§493.1262 Standard: Mycobacteriology

(a) Each day of use, the laboratory must check all reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction.

Interpretive Guidelines §493.1262(a)

When condition-level deficiencies in Mycobacteriology are identified in any or all phases of testing, use D5004.

For acid-fast stains (i.e., Ziehl-Neelsen, Kinyoun), use positive and negative stain controls each day of testing patient samples. Use D5473 for deficiencies in these practices. For fluorochrome acid-fast stains, use positive and negative stain controls each time of use. Use D5475 for deficiencies in these practices.

Controls for acid-fast and fluorochrome stains for clinical specimens may include previously processed specimens that contain confirmed acid-fast organisms such as Mycobacterium fortuitum or other non-tuberculous mycobacteria for the positive control, and a negative sputum seeded with Escherichia coli for a negative control. Control smears should be heat-fixed and stored in a protective box.

For controls when staining mycobacteriology cultures, use a previously confirmed acid-fast organism such as Mycobacterium fortuitum for the positive control, and a non-mycobacterial species such as Escherichia coli for the negative control.

For the BACTEC NAP test, positive and negative control organisms must be tested each week of use. Controls should include M. tuberculosis ATCC 27294 and M. kansasii ATCC 35775. M. tuberculosis should be inhibited by NAP, while M. kansasii should have increasing growth index values in the presence of NAP.

For molecular amplification testing guidelines, use D5455.

Probes §493.1262(a)

How often are mycobacteriology cultures checked for growth prior to the issuance of final patient reports? How long are negative cultures held before a final patient report is issued (e.g., minimum of six weeks)? Use D5411 and D5413 as appropriate.