

Appendix A

Tuberculosis Case Definition for Public Health Surveillance (Revised May 13, 2009)

Clinical Description

A chronic bacterial infection caused by *Mycobacterium tuberculosis*, usually characterized pathologically by the formation of granulomas. The most common site of infection is the lung, but other organs can be involved.

Clinical Case Definition

A case that meets *all* of the following criteria:

- A positive tuberculin skin test result or positive interferon gamma release assay for *M. tuberculosis*.
- Other signs and symptoms compatible with tuberculosis (TB) (e.g., abnormal chest radiograph, abnormal chest computerized tomography scan or other chest imaging study, or clinical evidence of current disease).
- Treatment with two or more anti-TB medications.
- A completed diagnostic evaluation.

Laboratory Criteria for Diagnosis

- Isolation of *M. tuberculosis* complex from a clinical specimen,^{*}
or
- Demonstration of *M. tuberculosis* complex from a clinical specimen by nucleic acid amplification test,[†]
or
- Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained or is falsely negative or contaminated.

Case Classification

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

Comment: A case should not be counted twice within any consecutive 12-month period. However, a case occurring in a patient who had previously had verified TB disease should be reported and counted again if >12 months have elapsed since the patient completed therapy. A case should also be reported and counted again if the patient was lost to supervision for >12 months and TB disease can be verified again. Mycobacterial diseases other than those caused by *M. tuberculosis* complex should not be counted in tuberculosis morbidity statistics unless concurrent tuberculosis occurs.

* Use of rapid identification techniques for *M. tuberculosis* (e.g., DNA probes and mycolic acid high-pressure liquid chromatography performed on a culture from a clinical specimen) are acceptable under this criterion.

† Nucleic acid amplification (NAA) tests must be accompanied by culture for mycobacteria species for clinical purposes. A culture isolate of *M. tuberculosis* complex is required for complete drug susceptibility testing and also genotyping. However, for surveillance purposes, CDC will accept results obtained from NAA tests approved by the Food and Drug Administration (FDA) and used according to the approved product labeling on the package insert, or a test produced and validated in accordance with applicable FDA and Clinical Laboratory Improvement Amendments (CLIA) regulations.