UTAH DEPARTMENT OF HEALTH

Report Immediately

Diphtheria

Disease Plan

Quick Links

Last updated: March 31, 2021 by Jared Ripplinger.

Questions about this disease plan?

Contact the Utah Department of Health Bureau of Epidemiology: 801-538-6191.

✓ CRITICAL CLINICIAN INFORMATION

Clinical Evidence

Signs/Symptoms

- Respiratory (toxigenic)
  - Sore throat
  - Malaise
  - Fever
  - Cervical lymphadenopathy and swelling of tonsils, uvula and submandibular and anterior neck tissues (causes classic "bull neck" appearance)
  - Grayish-white pseudo-membrane lining tissue in nose, throat, tonsils, and voice box, resulting in difficulty breathing
- Respiratory (non-toxigenic)
  - Membranous pharyngitis
- Non-respiratory
  - Non-distinctive sores or shallow ulcers

Period of Communicability

- Transmission may occur as long as virulent bacilli are present in discharges and lesions.
- Without antibiotics, organisms usually persist two weeks or less and seldom more than four weeks.
- Chronic carriers may shed bacilli for six months or more.

Incubation Period

- 1–10 days (average 2–5 days)

Mode of Transmission

- Person-to-person through respiratory droplets
- Direct contact with skin lesions or articles soiled with discharges from lesions of an infected person (fomites)

Laboratory Testing

Type of Lab Test/Timing of Specimen Collection

- **Culture:** Specimen should be obtained as soon as possible when diphtheria (involving any site) is suspected, even if treatment with antibiotics has already begun.
- **PCR:** Specimen should be collected at the same time as specimens for culture.

Type of Specimens

- Swab of nose, pharynx, tonsils, or larynx, and/or any mucosal or cutaneous lesion (e.g., skin, wound, conjunctiva, ear, genital mucosa)
- For respiratory sites, material should be obtained from beneath the membrane, or a portion of the membrane itself should be submitted

Treatment Recommendations

Type of Treatment

- For cases where there is a high clinical suspicion of this diagnosis, prompt administration of diphtheria antitoxin without waiting for lab confirmation AND antibiotics (erythromycin or penicillin) as a 14-day course is critical
- Providers should contact the CDC Emergency Operations Center (770-488-7100) to request diphtheria antitoxin. Information on antitoxin indications for use, sensitivity testing and administration can be found at http://www.cdc.gov/diphtheria/dat.html.
- Age-appropriate vaccine should be administered during convalescence because infection does not always confer immunity.

- **Prompt reporting to public health (1-888-EPI-UTAH) is important to assist the clinician with confirmation of the diagnosis and obtaining antitoxin, if indicated**

Time Period to Treat

- Treatment of suspected cases should begin immediately and should not be postponed until laboratory confirmation.

Prophylaxis

- Close contacts should receive a diphtheria booster and be given a 7–10 day course of erythromycin (PO, 40 mg/kg/day for children and 1 gram/day for adults) or a single dose of benzathine penicillin (IM) (600,000 units for persons under six years of age and 1.2 million units for persons six years of age or older); benzathine penicillin should be given when compliance is a concern.
- Household contacts should be prophylaxed **regardless** of immunization status.

Case and Contact Management

Isolation of Case

- Non-hospitalized patients should be voluntarily isolated in their house until proven to be culture negative.
- Hospitalized patients should be isolated until cultures from both nose and throat obtained 24 hours apart are negative.

Quarantine of Contacts

- Adult contacts whose occupations involve handling food, especially milk, or close association with non-immunized children should be excluded from work until treated and bacteriological examinations prove them not to be cases or carriers.

Infection Control Procedures

- Standard precautions
- Droplet precautions for respiratory diphtheria
- Contact precautions for non-respiratory diphtheria

✓ WHY IS DIPHTHERIA IMPORTANT TO PUBLIC HEALTH?

Diphtheria was recognized as one of the most common causes of illness and death among children prior to the introduction of the diphtheria toxoid vaccine in the 1940s. In the 1920s there were 100,000 to 200,000 cases of diphtheria every year, resulting in 13,000 to 15,000 deaths annually. Since the advent of the vaccine, diphtheria has been well controlled and is infrequently reported in the U.S. Although infrequently reported, public health remains vigilant for cases to control the spread of infection by the implementation of rapid chemoprophylactic interventions.

