than 24 hours after cessation of antimicrobial therapy, fail to show diphtheria bacilli. If cultures are not possible, patient should be kept in isolation for 14 days following appropriate antibiotic treatment.

SPECIFIC LABORATORY PROCEDURES

Isolation and identification of *Corynebacterium diphtheriae* is available through the TDH, Bureau of Laboratories.

- Swabs should be taken from the nose, throat, membrane, and behind the membrane, if possible.
- Ship swabs in Ames or Stewarts Transport or transfer to a Loefflers Slant for transport to TDH Labs.
- For PCR testing, ship swabs in a sterile empty container or silica gel sachets
- Use a G-1a form for specimen submission.
- Ship specimen to TDH Labs via an overnight courier service or overnight mail.
- Mail specimens to:

Bacteriology
Bureau of Laboratories
Texas Department of Health
1100 West 49th Street
Austin, TX 78756

Section 2: Hepatitis B

PART 1: Acute and Chronic Hepatitis B

Note: Refer to Table 2 for hepatitis B diagnostic test definitions and abbreviations and Table 3 for interpretation of hepatitis B serological tests.

CLINICAL CASE DEFINITIONS

- **Acute:** An acute onset of symptoms and jaundice or elevated serum aminotransferase levels. Clinical signs and symptoms of acute hepatitis B virus (HBV) infection include anorexia, nausea, malaise, vomiting, jaundice, dark urine, clay-colored or light stools, and abdominal pain. Occasionally, extrahepatic manifestations occur and include skin rashes, arthralgia, and arthritis.
- **Chronic:** A person who is HBsAg-positive for 6 months or who is IgM anti-HBc-negative and HBsAg-positive.

CASE CLASSIFICATION AND LABORATORY CONFIRMATION

- **Confirmed Acute:** A clinically compatible case that is positive for IgM antibody to hepatitis B core antigen.
- **Confirmed Chronic:** HBsAg positivity in serum for at least 6 months or IgM anti-HBc-negative and HBsAg-positive.

MODES OF TRANSMISSION

- Transfusion of contaminated blood or blood products
- Sharing or reusing non-sterilized needles, syringes, razors, toothbrushes, manicure equipment, or any other items which may contain the blood or body fluid of an infected person
- Percutaneous or mucous membrane exposure to blood or body fluids
- Sexual activity with an infected person
- Tattooing and/or body piercing
- Perinatally (either in utero or at delivery)

REPORTING OF CASES

Report all acute hepatitis B cases to the local or regional health department at **(800) 705-8868** or the Texas Department of Health, Immunization Division at **(800) 252-9152**. **NOTE:** HBsAg-positive pregnant women (acute and chronic infections) should also be reported to the Texas Department of Health, Immunization Division. *SEE PART 2: PERINATAL HEPATITIS B GUIDELINES

CASE INVESTIGATION

The following is required information on the Laboratory Reporting of Hepatitis B Antigen form:

- Patient demographics – name, date of birth, age, sex, race/ethnicity, address, and phone number
- Clinical information – onset date, method of diagnosis, physician name, address and phone number, and case status (acute, acute/pregnant, acute with newborn, chronic, chronic/pregnant, chronic with newborn, or unknown)

The following information is required for pregnant females identified as HBsAg-positive:

- Expected date of delivery
- Planned delivery hospital

The following information is required for acute or chronically infected females with newborns <1 year of age:

- Delivery hospital
- Name of infant and date of birth
- Name of infant's physician and phone number

Collection of additional information listed on the Acute Hepatitis B Case Track Record is **OPTIONAL.**

CONTROL MEASURES (Any person testing positive for HBsAg is potentially infectious)

- **Follow universal precautions to prevent exposure to blood and body fluids.**
- **Disinfect all equipment contaminated with blood or infectious body fluids.**
- **Investigate contacts and source of infection.**
  When two or more cases occur in association with a common exposure, search for additional cases. If a plasma derivative such as antihemophilic factor, fibrinogen, pooled plasma, or thrombin is implicated, withdraw lot from use and trace all recipients of the same lot to identify additional cases.
- **Counsel all household members** (applies to acute and chronically infected persons)
  Members of the household should be advised to keep their personal care items (razors, manicure equipment, and toothbrushes) separate from those of others in the home. Menstruating females should be advised to clean toilet seats with a solution of bleach and water after each use and to take extra precautions when disposing of used sanitary items.
- **Determine susceptibility of contacts**
  - **Susceptible:** persons who are not immune to HBV or who have not been appropriately vaccinated against HBV
  - **Protected:** persons with adequate antibody response (anti-HBs ≥10 milli-IUs/mL) due to vaccination or natural infection
  - **Primary non-responder:** persons who do not demonstrate adequate antibody response after three doses of hepatitis B vaccine
  - **Non-responder:** persons who have received two complete series of the hepatitis B vaccine but still do not demonstrate adequate antibody response
  - **Unknown**: persons whose anti-HBs status is unknown are always considered susceptible
- **Initiate post-exposure prophylaxis of contacts**
  - **Sexual contacts:**
    Susceptible[1] sexual partners should receive both a single dose of .06 mL/kg hepatitis B immune globulin (HBIG) and the first dose of hepatitis B vaccine at the same time and within 14 days of their last sexual contact. The remaining two doses of hepatitis B vaccine should be administered at one (1) and six (6) months from the date of the first vaccine. Sexual contacts whose immune status is unknown are considered susceptible.
  - **Non-sexual household contacts:**
    Infants who have not completed the three-dose hepatitis B vaccine series, and who have close contact with acutely infected primary care givers, should receive HBIG and complete the hepatitis B vaccine series. Other susceptible household contacts should begin the hepatitis B vaccine series, but HBIG is not indicated unless there has been an identified blood exposure such as the sharing of toothbrushes or razors. Contacts whose immune status is unknown should be considered susceptible.
  - **Percutaneous or mucous membrane exposures:**
    Determine whether or not the source and HBsAg status of the blood is known. If the HBsAg status is positive or unknown, refer to Table 1. If the blood is HBsAg-negative, no further action is necessary.

1 Susceptibility testing of sexual contacts should be considered only if it will not delay vaccination beyond 14 days.

Table 1. Summary of Recommendations for Prophylaxis Following Percutaneous or Permucosal Exposure to HBsAg

	Treatment When Source is Found to Be:		
Exposed Person	**HBsAg-positive**	**HBsAg-negative**	**Source not tested or unknown**
Unvaccinated	HBIG 1 dose[1] and initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated Known responder[2]	No treatment	No treatment	No treatment
Previously vaccinated Known non-responder	HBIG 2 doses or HBIG 1 dose **and** initiate re-vaccination[3]	No treatment	If known high-risk source, treat as if source were HBsAg-positive
Previously vaccinated Response unknown	Test exposed person for anti-HBs 1. If adequate[4], no treatment 2. If inadequate, HBIG 1 dose **and** HB vaccine booster dose	No treatment	Test exposed for anti-HBs 1. If adequate[4], no treatment 2. If inadequate, HB vaccine booster dose

1 Dose of HBIG, 0.06 mL/kg, intramuscularly

2 Responder is defined as a person with documentation of adequate levels of anti-HBs post-vaccination (adequate level of anti-HBs is $\geq$ 10 mIU/ML).

3 Persons known NOT to have responded to a 3-dose vaccine series and to re-vaccination with 3 additional doses should be given 2 doses of HBIG (0.06 mL/kg), 1 dose as soon as possible after exposure and the second one 1 month later.

4 Adequate anti-HBs is ≥10 mIU/mL

RECOMMENDED PREVENTION STRATEGIES:

- Identify HBsAg-positive pregnant women.
- Prevent hepatitis B acute and/or chronic infections in infants born to HBsAg-positive women.
- Serologically test household and sexual contacts of HBsAg-positive pregnant women.
- Vaccinate all susceptible household and sexual contacts of HBsAg-positive pregnant women.
- Vaccinate all infants, children, and adolescents.
- Vaccinate users of intravenous and illicit drugs.
- Vaccinate sexually active adults. Persons diagnosed with a sexually transmitted disease or who have had more than one sex partner in the previous six months should be vaccinated.
- Vaccinate health care workers and others at risk of exposure to blood or other body fluids.
- Vaccinate susceptible hemodialysis patients.
- Vaccinate patients who are receiving clotting factor concentrates. Pre-vaccination testing for HBsAg and anti-HBc is recommended for patients who have already received multiple infusions of clotting factors.
- Vaccinate household contacts and sexual partners of hepatitis B virus (HBV) carriers.
- Screen adoptees from countries where hepatitis B is endemic. Vaccinate susceptible family members and other household contacts if adoptee is HBsAg-positive.
- Vaccinate international travelers to areas where HBV infection is endemic.
- Vaccinate residents and staff of institutions for the developmentally disabled.
- Vaccinate inmates of long-term correctional facilities.

Table 2. Diagnostic Test for hepatitis B virus (HBV) Antigens and Antibodies

Marker	Abbreviation	Use
Hepatitis B surface antigen	**HBsAg**	Detection of acutely or chronically infected persons; antigen used in hepatitis B vaccine
M class immunoglobulin antibody to hepatitis B core antigen	**IgM Anti-HBc**	Identification of acute or recent HBV infections (including those in HBsAg-negative persons during the "window" phase of infection)
Antibody to hepatitis B core antigen	**Anti-HBc**	Identification of persons with acute, resolved, or chronic HBV infection (**not present after vaccination**)
Antibody to Hepatitis B surface antigen	**Anti-HBs**	Identification of persons who have resolved infection with HBV; determination of immunity after immunization
Hepatitis B e antigen	**HBeAg**	Identification of infected persons at increased risk for transmitting HBV
Antibody to Hepatitis B e antigen	**Anti-HBe**	Identification of infected person with lower risk for transmitting HBV

Source: American Academy of Pediatrics. Hepatitis B. In: Pickering LK, ed. *2000 Red Book: Report of the Committee on Infectious Diseases*. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2000: page 291.

