D5513
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1262 Standard: Mycobacteriology

(b) For antimycobacterial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using an appropriate control organism(s).

Interpretive Guidelines §493.1262(b)

A susceptible control strain of Mycobacterium tuberculosis, such as H37Rv or other appropriate control strain, must be used to check the susceptibility procedure.

For automated mycobacterial susceptibility testing, organisms which manufacturers recommend or require for use in their systems are acceptable strains of control organisms.

Probes §493.1262(b)

Are quality control samples tested at the same time specimens are tested? For example, a growth control without antimycobacterial agent should be inoculated at the time of patient testing.

(b)(1) The laboratory must establish limits for acceptable control results.

Probes §493.1262(b)(1)

Which control strains are used and how did the laboratory establish acceptable control limits for susceptibility tests?

(b)(2) Each week tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(b)(3) The results for the control organism(s) must be within established limits before reporting patient results.

Interpretive Guidelines 493.1262(b)(3)

The laboratory must ensure that it performs and documents all corrective action(s) taken whenever the test results do not meet the laboratory control limits for susceptibility. Use D5783.

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(c) The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1262(c)

QC records should include lot numbers, date prepared/opened, expiration dates, the actual

measurements, reactions, and/or observations and demonstrate that controls were tested when shipments of reagents, disks, stains, or antisera for identification systems were opened or when the laboratory prepared these materials.