✓ DISEASE AND EPIDEMIOLOGY

Clinical Description

Respiratory (toxigenic strains)

Diphtheria is caused by infection with toxigenic strains of gram-positive *Corynebacterium diphtheriae.* Important sites of infection are the respiratory mucosa (respiratory diphtheria) and the non-respiratory sites (e.g., skin, conjunctiva, ear, and genital mucosa).

Respiratory (nasal, pharyngeal, tonsillar, and laryngeal) diphtheria is typically caused by toxin-producing (toxigenic) strains of *C. diphtheriae.* The hallmark of respiratory diphtheria is the presence of a tough, grayish-white pseudo-membrane over the tonsils, the pharynx, or larynx. The pseudo-membrane is strongly adherent to the underlying tissue, and attempts to dislodge it usually result in bleeding. Initial symptoms of illness include a sore throat and low-grade fever. Swelling of the neck (“bull neck”) from soft-tissue inflammation and lymph nodes can develop and is a sign of severe disease. The pseudo-membrane may obstruct breathing and can be life threatening. Complications of diphtheria include myocarditis (inflammation of the heart) and nerve paralysis. The respiratory form of diphtheria usually lasts several days, and complications can persist for months.

Respiratory (non-toxigenic strains)

Nontoxigenic *C. diphtheriae* can also cause membranous pharyngitis. The disease is usually mild, but can lead to endocarditis. The isolation of *C. diphtheriae* from the throat does not necessarily indicate a pathogenic role in the illness. Although the frequency with which this occurs is unknown, a small percentage of the population may carry nontoxigenic or toxigenic strains of *C. diphtheriae* without disease symptoms.

Non-respiratory

Other non-respiratory sites of infection, such as the skin, conjunctiva, ear, and genital mucosa, may also be affected by toxin-producing *C. diphtheriae*, although rarely. These non-respiratory infections are most commonly cutaneous. Cutaneous diphtheria, caused by either toxigenic or nontoxigenic strains of *C. diphtheriae*, is usually mild, typically consisting of nondistinctive sores or shallow ulcers. While seldom developing into invasive or systemic disease, cutaneous diphtheria

lesions may act as a reservoir. Further transmission may result in respiratory or non-respiratory infections in other susceptible persons.

Causative Agent

Diphtheria is caused by toxin-producing strains of *Corynebacterium diphtheriae*, a pleiomorphic, gram-positive, irregularly staining bacterium. Rarely, other *Corynebacterium* species (*C. ulcerans* or *C. pseudotuberculosis*) may produce diphtheria toxin and can cause classic diphtheria. Whether diphtheria bacteria produce toxin depends on infection by a virus bacteriophage carrying the *tox* gene. There are four strains, or biotypes, of *C. diphtheriae:* gravis, mitis, intermedius, and belfanti. Toxin-producing strains of all biotypes produce an identical exotoxin. There is no consistent difference in pathogenicity or severity of disease among the biotypes; however, the order of their likelihood of producing toxin is: gravis, mitis, intermedius, and belfanti. On laboratory reports, *C. diphtheriae* should be distinguished from *Corynebacterium* diphtheroids*,* which are common skin commensals.

Differential Diagnosis

The primary diagnostic concern is to differentiate diphtheria from *Corynebacterium ulcerans*. This causes a disease that is clinically similar to *C. diphtheriae*. *C. ulcerans* is a zoonotic illness that can be transmitted from dairy animals and other pets. *C. ulcerans* is usually milder, but at least one report has identified *C. diphtheriae* toxins carried by *C. ulcerans.* Other pathogens can cause membranes in the respiratory tract, including *Streptococcus* species, Epstein-Barr virus, cytomegalovirus, *Candida,* and anaerobic organisms (Vincent's angina).

C. ulcerans infection in humans frequently has been associated with antecedent contact with farm animals or with consumption of unpasteurized dairy products, but human-to-human transmission has not been documented.