Table 3. Interpretation of Hepatitis B Serological Tests*

Tests	Results	Interpretation
HBsAg Anti-HBc Anti-HBs	Negative Negative Negative	Susceptible (Never infected or immunized)
HBsAg Anti-HBc Anti-HBs	Negative Negative or Positive Positive	Immune
HBsAg Anti-HBc IgM anti-HBc Anti-HBs	Positive Positive Positive Negative	Acutely Infected
HBsAg Anti-HBc IgM anti-HBc Anti-HBs	Positive Positive Negative Negative	Chronically Infected
HBsAg Anti-HBc Anti-HBs	Negative Positive Negative	Four interpretations possible*

* 1. May be recovering from acute HBV infection.
2. May be distantly immune and test not sensitive enough to detect very low level of anti-HBs in serum
3. May be susceptible with a false positive anti-HBc.
4. May be undetectable level of HBsAg present in the serum and the person is actually a carrier.

Source: Centers for Disease Control and Prevention

Part 2: Perinatal Hepatitis B

INTRODUCTION

The purpose of identifying HBsAg-positive pregnant women is to prevent transmission of the hepatitis B virus (HBV) to their infants. Infants born to HBsAg-positive women have a 70% to 90% chance of becoming infected if left untreated, and 85% to 90% of those infected will subsequently become chronic carriers. Up to 25% of infants infected perinatally will die of chronic liver disease as adults. Hepatitis B immune globulin (HBIG) and hepatitis B vaccine administered to newborns at birth, followed by two subsequent doses of hepatitis B vaccine at one and six months of age can prevent more than 90% of perinatal hepatitis B infections.

Local and regional health departments should take the lead role in coordinating perinatal hepatitis B prevention activities in their respective jurisdictions. These prevention services should be provided to all pregnant women identified as HBsAg-positive regardless of their source of payment for prenatal and delivery services. The TDH Laboratory in Austin will test specimens submitted on pregnant women and their household and sexual contacts and infants. Hepatitis B biologicals (HBIG and vaccine) are available from the TDH for infants born to HBsAg-positive women, as well as their household and current sexual contacts. The TDH Immunization Division and the Bureau of Women's Health will assist with educational and consultative services as needed.

Perinatal Hepatitis B prevention activities include:

- Serologic screening of pregnant women
- Reporting of HBsAg-positive women
- Education of HBsAg-positive women
- Identifying, serologically screening, and vaccinating susceptible household and sexual contacts
- Prophylactically treating infants delivered to HBsAg-positive women with hepatitis B vaccine and HBIG (hepatitis B immune globulin)
- Case management of infants born to HBsAg-positive women (including post-vaccination serologic testing)

SEROLOGIC SCREENING OF PREGNANT WOMEN

Since 1991, the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and the Advisory Committee on Immunization Practices (ACIP) have recommended that all pregnant women be serologically screened for HBV infection. In Texas, this recommendation became a requirement with the passage of Senate Bill 519 in 1999. All pregnant women must now be screened for hepatitis B infection **twice**--at their first prenatal visit **and** upon admission to the hospital for delivery. The requirement applies to the physician or other person who attends a pregnant woman during gestation and/or delivery of her infant. Pregnant women identified as positive for HBsAg should be retested after six months to determine their chronic carrier status.

Reports of HBsAg-positive women come to the attention of the Texas Department of Health from a variety of sources- laboratories, prenatal care providers, delivery hospitals, infant care providers, other public health agencies, drug rehabilitation facilities, hospital emergency rooms, as well as self-reports and reports from relatives, household members, and sex partners of the pregnant woman. TDH staff, in turn, refers the information to local and regional health department personnel for appropriate follow-up.

EDUCATION OF HBsAg-POSITIVE WOMEN

Explain to HBsAg-positive pregnant women and new mothers the serious consequences of hepatitis B infection, the lifesaving importance of hepatitis B biologics administered to their infants, and the importance of bringing their infants in for post-vaccination serologic testing. The following informational materials have been developed by the TDH for use in educating HBsAg-positive women and their health care providers:

- *If you are pregnant or think you may be pregnant, you need to know about vaccine-preventable diseases* (stock no. 6-34)
- *Immunotherapy Infants Born to HBsAg-Positive Women* (stock no. F11-10933)

PROPHYLACTIC TREATMENT OF INFANTS BORN TO HBsAg-POSITIVE WOMEN

Prior to the HBsAg-positive mother's expected delivery date, local or regional health department staff should assure that the delivery hospital has both HBIG and hepatitis B vaccine ready for administration to the newborn immediately after delivery. These biologics can be ordered from the TDH in Austin.

Infants Born to HBsAg-positive Women		
Biologic	**Dose**	**Age of Infant**
HBIG	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-dose 1	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-dose 2	0.5 mL	1 month
Hepatitis B Vaccine-dose3	0.5 mL	6 months
*The first dose of vaccine should be given at the same time as HBIG but at a separate site. The preferred sites are the anterolateral thighs. If necessary, HBIG can be administered up to seven days post-partum.		

Infants Born to Women Whose HBsAg Status is Unknown		
Biologic	**Dose**	**Age of Infant**
HBIG	0.5 mL	If mother is postnatally found to be HBsAg-positive, administer HBIG to infant as soon as possible, but no later than one (1) week after birth.
Hepatitis B Vaccine-dose 1	0.5 mL	Within 12 hours of birth
Hepatitis B Vaccine-dose 2	0.5 mL	1 to 2 months
Hepatitis B Vaccine-dose 3	0.5 mL	6 months

The third dose of hepatitis B vaccine should not be given prior to 6 months of age. The third dose confers optimal protection, acting as a booster dose.

HBsAg-positive mothers need not be separated from their infants nor their infants placed in special isolation. HBsAg-positive mothers are not precluded from breast-feeding unless there is significant breast pathology. Although HBsAg has been detected in some samples of breast milk, special concentration techniques were needed in most studies. In Taiwan, studies revealed that infants breast-fed by carrier mothers were no more likely to be infected at one year of age than were infants from whom breast-feeding was withheld.

CASE MANAGEMENT OF INFANTS BORN TO HBsAg-POSITIVE WOMEN

Before the infant leaves the hospital, arrangements should be made to ensure administration of the second and third doses of hepatitis B vaccine. Follow-up vaccination can be arranged through public health or by the infant's private pediatrician or other health care provider. Infants born to HBsAg-positive mothers can receive state-supplied vaccine and HBIG even if they receive health care in the private sector. If the mother chooses to have the baby's private pediatrician or other health care provider administer doses two and three of hepatitis B vaccine, local or regional health department staff are still responsible for providing case management services to ensure that the subsequent doses of vaccine are given on time and for post-vaccination serologic testing. Infants born to HBsAg-positive mothers should be followed closely to determine the success of treatment. Serologic testing for HBsAg and its corresponding antibody (anti-HBs) should be performed when the infant is 12 months of age to determine the success of perinatal hepatitis B prevention biologics.

HBsAg	Anti-HBs	Interpretation and Necessary Action
-	+	The infant is immune to HBV.
-	-	The infant is NOT immune to HBV. In this situation, the infant must receive a second series of hepatitis B vaccine. The first dose should be given as soon as possible after post-vaccination serology results are known. The second dose should be given one month later, and the infant should be tested again for anti-HBs. If the infant is anti-HBs positive after administration of these two doses of vaccine in the second series, dose 3 is not needed. If, however, the infant is still anti-HBs-negative, the third dose of hepatitis B vaccine should be administered 4 to 5 months after dose 2 (of the second series). The final test for immune response should follow 30 days after dose 3, and further vaccination or follow-up is not indicated. For infants who remain HBsAg-negative and anti-HBs negative following completion of the second series, an anti-HBc test should be performed. A positive anti-HBc test result indicates a resolved infection.
+	-	The vaccination effort failed. The infant is infected with HBV and is likely to become a chronic carrier. Refer the child for clinical follow-up.

IDENTIFYING, SEROLOGICALLY SCREENING, AND VACCINATING (IF NECESSARY) HOUSEHOLD AND SEXUAL CONTACTS

Household contacts are defined as persons currently residing in the home; who keep their personal belongings, clothes, and/or toiletries in the home; who sleep overnight in the home at least half the time. Sexual contacts are defined as either a current, steady sexual partner or person(s) with whom the HBsAg-positive woman has had sex in the past 30 days.

Sexual contacts to HBsAg-positive women are at greatest risk of HBV infection, but household contacts are at are also at high risk. Sexual and household contacts of HBV carriers should be serologically tested and vaccinated against hepatitis B if their test results reveal they are susceptible to hepatitis B. If any HBV serology marker (HBsAg, anti-HBs, anti-HBc) is positive, the sexual or household contact is not a candidate for hepatitis B vaccine. The hepatitis B vaccine schedule for sexual and household contacts is 0,1, and 6 months.

Post-vaccination serology (for HBsAg, anti-HBs, and anti-HBc) is necessary **only for sexual contacts** and is performed 1 to 2 months after receipt of the third dose of hepatitis B vaccine. Sexual contacts should be tested for HBsAg and anti-HBs. Sexual contacts who do not respond after the initial series of hepatitis B vaccine should be re-vaccinated.

Children residing in the household who have received the complete hepatitis B vaccine series as part of their routine childhood immunizations should be tested for HBsAg, anti-HBs, and anti-HBc. Children who were previously identified as infants born to HBsAg-positive mothers and who were serologically tested after vaccination need not be re-tested.

REPORTING

If a pregnant woman is identified as HBsAg-positive:

- Complete and submit Mother Summary Report for Perinatal Hepatitis B Prevention **and** Contact Summary Report for Perinatal Hepatitis B Prevention.
- A Contact Summary Report should be completed and submitted for each household or sexual contact identified.
- Notify the hospital where the woman plans to deliver.
- Make sure the hospital has HBIG and the hepatitis B vaccine available in advance of the delivery.
- Complete and submit Infant Summary Report for Perinatal Hepatitis B Prevention after birth of infant.

