
42 C.F.R. § 493.913

Mycobacteriology.

(a) *Types of services offered by laboratories.* In mycobacteriology, there are five types of laboratories for proficiency testing purposes:

- (1) Those that interpret acid-fast stains and refer specimen to another laboratory appropriately certified in the subspecialty of mycobacteriology;
- (2) Those that interpret acid-fast stains, perform primary inoculation, and refer cultures to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification;
- (3) Those that interpret acid-fast stains, isolate and perform identification and/or antimycobacterial susceptibility of *Mycobacterium tuberculosis*, but refer other mycobacteria species to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification and/or susceptibility tests;
- (4) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, but refer antimycobacterial susceptibility tests to another laboratory appropriately certified in the subspecialty of mycobacteriology; and
- (5) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, and perform antimycobacterial susceptibility tests on the organisms isolated.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycobacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least two testing events per year. The samples may be provided through mailed shipments or, at HHS' option, provided to HHS or its designee for on-site testing events. For types of laboratories specified in paragraphs (a)(1) and (a) (3) through (5) of this section, an annual program must include samples that contain species that are representative of the 5 major groups (complexes) of mycobacteria encountered in human specimens. The specific mycobacteria included in the samples may vary from year to year.

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