Laboratory Identification

If diphtheria is strongly clinically suspected, treatment should begin prior to laboratory confirmation. However, laboratory diagnosis remains essential for public health purposes.

Culture

Bacteriological culture is essential for determining biotype and toxigenicity of the diphtheria isolate. A clinical specimen for culture should be obtained as soon as possible when diphtheria involving any anatomical site is suspected, even if treatment with antibiotics has already begun. If respiratory diphtheria is suspected, specimens should be taken from the nose and throat and from the membrane. If possible, swabs also should be taken from beneath the membrane. If non-respiratory diphtheria is suspected, specimens should be taken from the mucosal or cutaneous lesion in question (e.g., skin, wound, conjunctiva, ear, genital mucosa). After *C. diphtheriae* has been isolated, the biotype (substrain) should be determined. Only large reference laboratories are likely capable of culturing diphtheria. Laboratory personnel should be notified if *C. diphtheriae* is suspected because special media are required. However, because isolation of *C. diphtheriae* is not always possible (many patients have already received several days of antibiotics by the time a diphtheria diagnosis is considered), and because of the extended time required for the test, PCR testing should always be performed for a faster result. For additional information on the collection

of specimens for diphtheria testing, please see **Appendix 1: Collection of Specimens for Isolation of *C. diphtheriae*** from the *CDC's Manual for the Surveillance of Vaccine-Preventable Diseases* at: http://www.cdc.gov/diphtheria/downloads/dip-collection.pdf.

PCR

Specimens for PCR should always be collected at the same time as specimens for culture. Because isolation of *C. diphtheriae* is not always possible (many patients have already received several days of antibiotics by the time a diphtheria diagnosis is considered), PCR can provide additional supportive evidence for the diagnosis of diphtheria. PCR should not be used as a replacement for culture.

Serology

Serologic results do not provide a clear diagnostic answer. Therefore, serology is not the preferred method for diagnosis.

Submission of *C. diphtheria* isolates and other Corynebacterium species

All *C. diphtheriae* isolates should be sent to the CDC Diphtheria Laboratory for reference testing to determine whether the isolate is toxigenic or nontoxigenic, regardless of association with disease, and from any anatomic site. Although uncommon, other diphtheria toxin producing *Corynebacterium* species (e.g., *C. ulcerans* or *C. pseudotuberculosis*) may be isolated from patients. Such isolates should also be sent to the CDC Laboratory. The Utah Department of Health (UDOH) should be contacted to arrange for specimen shipping.

Treatment

If diphtheria is suspected, diphtheria antitoxin should be administered, even before laboratory confirmation. Antitoxin is available through the CDC and requires an approval process for distribution. The UDOH will assist with this process; please call 1-888-EPI-UTAH (374-8824) to discuss any suspect case.

A test for sensitivity to diphtheria antitoxin should be conducted each time diphtheria antitoxin is administered. The recommended dosage and route of administration depend on the extent and duration of disease. Antibiotics are not a substitute for antitoxin. For more detailed information on antitoxin indications for use, sensitivity testing and administration, please see the CDC's **Use of Diphtheria Antitoxin (DAT) for Suspected Diphtheria Cases** (http://www.cdc.gov/diphtheria/dat.html). Providers should contact the CDC Emergency Operations Center (770-488-7100) to request diphtheria antitoxin. UDOH can assist with requesting diphtheria antitoxin and transport, if needed.

The recommended antibiotic treatment for diphtheria is erythromycin orally or by injection (40 mg/kg/day; maximum, 2 gm/day) for 14 days, or procaine penicillin G daily, intramuscularly (300,000 units every 12 hours for those weighing 10 kg or less, and 600,000 units every 12 hours for those weighing more than 10 kg) for 14 days. Oral penicillin V 250 mg four times daily is given instead of injections to persons who can swallow. The disease is usually not contagious 48 hours after antibiotics are instituted. Elimination of the organism should be documented by two consecutive negative cultures, performed 24 hours apart, after therapy is completed. Antimicrobial

therapy is required to stop toxin production, to eradicate the *C. diphtheriae* organism, and to prevent transmission, but it is not a substitute for antitoxin, which is the primary therapy. Some erythromycin-resistant strains of *C. diphtheriae* have been identified, but they are uncommon and not a public health threat at this time. Newer macrolide antibiotics, including azithromycin and clarithromycin, do not offer any substantial advantage over erythromycin.