INVESTIGATION: REQUIRED

CONTROL MEASURES

- Provide or make available to the woman information relating to the treatment of hepatitis B or refer the woman to an entity that provides treatment for infected individuals.
- Provide or make available to the woman hepatitis B counseling which includes:
  - the meaning of the test result
  - the possible need for additional testing
  - measures to prevent transmission of hepatitis B, especially the reduction of perinatal transmission
  - the availability of appropriate health services
  - the availability of prevention services provided for sexual and household contacts
  - increased understanding of hepatitis B infection
  - explanation of the potential need for confirmatory testing
  - explanation of behavior changes to decrease the potential of disease transmission
  - encouragement to seek appropriate medical care
  - encouragement to notify persons with whom there has been contact capable of transmitting the disease

SPECIFIC LABORATORY PROCEDURES

Laboratory Specimen Labeling and Shipping Instructions for Maternal and Child Health (MCH) Providers:

To submit specimens to the TDH laboratory for screening pregnant women and conducting susceptibility testing, providers must have a Maternal and Child Health (MCH) provider identification number on file with the laboratory.

Specimen Collection:

- Collect 6-8 mL whole blood aseptically in a tube without additives ("red-top" or clot activator).
- Specimens should be shipped to TDH in the original collection container. Specimens that have been transferred to a second container are more apt to leak in transit, causing the specimen to be unsatisfactory for testing.
- Refrigerate specimens at 2-8°C prior to shipment; do not freeze.
- Refrigeration of specimens is not required during shipment, unless there will be a delay of 3 or more days between shipping and receipt at TDH labs.

Specimen Submission Forms:

- Medical Serology Forms G-32E (Hepatitis, Rubella, Syphilis, and HIV) or G-32E1 (without HIV test)--submit with specimen to request prenatal screening tests, which include HBsAg testing for pregnant women.
- G-1b Specimen Submission Form--submitted with specimen for susceptibility testing of contacts and post-vaccination testing of infants. In section marked **PATIENT INFORMATION: REQUIRED** write "MCH follow-up" for **Diagnosis/Symptoms**; in the section **FOR TDH PROGRAMS ONLY,** write "Perinatal Hepatitis B Prevention" and select "Hepatitis B Surface Antibody" and "Hepatitis B Surface Antigen" for infants; for other contacts select "Hepatitis B Surface Antibody," "Hepatitis B Surface Antigen" and "Hepatitis B Core Antibody."
- Information and consultation on testing are available by calling the TDH Bureau of Laboratories, Microbiological Division, Medical Serology Branch, at (512) 458-7592 or (512) 458-7514.

Shipping:

- Mail specimens via priority mail (first class), bus, or overnight courier service to:

Bureau of Laboratories
Texas Department of Health
1100 West 49th Street
Austin, TX 78756

****LABORATORY TESTING AND VACCINE AVAILABLE TO NON-MCH PROVIDERS****

HBIG, hepatitis B vaccine, and post-vaccination testing of infants born to HBsAg-positive mothers are provided by the TDH at no charge to providers as are pre-vaccination susceptibility testing and hepatitis B vaccine for household and sexual contacts of HBsAg-positive pregnant women. The Texas Department of Health, Immunization Division must, however, be notified in advance of submitting specimens on clients of non-MCH providers; call (800) 252-9152.

Use form G-68 to order HBIG or hepatitis B vaccine. Hepatitis B biologics may be shipped directly to an address other than a health department if a specific health care provider has been designated to receive them.

Section 3: Invasive *Haemophilus influenzae* type b

CLINICAL CASE DEFINITION

Haemophilus influenzae type b may produce any of several clinical syndromes. Only invasive manifestations, however, are reportable. These include meningitis, bacteremia/septicemia, epiglottitis, pericarditis, osteomyelitis, septic arthritis, and cellulitis.

REPORTING

Immediately report suspected cases to a local or regional health department at **(800) 705-8868** or the Texas Department of Health (TDH), Immunization Division at **(800) 252-9152**. Conjunctivitis, otitis media, and bronchitis caused by *H. influenzae* are not invasive infections, and do not need to be reported.

CASE INVESTIGATION

A completed case track record must be submitted by the local health department on all suspected cases to the TDH Immunization Division within 30 days of initial report. Children < 5 years of age with Haemophilus Influenzae Type B will need to have a CDC Expanded Case Report Form submitted along with the case track record. In the event of death, please provide copies of the hospital discharge summary, death certificate, and autopsy report.

CASE CLASSIFICATIONS

- **Confirmed:** A clinically compatible case that is culture confirmed and identified specifically as type b
- **Probable:** A clinically compatible illness with detection of *Haemophilus influenzae* type b antigen in cerebrospinal fluid (CSF). Antigen test results in urine or serum are unreliable for diagnosis of *H. influenzae* disease.

LABORATORY CONFIRMATION

- Isolation of *H. influenzae* from a normally sterile site (blood, CSF, joint fluid, or pericardial fluid).
- All *H. influenzae* isolates from sterile sites should be serotyped.

CONTROL MEASURES

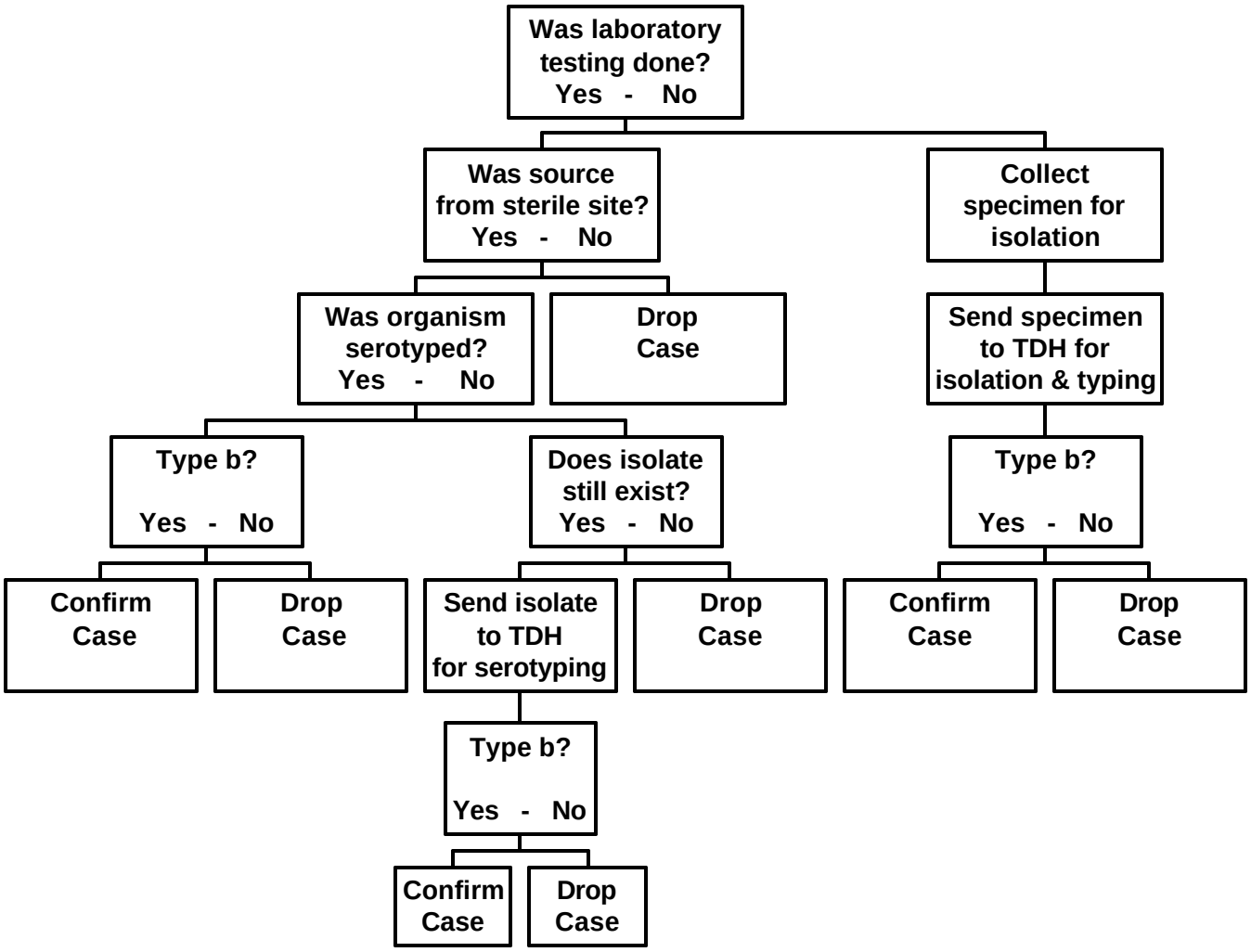
- Reports of invasive Hib disease in children <5 years of age should be investigated **immediately**.
- Identify all exposed contacts <5 years of age.
- In households with one or more infants <12 months of age (regardless of vaccination status) or with a child 1-3 years of age who is inadequately vaccinated, all household contacts should receive rifampin prophylaxis following a case of invasive Hib disease that occurs in any household member.
- If a case of Hib disease occurs in a child-care facility, and a child <2 years of age has been exposed, all parents should be notified. All students and staff in the classroom where this case occurred should receive rifampin prophylaxis; however, rifampin is not necessary if **ALL** children <4 years of age are fully vaccinated.
- Hospital personnel exposed to a child with invasive Hib disease do not need prophylaxis.
- The recommended dose of rifampin is 20 mg/kg as a single daily dose (maximum daily dose 600 mg) for 4 days. Neonates (<1 month of age) should receive 10 mg/kg once daily for 4 days.
- Rifampin prophylaxis should be instituted as rapidly as possible.
- The index patient should also receive rifampin prophylaxis preferably just before hospital discharge.
- Children <24 months of age who have had invasive Hib disease (culture confirmed) should still receive Hib vaccine, since many children of that age fail to develop adequate immunity following natural disease.

