Clinical criteria for case classification

**Confirmatory:**
Either of the following:
- Both of the following:
  - Upper respiratory tract illness
  - **And** 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).

**Supportive:**
In the absence of a more likely diagnosis, both of the following:
- Upper respiratory tract illness
- **And** an adherent membrane of the nose, pharynx, tonsils, or larynx.

Laboratory criteria for case classification

**Confirmatory:**
Both of the following:
- Isolation of *Corynebacterium diphtheriae* from the nose or throat, if person has respiratory tract illness with adherent membrane, or site of non-respiratory anatomical infection
- **And** confirmation of toxin production.

**Supportive:**
Histopathologic diagnosis.

Epidemiological criteria for case classification

A person with direct contact with a case of diphtheria with laboratory criteria.

Case classification

**Confirmed:**
Either of the following:
- A person with confirmatory clinical criteria and confirmatory laboratory criteria
- **Or** a person with confirmatory clinical criteria and epidemiological criteria.

**Suspect:**
Either of the following:
- A person with supportive clinical criteria
- **Or** a person with supportive laboratory criteria.
Criteria to distinguish a new case from previous reports

Individuals without evidence of clinical criteria as described by the diphtheria surveillance case definition but for whom toxin-producing *C. diphtheriae* is confirmed via laboratory testing (isolation and toxigenicity testing by modified Elek test or other validated test capable of confirming toxin-production) should not be classified as cases. These individuals are considered carriers of the bacteria and are not reportable.

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. When used, these tests should always be combined with a test that confirms toxin production, such as the Elek test.