Case Fatality

The case fatality rate of 5–10% for respiratory diphtheria has changed little in 50 years. Higher case fatality rates (up to 20%) have been documented among persons younger than five years of age and older than 40 years of age.

Reservoir

Humans are the only host of *C. diphtheriae*.

Transmission

Transmission is most often person-to-person spread from the respiratory tract. Rarely, transmission may occur from skin lesions or articles soiled with discharges from lesions of infected persons (fomites).

Incubation period

Incubation period of diphtheria is typically between 2–5 days, but can range from 1–10 days.

Period of communicability

Transmission may occur as long as virulent bacilli are present in discharges and lesions. The time is variable, but without antibiotics, organisms usually persist two weeks or less and seldom more than four weeks. Chronic carriers may shed bacilli for six months or more.

Susceptibility

Unimmunized and under-immunized individuals are susceptible. Infants born to immune mothers have passive protection, which is usually lost before the sixth month. Disease or asymptomatic infection usually, but not always, induces lifelong immunity.

Epidemiology

Infection can occur in immunized, partially immunized, and unimmunized persons. However, disease is usually less severe in those who are partially or fully immunized. Diphtheria is endemic in many parts of the world, including countries of the Caribbean and Latin America. The incidence of respiratory diphtheria is greatest in the winter and spring in temperate regions such as Utah, but summer epidemics may occur in warm, moist climates, where skin infections are prevalent. Seasonal and geographic patterns of infection are no longer observed in the U.S. because diphtheria cases are so rare.

Most cases of diphtheria reported recently in the U.S. were related to importation. Utah reported one internationally-imported case in 2020. Prior to that the last known case in Utah occurred in 1960.

✓ PUBLIC HEALTH CONTROL MEASURES

Public health responsibility

- Immediately contact the Bureau of Epidemiology at the UDOH for assistance with obtaining laboratory confirmation and antitoxin.
- Investigate all suspect respiratory cases of disease, and fill out and submit appropriate disease investigation forms.
- Provide education to the general public, clinicians, and first responders regarding disease transmission and prevention, and alert them of any events of disease circulation.
- Assure early and appropriate treatment with diphtheria antitoxin and antibiotics.
- Assure appropriate laboratory confirmation is performed.
- Recommend routine immunization against diphtheria.
- Identify clusters or outbreaks of this disease.
- Identify and evaluate contacts, and provide necessary antimicrobial prophylaxis to prevent further spread of the disease.

Prevention

The most effective control is widespread active immunization with diphtheria toxoid.

Chemoprophylaxis

Close contacts should be given (preferably) a 7–10 day course of erythromycin (PO, 40 mg/kg/day for children and 1 gram/day for adults) or a single dose of benzathine penicillin (IM) (600,000 units for persons under six years of age and 1.2 million units for persons six years of age or older). If close contacts are culture positive, treat them as patients, not contacts. Household contacts should be prophylaxed **regardless** of immunization status.

Vaccine

Primary diphtheria immunization with diphtheria-tetanus toxoids-acellular pertussis vaccine (i.e., DTaP) is recommended for all persons at least 6 weeks but less than seven years of age and without a history of contraindications. DTaP is the preferred vaccine for all doses in the infant and childhood vaccination series. The primary vaccination with DTaP series consists of a 3-dose series, administered at 2, 4, and 6 months of age, with a minimum interval of four weeks between doses. The fourth (first booster) dose is recommended at 15 through 18 months of age to maintain adequate immunity during preschool years. The fourth dose should be administered at least six months after the third. The fifth dose is recommended for children 4–6 years of age.

Adolescents and adults should receive a booster dose of Tdap. Adolescents 11 through 18 years of age who have completed the recommended childhood DTP/DTaP vaccination series should receive a single dose of Tdap at age 11 or 12 years of age. For adolescents and adults who previously have not received a dose of Tdap, a single dose of Tdap should be given and can be administered regardless of interval since the last diphtheria-tetanus-toxoids-containing vaccine. After receipt of Tdap, persons should continue to receive Td for routine booster vaccination against tetanus and diphtheria at 10-year intervals.