SPECIFIC LABORATORY PROCEDURES:
Serotyping of *H. influenzae* isolates is important in determining which cases are vaccine-preventable. **DO NOT** submit isolates from sputum for serotyping.

- Submit isolates of *H. influenzae* on chocolate agar slants (or media that has the necessary growth requirements for *Haemophilus*.
- If a delay in transport is anticipated, use a CO_2 generator bag.
- Use Specimen Submission form G-1a.
- Ship specimen to the TDH laboratory via overnight delivery. The viability of the organism is short lived, therefore, isolate must arrive at the TDH lab in Austin within two (2) days after collection.
- **Mail specimens to:**

  Bacteriology
  Bureau of Laboratories
  Texas Department of Health
  1100 West 49th Street
  Austin, TX 78756

Haemophilus influenzae type b: Laboratory Testing and Interpretation



Section 4: Measles

CLINICAL CASE DEFINITION
An illness characterized by the following:
- a generalized rash lasting at least 3 days
- temperature $\geq 101^0$ F
- cough, coryza, or conjunctivitis

REPORTING
Immediately report suspected cases to the local or regional health department at **(800) 705-8868** or the Texas Department of Health (TDH), Immunization Division at **(800) 252-9152**.

CASE INVESTIGATION
Completed case track records on all suspected cases must be submitted by the local health department to the TDH Immunization Division within 30 days of initial report.

CASE CLASSIFICATIONS
- **Confirmed:** A case that is laboratory confirmed, or meets the clinical case definition AND is epidemiologically linked to a laboratory confirmed case.
- **Probable:** Meets the clinical case definition, has no or noncontributory serologic or virologic testing, AND is not epidemiologically linked to a confirmed case.
- **Suspect:** Any rash illness with fever.

LABORATORY CONFIRMATION
- Positive serologic test for measles-specific IgM antibody **(preferred)**, or
- Significant rise in measles antibody by any standard serologic assay (i.e. four-fold rise in IgG antibody from acute to convalescent samples), or
- Isolation of measles virus from a clinical specimen.

IMMEDIATE ACTION
- Treat all suspected cases as confirmed until serological testing is completed.
- Begin investigation **immediately.**
- Alert appropriate local and regional health departments as well as the TDH in Austin.
- Identify all susceptible contacts and initiate control measures.
- Collect virology specimens as soon as possible.
- Collect serology specimens as soon as possible.

CONTROL MEASURES
- Susceptible contacts to suspected cases should be vaccinated with measles vaccine within 72 hours of exposure OR should have immune globulin administered within six (6) days of exposure.
- Children $\geq$1 year and <4 years should have history of at least one (1) dose of MMR vaccine.
- Persons $\geq$4 years and born after 1956 should have history of two (2) doses of MMR vaccine.
- If vaccination of exposed contact is contraindicated, exclude exposed contact from school or child-care facility for at least 14 days after last rash onset.
- Persons who cannot readily provide documentation of measles immunity should be vaccinated or excluded from the setting (e.g., school, child-care facility, work place).

EXCLUSION: Four (4) days from rash onset. In an outbreak, unvaccinated children should be excluded for at least 14 days after last rash onset.

SPECIFIC LABORATORY PROCEDURES: IgM preferred

IgM: A single specimen collected early in the course of illness--can be done on day of rash onset to 30 days after rash onset. A negative IgM result from a specimen collected before the fifth day of rash onset may not, however, rule out the diagnosis of measles

IgG: Acute AND convalescent samples. Collect acute early in the course of illness and convalescent 10-14 days later.

- Collect a minimum of 5 mL of blood in a red-top tube or any collection tube without anticoagulant.
- Separate serum and freeze if there will be more than three (3) days between collection and receipt in lab. Whole blood may be sent if specimen is shipped on day of collection. **Do not freeze whole blood**.
- Label blood tubes or serum containers with the patient's name and date of birth or social security number.
- Use Specimen Submission Form G-1b. Make sure the patient's name and date of birth/ social security number match exactly what is written on the tube. Mark the laboratory test requested, date of onset, and date of collection. Be certain that the names on acute and convalescent sera match exactly.
- Send serum to the TDH laboratory via overnight delivery (preferred) OR on cold packs.
- **Mail specimens to:**

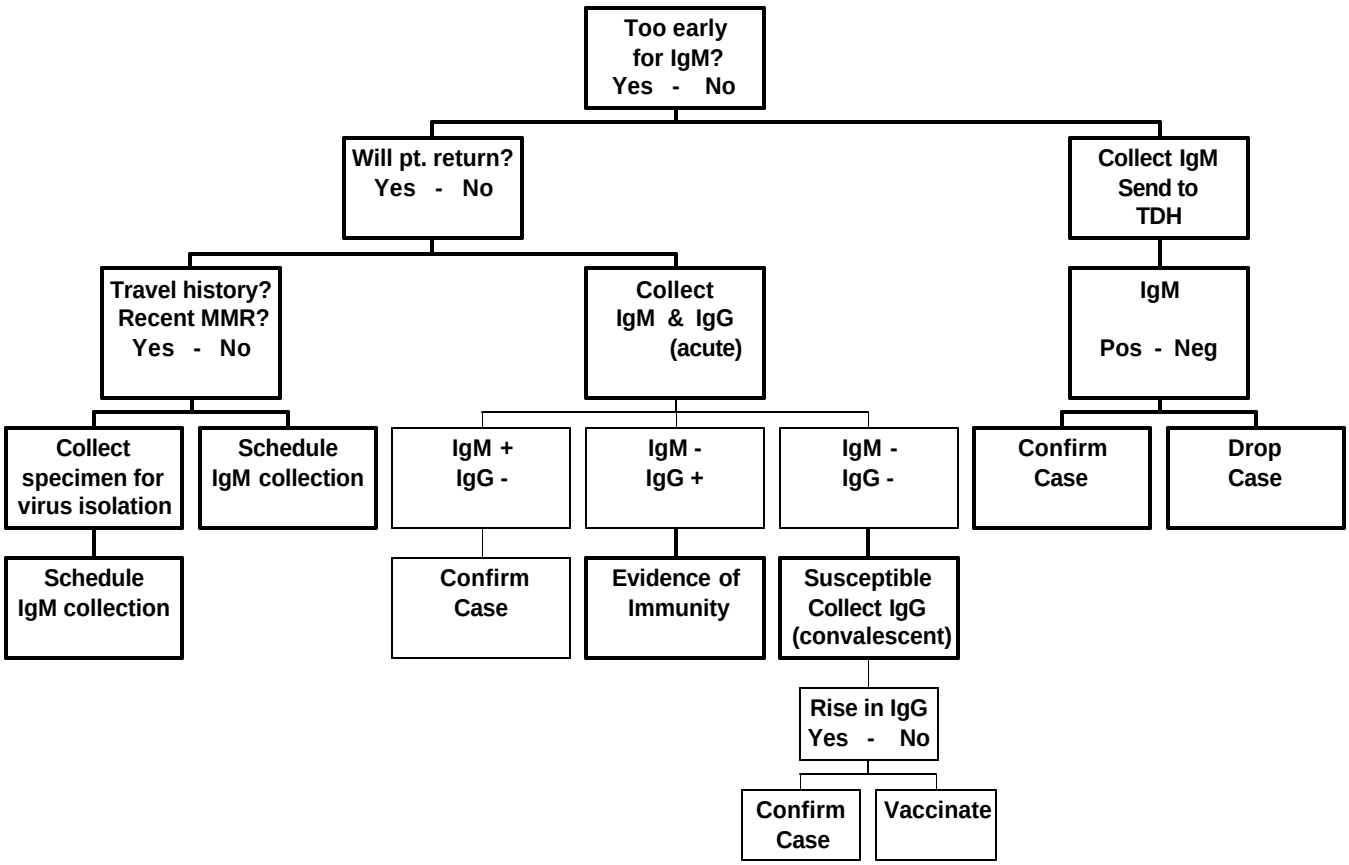
  Medical Serology
  Bureau of Laboratories
  Texas Department of Health
  1100 West 49th Street
  Austin, TX 78756

Virus Isolation: The diagnosis of measles should be based on detection of measles-specific IgM antibody in serum. If, however, the suspected case has received a measles-containing vaccine in the last three months, specimens for virus isolation should be obtained to differentiate between wild and vaccine strains. Molecular epidemiologic techniques are also used to genetically type measles viruses and identify the source of wild viruses.

- Collect 50-100 mL of urine (first morning voided urine is ideal).
- Specimen should be collected within four (4) days of rash onset.
- Keep specimen at 4ºC.
- Use Specimen Submission Form G-1a. Make sure the patient's name and date of birth/ social security number match exactly what is written on the specimen container. Mark the laboratory test requested (virus isolation), disease suspected (measles), date of onset, and date of collection.
- Ship specimen via overnight delivery on wet ice within 48 hours of collection.
- **Mail Specimens To:**

  Virology
  Bureau of Laboratories
  Texas Department of Health
  1100 West 49th Street
  Austin, TX 78756

Measles:
Laboratory Testing and Interpretation



Section 5: Mumps

CLINICAL CASE DEFINITION
An illness with acute onset of unilateral or bilateral tender, self-limited swelling of the parotid or other salivary gland, lasting ≥2 days, and without other apparent cause (as reported by a health professional).

Note: Influenza, parainfluenza type 3, and cytomegaloviruses (CMV) can also cause parotitis. In addition, there are numerous other non-infectious causes of parotid swelling. Approximately 30% of sporadic parotitis cases are NOT caused by the mumps virus, and 20% to 40% of mumps cases may not have parotid swelling. Mumps can be confirmed only through mumps-specific laboratory testing.

REPORTING
Immediately report suspected cases to the local or regional health department at **(800) 705-8868** or the Texas Department of Health (TDH), Immunization Division at **(800) 252-9152**.

CASE INVESTIGATION
A completed case track record on all suspected cases must be submitted by the local health department to the TDH Immunization Division within 30 days of initial report. In the event of death, please provide copies of the hospital discharge summary, death certificate, and autopsy report.