Current ACIP recommendations for DTaP/Tdap/Td vaccine can be found here: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/dtap.html.

Isolation and Quarantine Requirements

Isolation: Non-hospitalized patients with respiratory diphtheria, caused by toxigenic or non-toxigenic strains, and non-hospitalized patients with non-respiratory diphtheria, caused by toxigenic strains, should be voluntarily isolated in their house until proven to be culture negative.

Hospital: In addition to standard precautions, use Droplet Precautions for respiratory diphtheria, and contact precautions for non-respiratory diphtheria. Isolation measures should be continued until two negative cultures from both nose and throat are obtained (not less than 24 hours apart, and not less than 24 hours after completion of antibiotic therapy). When culture is impractical, isolation may end following 14 days of appropriate antibiotic therapy.

Quarantine: Adult contacts whose occupations involve handling food, especially milk, or close association with non-immunized children should be excluded from work until treated and bacteriological examinations prove them not to be cases or carriers.

✓ CASE INVESTIGATION

Reporting

All suspected and confirmed cases of diphtheria should be immediately reported to public health.

Table 1: Criteria to determine whether a case should be reported

Criterion	Reporting			
Clinical Evidence				
Acute respiratory illness with membrane on the tonsil(s), pharynx, larynx, or nose.	N			
Diagnosis of possible diphtheria by a healthcare provider	N	N		
Death certificate lists the condition as a cause of death or significant condition contributing to death				S
Laboratory Evidence				
Isolation of *C. diphtheriae* from any anatomical site			S	
Histopathologic diagnosis			S	
Epidemiologic Evidence				
Contact with a laboratory-confirmed diphtheria case		N		

Notes:
S = This criterion alone is SUFFICIENT to report a case.
N = All "N" criteria in the same column are NECESSARY to report a case.
O = At least one of these "O" (ONE OR MORE) criteria in each category (categories=clinical evidence, laboratory evidence, and epidemiological evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to report a case.

* A requisition or order for any of the "S" laboratory tests is sufficient to meet the reporting criteria.

Case Definition

Diphtheria (*Corynebacterium diphtheriae*) (CSTE, 2019)

Clinical Criteria

- Upper respiratory tract illness with an adherent membrane of the nose, pharynx, tonsils, or larynx, **OR**
- Infection of a non-respiratory anatomical site (e.g., skin, wound, conjunctiva, ear, genital mucosa)

Laboratory Criteria

- Isolation of *C. diphtheriae* from any site, **AND**
- Confirmation of toxin-production by Elek test or by another validated test capable of confirming toxin-production
- *Supportive laboratory evidence*: Histopathologic diagnosis

Case Classification

Suspect:

- In the absence of a more likely diagnosis, an upper respiratory tract illness with each of the following:
    - an adherent membrane of the nose, pharynx, tonsils, or larynx, **AND**
    - absence of laboratory confirmation, **AND**
    - lack of epidemiologic linkage to a laboratory-confirmed case of diphtheria

OR

- Histopathologic diagnosis

Confirmed:

- An upper respiratory tract illness with an adherent membrane of the nose, pharynx, tonsils, or larynx and any of the following:
    - isolation of toxin-producing *Corynebacterium diphtheriae* from the nose or throat, **OR**
    - epidemiologic linkage to a laboratory-confirmed case of diphtheria, **OR**
- An infection at a non-respiratory anatomical site (e.g., skin, wound, conjunctiva, ear, genital mucosa) with
    - isolation of toxin-producing *Corynebacterium diphtheriae* from that site

Comments:

- Cases of laboratory-confirmed, non-toxin-producing *C. diphtheriae* (respiratory or non-respiratory) should not be reported as diphtheria cases.
- Negative laboratory results may be sufficient to rule-out a diagnosis of diphtheria; however, clinicians should carefully consider all lab results in the context of the patient's vaccination status, antimicrobial treatment, and other risk factors.