CASE CLASSIFICATIONS
- **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.
- **Probable:** a case that meets the clinical case definition, has no serologic or virologic testing, AND is not epidemiologically linked to a confirmed or probable case.
- Two probable cases that are epidemiologically linked are considered confirmed.

LABORATORY CONFIRMATION
- Positive serologic test for mumps IgM antibody **(preferred)**, or
- Significant rise in mumps antibody level by any standard serologic assay, or
- Isolation of mumps virus from a clinical specimen.
- An elevated serum amylase is **not** confirmatory for mumps

CONTROL MEASURES
- Although vaccination after exposure to mumps may not prevent disease, the vaccine will protect persons from subsequent exposures; therefore, susceptible contacts should be vaccinated.
- Persons who are unsure of their mumps disease history or mumps vaccination history should be vaccinated.
- IG is not effective and not recommended.

EXCLUSION: Nine (9) days after onset of swelling

SPECIFIC LABORATORY PROCEDURES

IgM: Single specimen collected ≥ 3 days following onset of symptoms--can be collected up to 30 days after parotid swelling, **OR**

IgG: Acute AND convalescent samples. Collect acute early in course of illness and convalescent 10-14 days later.

- Collect a minimum of 5 mL of blood in a red-top tube or any collection tube without anticoagulant.
- Separate serum and freeze if there will be more than three (3) days between collection and receipt in lab. Whole blood may be sent if specimen is shipped on day of collection. **Do not freeze whole blood**.
- Label blood tubes or serum containers with the patient's name and date of birth or social security number.
- Use Specimen Submission Form G-1b. Make sure the patient's name and date of birth/ social security number match exactly what is written on the tube. Mark the laboratory test requested, date of onset, and date of collection.
- Send serum to the TDH laboratory via overnight delivery (preferred) OR on cold packs.
- **Mail specimens to:**

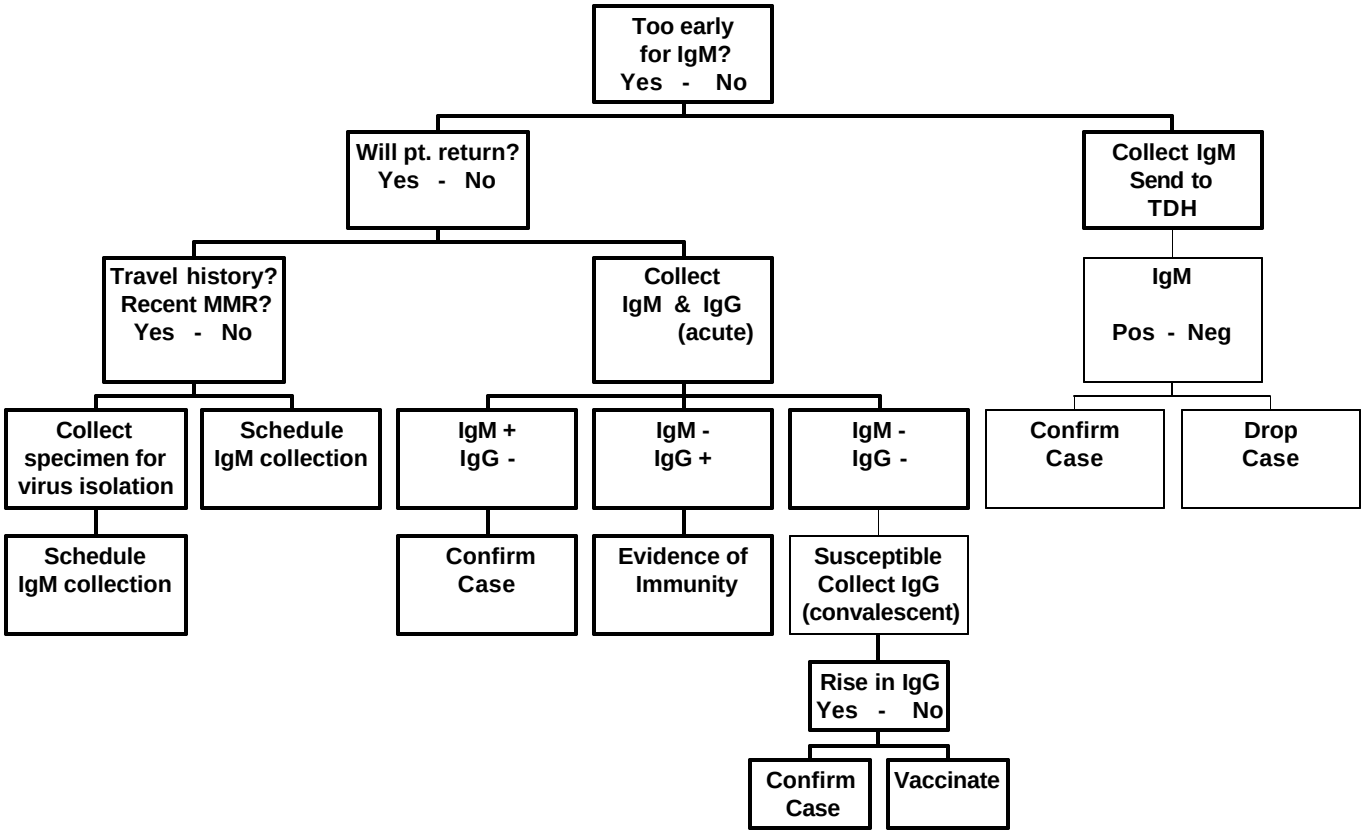
  Medical Serology
  Bureau of Laboratories
  Texas Department of Health
  1100 West 49th Street
  Austin, TX 78756

Virus Isolation: Specimens should be obtained early in the course of illness when the quantity of virus shed is highest. Respiratory specimens (nasopharyngeal swab, Stensen's duct swab, or nasal aspirate) are preferred, although references indicate that mumps virus can be isolated from blood, urine, and cerebrospinal fluid.

- **Nasopharyngeal swab and Stensen's duct specimens:** The oropharynx or Stensen's duct should be rubbed vigorously with the swab to scrape off mucosal cells. The swab should then be agitated for at least 30 seconds in 2-4 mL of viral transport media, e.g., cold veal infusion broth. A viral culturette may also be used.
- **Nasal Aspirates:** Obtain nasal specimen with a sterile rubber bulb aspirator. The aspirate should be discharged into a small sterile container.
- **Urine:** Urine specimens should be collected aseptically in a sterile container; up to 45 mL placed in a sterile 50 mL centrifuge tube.
- Use specimen submission for G1a.
- All clinical specimens for virus isolation should be kept at 4ºC during storage and shipment. Ship specimens on ice via overnight delivery.
- **Mail specimens to:**

  Virology
  Bureau of Laboratories
  Texas Department of Health
  1100 West 49th Street
  Austin, TX 78756

Mumps:
Laboratory Testing and Interpretation



Section 6: Pertussis

CLINICAL CASE DEFINITION
For endemic or sporadic cases, a cough illness lasting at least two (2) weeks with one of the following without other apparent cause (as reported by a health professional):

- paroxysms of coughing
- inspiratory whoop
- post-tussive vomiting

OUTBREAK SETTINGS
In outbreak settings, including household exposures, the case definition used can be modified to a "cough illness lasting at least 14 days."

REPORTING
Immediately report suspected cases to the local or regional health department at **(800) 705-8868** or the Texas Department of Health (TDH), Immunization Division at **(800) 252-9152**.

CASE INVESTIGATION
Notify the TDH Immunization Division of the initial report, and submit a completed case track record on all suspected cases within 30 days. In the event of a death, include a pertussis death investigation form and copies of the hospital admission and discharge summaries, death certificate, and autopsy report.

LABORATORY CONFIRMATION

- Isolation of *Bordetella pertussis* from a clinical specimen, or
- Positive polymerase chain reaction (PCR) assay for *Bordetella pertussis*
- Because *B. pertussis* can be difficult to culture, a negative culture result does not rule out pertussis

CASE CLASSIFICATIONS

- **Confirmed:** A person with an acute cough illness of any duration who is culture positive, or who meets the case definition and is PCR positive or is epi linked to a laboratory confirmed case.
- **Probable:** Meets the clinical case definition (or outbreak definition for close contacts of cases), and is not laboratory confirmed (not tested or tests are negative) or epi linked to a laboratory-confirmed case

CONTROL MEASURES

- Investigate reports of suspected pertussis promptly.
- Identify all exposed contacts.
- Erythromycin prophylaxis (40-50 mg/kg/d, orally in four divided doses; maximum, 2g/d, for 14 days) is recommended for all household contacts and other close contacts, **irrespective of vaccination status,** if initiated within 21 days of exposure. Initiating antibiotic treatment more than 3 weeks after exposure has limited benefit and is not recommended except for high-risk contacts who may benefit from antibiotic prophylaxis up to 6 weeks after exposure. For those who cannot tolerate erythromycin, trimethoprim-sulfamethoxazole is an alternative.
- Local and regional immunization programs should coordinate antibiotic treatment and prophylaxis to patients and contacts including providing prescriptions and/or furnishing antibiotics for those who do not have a regular medical provider or who are unable to purchase it.
- Exposed children should be observed for 14 days after last contact with the exposed person.
- Close contacts younger than seven (7) years who are unvaccinated or who have fewer than four (4) doses of DTP vaccine should be vaccinated according to the recommended schedule. Children who received their third dose of DTaP vaccine six (6) months or more before exposure should be given a fourth dose at this time. Those who have had at least four (4) doses of DTP should receive a booster dose of DTaP unless a dose has been given within the last three (3) years or they are seven (7) years of age or older.

EXCLUSION: Until completion of five (5) days of antibiotic therapy.

SPECIFIC LABORATORY PROCEDURES

Isolation of the organism by culture is preferred. Direct fluorescent antibody (DFA) testing of nasopharyngeal secretions has been shown to have low sensitivity and variable specificity, therefore, it **should only** be used for screening and **not** relied upon for laboratory confirmation.

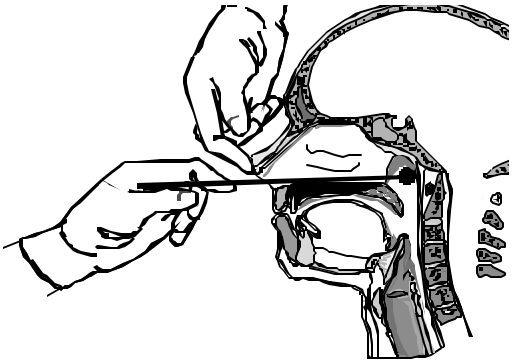
To obtain Regan-Lowe transport media kits or direct fluorescent antibody (DFA) kits, contact the TDH Bureau of Laboratories, Bacteriology Division, at **(512) 458-7661**.

- Refrigerate media upon arrival.
- Both nasopharyngeal (NP) swabs and aspirates are acceptable specimens for culture or DFA.
- An NP aspirate can be split to inoculate culture and transport media and prepare DFA slides.
- If nasopharyngeal swabs are used, inoculate the transport and culture media with the first swab and the DFA slides only if a second swab is obtained.

Nasopharyngeal Swab

- Immobilize the patient's head.
- Gently insert nasopharyngeal swab into a nostril until the posterior nares is reached.
- Leave the swab in place for up to 10 seconds. This procedure may induce coughing and tearing.
- If resistance is encountered during insertion of the swab, remove it and attempt insertion on the opposite nostril.
- Remove the swab slowly.

Appropriate positioning of a nasopharyngeal swab



Pertussis Culture

- Use Regan-Lowe (RL) transport media (shelf life of three months). DO NOT USE MEDIA AFTER THE EXPIRATION DATE PRINTED ON THE TUBE.
- Roll the swab across the **slanted** surface of an RL transport slant, and then place the swab into an RL transport deep, pushing swab down into the medium. Cut off the shaft of the swab at the top of the tube. Replace cap.
- Label the slant and deep tubes with the patient's name and date of birth or social security number.
- If there is a delay of more than two (2) hours between collection and shipment, refrigerate specimens.

Direct Florescent Antibody (DFA)

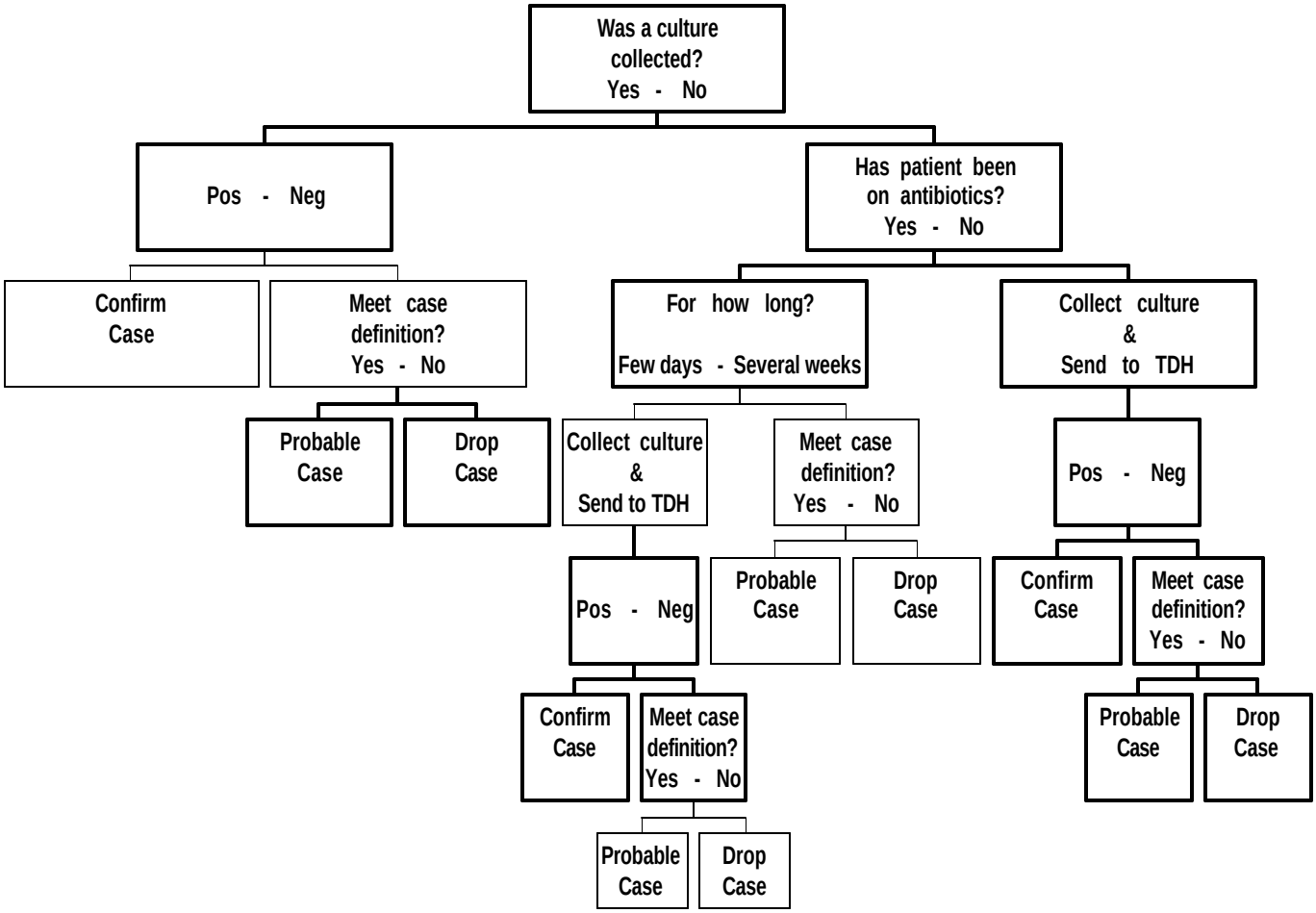
- Using a plastic transfer pipe, transfer one drop of sterile distilled water or one drop of a nasopharyngeal aspirate to each circle of the fluorescent antibody (FA) slide.
- Apply the swab to each circle on the slide. Swirl the swab in the drop of fluid to mix well.
- Air dry the slide and label with the patient's name (at least last name, first initial) or the social security number (must also be on the form to verify identification).

Specimen Shipment

- If available, use a **Texas Department of Health G-1a Specimen Submission Form**.
- Make sure the patient's name and date of birth or social security number match exactly what is written on the transport tubes. Mark the **pertussis only** test. Fill in the date of collection, date of onset, and diagnosis/symptoms.
- Ship specimens via overnight delivery on cold packs or wet ice within 48 hours of collection.
- Mark Saturday delivery if shipped on Friday and label mailer "Refrigerate Upon Arrival".
- **Mail specimens to:** Bacteriology
  Bureau of Laboratories
  Texas Department of Health
  1100 West 49th Street
  Austin, TX 78756
  (512) 458-7211

  Contact:
  Mary Goff, Section Chief
  Clinical Bacteriology
  (512) 458-7582

Pertussis:
Laboratory Testing and Interpretation



Pertussis Death Worksheet

Name (last, first):			Caseid:
Address:	City:	County:	Zip:
Reporting Provider:		Address:	Phone:

Data related to case:

1. Were there any other underlying causes or complications with the death, other than pertussis?
   ❑ Yes ❑ No ❑ Unknown
   a. If yes, please list:

2. Was patient hospitalized? ❑ Yes ❑ No
   a. If yes, please submit a copy of the hospital admission and discharge summary to CDC.
   b. If yes, was patient on mechanical ventilation? ❑ Yes ❑ No
      1. If yes, how many days was the patient intubated? ____ days

3. Was an autopsy performed? ❑ Yes ❑ No
   a. If yes, please submit a copy to CDC.

If blood work was done, please complete 4 and 5, otherwise go to #6.

4. What was the leukocyte count? _____

5. What was the lymphocyte percentage? _____%

6. Did the patient have a contact who had a cough illness? ❑ Yes ❑ No ❑ Unknown
   a. If yes, then who?

7. Who were the other contacts of the patient?

Data related to the family of the case:
If the patient was <1 year of age:
8. What was the gestational age of the case? _____ weeks

If the patient was <12 years of age:
9. What was the mother's age at time of patient's onset of coughing due to pertussis? ____ years

10. Was the mother immunosuppressed? ❑ Yes ❑ No ❑ Unknown

11. Do any household member smoke cigarettes? ❑ Yes ❑ No ❑ Unknown
    If yes, how many cigarettes? _____

continued on the next page

12. If case has siblings, please complete the following:

Age	DOB	Sex	Day care or school?	# of children in classroom?	# Doses of pertussis vaccine	Date of last vaccine containing pertussis

Notes:

Section 7: Paralytic Poliomyelitis (including VAPP)

CLINICAL CASE DEFINITION

Acute onset of a flaccid paralysis of one or more limbs with decreased or absent tendon reflexes in the affected limbs, without other apparent cause, and without sensory or cognitive loss (as reported by a physician).

REPORTING

Immediately report suspect cases to the local or regional health department at **(800) 705-8868** or the Texas Department of Health (TDH), Immunization Division at **(800) 252-9152**.

CASE INVESTIGATION

There is no specific case-investigation form, however, a detailed written report will be required by the TDH.

CASE CLASSIFICATIONS

- **Confirmed:** A case that meets the clinical case definition, is laboratory confirmed, and in which the patient has a neurologic deficit 60 days after onset of initial symptoms, has died, or has unknown follow-up status.
- **Probable:** A case that meets the clinical case definition.

All suspected cases of paralytic poliomyelitis are reviewed by a panel of expert consultants at the Centers for Disease Control and Prevention (CDC) before final case classification occurs. Final case classification could take 6 to 12 months.