- PCR and MALDI-TOF diagnostics for *C. diphtheriae*, when used alone, do not confirm toxin production. These tests, when used, should always be combined with a test that confirms toxin production, such as the Elek test.

Table 2: Criteria that must be met for a case to be classified

Criterion	Suspect	Confirmed (Laboratory)	Confirmed (Epi-linked)
Clinical Evidence			
Acute respiratory illness with membrane on the tonsil(s), pharynx, larynx, or nose	S	O	N
Infection of a non-respiratory anatomical site (e.g., skin, wound, conjunctiva, ear, genital mucosa)		O	
Laboratory Evidence			
Isolation of *C. diphtheriae* from any anatomical site		N	
Confirmation of toxin-production by Elek test or other validated test capable of confirming toxin-production		N	
Histopathologic diagnosis	S		
Epidemiologic Evidence			
Contact with a laboratory-confirmed diphtheria case			N

Notes:
S = This criterion alone is SUFFICIENT to classify a case.
N = All "N" criteria in the same column are NECESSARY to classify a case. A number following an "N" indicates that this criterion is only required for a specific disease/condition subtype (see below). If the absence of a criterion (i.e., criterion NOT present) is required for the case to meet the classification criteria, list the absence of criterion as a necessary component.
O = At least one of these "O" (ONE OR MORE) criteria in each category (categories=clinical evidence, laboratory evidence, and epidemiologic evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to classify a case. A number following an "O" indicates that this criterion is only required for a specific disease/condition subtype.

Case Investigation Process

All highly suspect cases of diphtheria warrant immediate action until they are shown not to be caused by toxigenic *C. diphtheriae*. Cases or carriers of toxigenic *C. diphtheriae* should be managed as follows:

- Local and state public health and the CDC should be immediately notified.
- Appropriate laboratory samples and preliminary clinical and epidemiologic information (including vaccine history) should be obtained.
- Presumptive treatment with antibiotics and antitoxin should be started.
- Strict isolation should be imposed until at least two cultures are negative 24 hours after antibiotics are discontinued.
- All case contacts should be identified and appropriately managed (explained in detail below).
- If case is not imported, the source of infection should be identified.

Outbreaks

A single case of diphtheria without any travel history will be considered an outbreak. Identify all close contacts, define population groups at specific risk, and provide prophylaxis as needed. An epidemiologically-linked case is one in which the patient has had contact with one or more persons who have or had the disease, and transmission of the agent by the usual modes of transmission is plausible. A case may be considered epidemiologically linked to a laboratory-confirmed case if at least one case in the chain of transmission is laboratory confirmed.

Identifying case contacts

Close contacts are defined as persons who have been within three feet (large droplet range) of the patient. This would typically include household members, persons who shared food, drink, or eating/drinking utensils with the patient, and healthcare workers in contact with the patient's oral or respiratory secretions. Contacts that were in brief contact with the case, but who do not meet the definition for close contact, are not considered significant contacts.

Case (close) contact management

Close contact management is necessary for all cases of respiratory diphtheria and non-respiratory diphtheria, caused by toxigenic strains.

For close contacts, especially household contacts, a diphtheria toxoid booster, appropriate for age, should be given. Contacts should also receive antibiotics; a 7- to 10-day course of oral erythromycin (40 mg/kg/day for children and 1 g/day for adults). If surveillance of contacts cannot be maintained they should receive IM benzathine penicillin (600,000 units for persons younger than six years of age and 1,200,000 units for those six years of age and older). Identified carriers in the community should also receive antibiotics. Contacts should be closely monitored and antitoxin given at the first sign(s) of illness.

Contacts of non-respiratory diphtheria should be treated as described above. However, if the strain is shown to be nontoxigenic, investigation of contacts can be discontinued.

✓ REFERENCES

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✓ VERSION CONTROL

01.02.2016: Updated format as described in current protocol. Epidemiology section was updated to reflect current information. Treatment of cases and close contacts was updated to show current recommendations. Reporting and case classification criteria were changed to match CSTE guidelines.

02.26.2016: Updated references and formatting.

10.02.2017: Updated references, treatment, case fatality; added Critical Clinician Information and Diphtheria Rules for Entering Laboratory Test Results sections.