LABORATORY CONFIRMATION

- Isolation of poliovirus type 1, 2, or 3 from a clinical specimen (stool or CSF)

SPECIMEN COLLECTION

- 5-gram specimen of stool (transport media not needed for stool)
- 1 mL of CSF; freeze at 15° to -20°C and ship on dry ice

INVESTIGATION OF SUSPECTED CASES (collect the following information)

- Demographic data (name, age, sex, race, complete address, and occupation of patient).
- Complete immunization history (the number, dates, and lot numbers of all previous doses of polio vaccine).
- Clinical information (include the course of illness and sites of paralysis and any complications).
- Immunologic status (if any doubt exists about the patient's status, an immunologic evaluation of quantitative immunoglobulins, T and B cell quantification, lymphocyte transformation, etc. should be considered).
- Exposure history
  - recent travel of patient or a close contact outside of the US.
  - contact with any known case of poliomyelitis.
  - contact within previous 30 days with any person who received oral poliovirus vaccine (OPV) within the last 60 days (include date of contact, nature of contact, date contact received OPV, lot number of vaccine, age of contact, and relationship to patient).
- Obtain copy of hospital discharge summary.
- Obtain copy of 60-day follow-up report to ascertain if there is any residual paralysis.
- If patient died, obtain copy of autopsy report or death summary.

Poliovirus Isolates

It is not uncommon for a poliovirus to be identified in a clinical specimen from an infant or young child who has recently received a dose of OPV. If you receive a laboratory report indicating that a poliovirus has been identified, obtain the following information on the patient:

- Complete immunization history (the number, dates, and lot numbers of all previous doses of OPV and inactivated poliovirus vaccine (IPV) vaccine)
- Clinical history (were there any clinical signs of paralysis?)
- Diagnosis

If there was no suspicion of paralytic poliomyelitis, no further action is needed. If the patient is suspected of having paralytic poliomyelitis, investigate case according to paralytic poliomyelitis guidelines.

Section 8: Rubella

CLINICAL CASE DEFINITION

An illness characterized by the following symptoms:

- Generalized maculopapular rash, and
- Temperature $\geq 99^{o}$F, if measured
- Arthralgia/arthritis, lymphadenopathy, or conjunctivitis.
- **Fifty percent of infected persons do not have symptoms**.

REPORTING

Immediately report suspected cases to the local or regional health department at **(800) 705-8868** or the Texas Department of Health (TDH), Immunization Division at **(800) 252-9152**.

CASE INVESTIGATION

A completed case track record on all suspected cases must be submitted by the local health department to the TDH Immunization Division within 30 days of initial report. In the event of death, please provide copies of the hospital discharge summary, death certificate, and autopsy report.

CASE CLASSIFICATIONS

- **Confirmed:** A case that is laboratory confirmed, or meets the clinical case definition and is epidemiologically linked to a laboratory-confirmed case.
- **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.
- **Suspect:** Any generalized rash illness with acute onset.

LABORATORY CONFIRMATION

- Positive serologic test for rubella-specific IgM antibody **(preferred)**, or
- Significant rise in rubella antibody by any standard serologic assay (i.e. four-fold rise in IgG antibody from acute to convalescent samples), or
- Isolation of rubella virus from a clinical specimen.

CONTROL MEASURES

- All reports of suspected rubella should be investigated promptly. Treat all cases as confirmed until laboratory testing or other information rules out rubella.
- Identify all exposed contacts.
- Determine vaccine status of exposed contacts. If not up-to-date with vaccination, vaccinate with MMR according to the recommended immunization schedule.
- Person's ≥1 year should have history of one (1) dose of MMR or serologic evidence of immunity to rubella.
- Persons who cannot readily provide laboratory evidence of rubella or a documented history of vaccination on or after their first birthday should be considered susceptible and should be vaccinated if there are no contraindications.
- If vaccination of exposed contact is contraindicated, exclude exposed contact from school or child-care facility for at least three (3) weeks after last rash onset.
- If a pregnant woman is exposed to rubella, evidence of rubella immunity should be obtained as soon as possible. If rubella IgG antibodies are not detected, a second specimen should be obtained 3-4 weeks later and tested again for rubella IgM and rubella IgG antibodies. If IgG is present, infection is assumed to have occurred.

EXCLUSION: Seven (7) days after onset of rash. In an outbreak, unvaccinated children and pregnant women should be excluded for at least three weeks after rash onset.

SPECIFIC LABORATORY PROCEDURES: IgM is preferred.

IgM: Single specimen collected early in the course of illness. Because rubella IgM antibodies rise more slowly in some individuals, a negative rubella IgM result on a specimen collected within 5 days of rash onset will NOT rule out a diagnosis of rubella; the only exception to this is when the specimen is IgG positive, indicating prior immunity. Therefore if the patient is an unvaccinated infant, a specimen for IgM testing should be collected at least 5 days post rash onset; all other specimens should be collected as soon as possible.

IgG: Acute AND convalescent samples required. Collect acute early in course of illness and convalescent 10-14 days later. Evidence of rubella immunity by measuring IgG antibody (e.g. in an exposed pregnant woman) can be determined with a single blood specimen.

- Collect a minimum of 5 mL of blood in a red-top tube or any collection tube without anticoagulant.
- Separate serum and freeze if there will be more than three (3) days between collection and receipt in lab. Whole blood may be sent if specimen is shipped on day of collection. **Do not freeze whole blood**.
- Label blood tubes or serum containers with the patient's name and date of birth or social security number.
- Use Specimen Submission Form G-1b. Make sure the patient's name and date of birth/ social security number match exactly what is written on the tube. Mark the laboratory test requested, date of onset, and date of collection. Be certain that the names on acute and convalescent sera match exactly.
- Send serum to the TDH laboratory via overnight delivery (preferred) OR on cold packs.
- **Mail specimens to:**

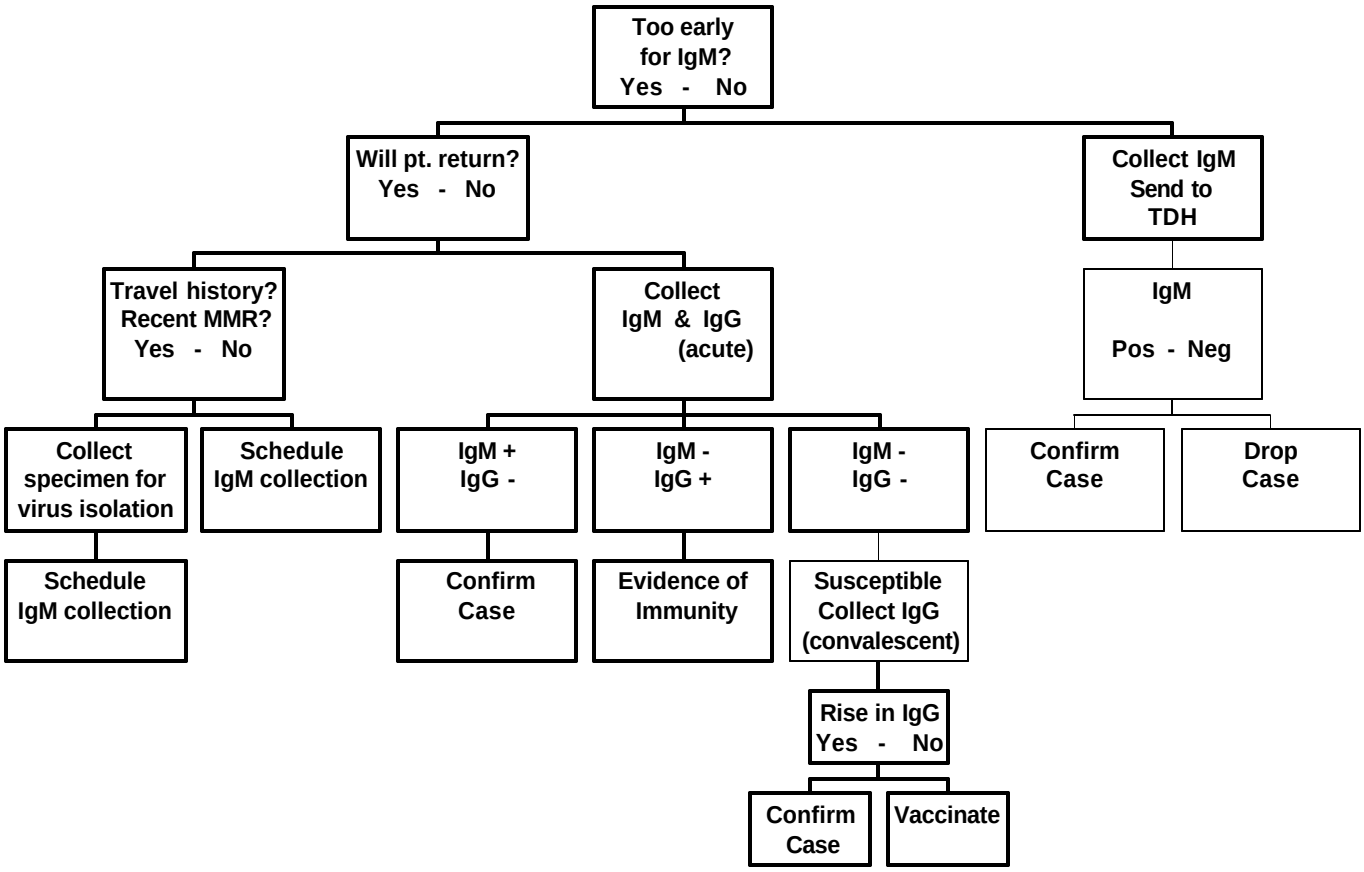
  Medical Serology
  Bureau of Laboratories
  Texas Department of Health
  1100 West 49th Street
  Austin, TX 78756

Virus Isolation
Rubella virus isolates can be useful in the diagnosis of acute rubella and CRS, and are needed to establish the molecular epidemiology of rubella. To submit a specimen to the TDH laboratory for rubella viral isolation:

- Use a viral culturette (collection and transport system).
- Obtain a pharyngeal swab within 4 days of rash onset.
- Label the culturette with the patient's name and date of birth or social security number.
- Keep the specimen at 4ºC and ship overnight on wet ice within 48 hours.
- If the specimen must be held longer, freeze it at -70ºC and ship it on dry ice.
- Use Specimen Submission Form G-1a. Make sure the patient's name and date of birth/ social security number match exactly what is written on the culturette. Mark the laboratory test requested (virus isolation-rubella), disease suspected, date of onset, and date of collection.
- Send the specimen to the laboratory via overnight delivery on wet or dry ice as noted above.
- **Mail Specimens To:**

  Virology
  Bureau of Laboratories
  Texas Department of Health
  1100 West 49th Street
  Austin, TX 78756

Rubella:
Laboratory Testing and Interpretation



Section 9: Congenital Rubella Syndrome (CRS)

CLINICAL CASE DEFINITION
An illness of newborns 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, peripheral pulmonary artery stenosis), hearing loss, pigmentary retinopathy.
(B) Purpura, splenomegaly, jaundice, microcephaly, mental retardation, meningoencephalitis, radiolucent bone disease.

REPORTING
Immediately report suspected cases to the local or regional health department at **(800) 705-8868** or the Texas Department of Health (TDH), Immunization Division at **(800) 252-9152**.

CASE INVESTIGATION
A completed case track record on all suspected cases must be submitted by the local health department to the TDH Immunization Division within 30 days of initial report. In the event of death, please provide copies of the hospital discharge summary, death certificate, and autopsy report.

CASE CLASSIFICATIONS
- **Confirmed:** A clinically compatible case that is laboratory confirmed.
- **Probable:** A case that is not laboratory confirmed and that has any two complications listed in **(A)** above, or one complication from **(A)** and one from **(B)** and lacking evidence of any other etiology.
- **Possible:** A case with some compatible clinical findings but not meeting the criteria for a probable case.
- **Infection only:** A case with laboratory evidence of infection, but without any clinical signs or symptoms.

LABORATORY CONFIRMATION
- Isolation of the rubella virus
- Serologic evidence of rubella-specific IgM antibody, or
- An infant's rubella antibody level that persists above and beyond that expected from passive transfer of maternal antibody (i.e., rubella titer that does not drop at the expected rate of a two-fold dilution per month)

CONTROL MEASURES
- All reports of suspected congenital rubella syndrome should be investigated promptly.
- Identify all exposed contacts and determine their susceptibility to rubella.
- Patients with congenital rubella syndrome should be considered contagious until they are one (1) year of age, unless nasopharyngeal and urine cultures are negative for rubella.
- Mothers should be made aware of the potential hazard of their infants to susceptible, pregnant contacts.

EXCLUSION
Infants with CRS should be placed in contact isolation. These precautions should be enforced during any hospital admission before the child's first birthday, unless pharyngeal and urine cultures are negative for virus after age 3 months.

SPECIFIC LABORATORY PROCEDURES

IgM: Single specimen collected soon after birth or soon after suspected diagnosis of CRS is made.

- Collect a minimum of 5 mL of blood in a red-top tube or any collection tube without anticoagulant.
- Separate serum and freeze if there will be more than three (3) days between collection and receipt in lab. Whole blood may be sent if specimen is shipped on day of collection. **Do not freeze whole blood**.
- Label blood tubes or serum containers with the patient's name and date of birth or social security number.
- Use Specimen Submission Form G-1b. Make sure the patient's name and date of birth/social security number match exactly what is written on the tube. Mark the laboratory test requested, date of onset, and date of collection. Be certain that the names on acute and convalescent sera match exactly.
- Send serum to the TDH laboratory via overnight delivery (preferred) OR on cold packs.
- **Mail specimens to:**

  Medical Serology
  Bureau of Laboratories
  Texas Department of Health
  1100 West 49th Street
  Austin, TX 78756

Virus Isolation

Rubella virus can be isolated from throat, nasopharynx, blood, urine, and cerebrospinal fluid specimens from rubella and CRS cases. Efforts should be made to obtain clinical specimens (particularly pharyngeal swabs) for viral isolation from infants at the time of the initial investigation. Infants with CRS may, however, shed virus for a prolonged period (up to one year) so specimens obtained later may also yield rubella virus. Specimens for virus isolation (pharyngeal swabs) should be obtained monthly until cultures are repeatedly negative.

- Use a viral culturette (collection and transport system) to obtain a pharyngeal swab.
- Label the culturette with the patient's name and date of birth or social security number.
- Keep the specimen at 4ºC and ship overnight on wet ice within 48 hours.
- If the specimen must be held longer, freeze it at -70ºC and ship it on dry ice.
- Use Specimen Submission Form G-1a. Make sure the patient's name and date of birth/ social security number match exactly what is written on the culturette. Mark the laboratory test requested (virus isolation-rubella), disease suspected, date of onset, and date of collection.
- Send the specimen to the laboratory via overnight delivery on wet or dry ice as noted above.
- **Mail Specimens To:**

  Virology
  Bureau of Laboratories
  Texas Department of Health
  1100 West 49th Street
  Austin, TX 78756

Section 10: Tetanus

CLINICAL CASE DEFINITION
Acute onset of hypertonia and/or painful muscular contractions (usually of the muscles of the jaw and neck) and generalized muscle spasms without other apparent medical cause (as reported by a health professional).

REPORTING
Immediately report suspect cases to the local or regional health department at **(800) 705-8868** or the Texas Department of Health (TDH), Immunization Division at **(800) 252-9152**.

INVESTIGATION FORM
A completed case track record on all suspected cases must be submitted to the TDH Immunization Division within 30 days of initial report. In the event of death, please provide copies of the hospital discharge summary and autopsy report.

CASE CLASSIFICATION
- **Confirmed:** A case that meets the clinical case definition

LABORATORY CONFIRMATION: None

CONTROL MEASURES: None (tetanus is not directly transmitted from person to person).
- The best method for controlling tetanus is preventing tetanus through active immunization with adsorbed tetanus toxoid; combined tetanus-diphtheria toxoid is recommended.
- Tetanus toxoid is recommended for universal use regardless of age, especially for persons employed in occupations which put them in contact with soil, sewage, or domestic animals; military personnel, policemen, firefighters, and others with greater than usual risk of traumatic injury; the elderly; and international travelers.

Section 11: Varicella (Chickenpox)

CLINICAL CASE DEFINITION
An illness with acute onset of diffuse (generalized) papulovesicular rash without other apparent cause (as reported by a health professional).

REPORTING
Effective January 1, 2001, suspected cases of varicella (chickenpox) are reportable weekly by name, address, date of birth or age, sex, race, and ethnicity to local or regional health departments by calling **(800) 705-8868** or the Texas Department of Health (TDH), Immunization Division at **(800) 252-9152**. The Varicella Reporting Form is provided in the forms section of this document.

CASE INVESTIGATION
No individual case investigation is required, however, in the event of death, include a varicella death investigation worksheet, copies of the hospital admission and discharge summaries, death certificate, and autopsy report, and submit to the TDH Immunization Division.

CASE CLASSIFICATION
- **Confirmed:** A case that meets the clinical case definition or is laboratory confirmed.

LABORATORY CONFIRMATION: None required

CONTROL MEASURES
- **Pregnant woman:**
  Evidence of varicella immunity should be obtained as soon as possible. If no varicella antibody is detectable, Varicella-Zoster Immune Globulin (VZIG) given within 96 hours of exposure may prevent or modify disease in susceptible close contacts of cases. VZIG is indicated for newborns of mothers who develop chickenpox within 5 days prior to delivery or within 48 hours after delivery. There is no evidence that administration of VZIG to a pregnant woman will prevent fetal infections.
- **Health care setting:**
  Health care workers should ensure they are immune to varicella either through a reliable history of disease or vaccination against varicella. Should an exposure occur in a health care setting, exposed, susceptible personnel and patients should be identified as soon as possible. Varicella-zoster immune globulin (VZIG) given within 96 hours of exposure may prevent or modify disease in susceptible close contacts of cases. All exposed, susceptible patients should be isolated. All exposed, susceptible personnel should be either furloughed or excused from patient contact from day 8 to day 21 after exposure to an infectious patient. Varicella vaccine is recommended for all susceptible contacts.
- **Child-care facility setting:**
  Varicella vaccine (or history of prior disease) is required for all children ($\geq$ 12 months of age) to enroll in any licensed child-care facility in Texas, and vaccine is recommended for all susceptible children ($\geq$ 12 months of age).
- **VZIG:**
  VZIG is manufactured by the Massachusetts Public Health Biologics Laboratories (617) 522-3700. It is readily available through FFF Enterprises at (800) 843-7477.

EXCLUSION
- At least five days after the eruption first appears or until vesicles become dry.
- Avoid contact with susceptibles.
- In the hospital, strict isolation is appropriate because of the risk of serious varicella complications in immunocompromised susceptible patients.

Section 12: List of Forms

Name	TDH Stock Number	Revision Date
Acute Hepatitis B Case Track Record	F11-10866	11/14/2000
Haemophilus influenzae Case Track Record	F11-10871	11/14/2000
CDC Expanded Form: H influ Type B in Children < 5 years		7/19/2002
Mumps Case Track Record	F11-10869	11/14/2000
Pertussis Case Track Record	F11-10870	4/10/2002
CDC Pertussis Death Worksheet		4/10/2002
Rash-Fever Illness Case Track Record	F11-10868	7/19/2002
Tetanus Case Track Record	F11-10867	11/14/2000
Mother Summary Report for Perinatal Hepatitis B	F11-10932	11/14/2000
Infant Summary Report for Perinatal Hepatitis B	F11-10931	11/14/2000
Contact Summary Report for Perinatal Hepatitis B	F11-10934	11/14/2000
Varicella Report Form	F11-11046	11/14/2000
CDC Varicella Death Investigation Worksheet		07/19/2002

Forms can be ordered from the Surveillance and Epidemiology Section, Immunization Division, Texas Department of Health at **(800) 252-9152**. Please have the stock number and name of form available when placing an order.