05.07.2018: Updated sections based on comments from EAG.

06.15.2018: Updated Case Definition and Case Classification sections to reflect 2018 CSTE position statement update.

03.31.2021: Enhanced clarity of Critical Clinician Information, added pre-vaccine morbidity and mortality to Why Is Diphtheria Important to Public Health?, updated Disease and Epidemiology section with current surveillance data.

✓ UT-NEDSS/EPI-TRAX MINIMUM/REQUIRED FIELDS BY TAB

Demographic

- Age
- Area Code
- Birth Gender
- City
- County
- Date of Birth
- Ethnicity
- First Name
- Last Name
- Phone Number
- Race
- State
- Street
- Zip Code
- Name and location of school:

Clinical

- Clinician First Name
- Clinician Last name
- Date Diagnosed
- Date of Death
- Diagnostic Facility (DF)
- DF State
- DF City
- DF County
- Died
- Disease
- Was patient administered antitoxin?
- Onset Date
- Membrane on nose, pharynx, tonsils, or larynx*
- When did treatment start?

Laboratory

- Collection Date
- Lab
- Organism
- Result Value
- Test Result
- Test Type
- Units

- **Epidemiological**
- Food Handler
- Imported From
- Other Data 1
- Other Data 2
- Did patient travel out of the country in the 30 days prior to onset?
- Were any of the countries known to have endemic disease?
- Did patient travel out of the U.S. in the 25 days before symptom onset?
- Dates and places of travel
- Epi-linkage to a laboratory-confirmed case
- Did patient have contact with any people who recently returned from a country with endemic or epidemic diphtheria? If so, what were the dates of exposure and what were the countries?
- History of vaccination for the indicated disease?
- Year of last known tetanus-diphtheria booster vaccine received
- What is the country of birth?

Contacts

- Does case have workplace contacts? If YES, please fill out contact information below.
- Name and location of workplace:
- Does the case participate in any extra-curricular activities?

- Name and location of activity:

Reporting

- Date first reported to public health

Administrative

- LHD investigation/ intervention started
- State Case Status
- Outbreak Name
- Outbreak Associated

✓ DIPHTHERIA RULES FOR ENTERING LABORATORY TEST RESULTS

The following rules describe how laboratory results reported to public health should be added to new or existing events in UT-NEDSS/EpiTrax. These rules have been developed for the automated processing of electronic laboratory reports, although they apply to manual data entry, as well.

Test-Specific Rules

Test specific rules describe what test type and test result combinations are allowed to create new morbidity events in UT-NEDSS/EpiTrax, and what test type and test result combinations are allowed to update existing events (morbidity or contact) in UT-NEDSS/EpiTrax.

Test Type	Test Result	Create a New Event	Update an Existing Event
Culture	Positive	Yes	Yes
	Negative	No	Yes
IgG Antibody	Positive	No	Yes
	Negative	No	Yes
	Equivocal	No	Yes
IgM Antibody	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	No	Yes
PCR/Amplification	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	No	Yes

Whitelist Rules

Whitelist rules describe how long an existing event can have new laboratory data appended to it. If a laboratory result falls outside the whitelist rules for an existing event, it should not be added to that event, and should be evaluated to determine if a new event (CMR) should be created.

Diphtheria Morbidity Whitelist Rule: If the specimen collection date of the laboratory result is two years or less after the event date of the morbidity event, the laboratory result should be added to the morbidity event.

Diphtheria Contact Whitelist Rule: If the specimen collection date of the laboratory result is 14 days or less after the event date of the contact event, the laboratory result should be added to the contact event.

Graylist Rule

We often receive laboratory results through ELR that cannot create cases, but can be useful if a case is created in the future. These laboratory results go to the graylist. The graylist rule describes how long an existing event can have an old laboratory result appended to it.

Diphtheria Graylist Rule: If the specimen collection date of the laboratory result is 30 days before to seven days after the event date of the morbidity event, the laboratory result should be added to the morbidity event.

Other Electronic Laboratory Processing Rules

If an existing event has a state case status of “not a case,” ELR will never add additional test results to that case. New labs will be evaluated to determine if a new CMR should be created.