



CONTROL PROCEDURES FOR MICROBIOLOGY

The specialty of Microbiology includes, Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology. These subspecialties of microbiology all have subspecialty-specific requirements for control procedures (quality control) that are given in this fact sheet. These specific control requirements are in addition to all applicable general requirements described in *CLIA Facts 16E: Analytic Systems: Control Procedures*.

The final CLIA regulations, published in 2003, streamlined many quality control (QC) procedures. Less frequent QC is now required for Bacteriology and Mycology reagent checks. For each test system, your laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytical process.

In addition, you are required to document all control procedures performed for each specialty and subspecialty.

Bacteriology

You must use control organisms to check for positive and negative reactivity:

- Each day of use for beta-lactamase methods other than Cefinase™
- Each week of use for Gram stains
- When each batch (prepared in-house), lot number (commercially prepared), and shipment of antisera is prepared or opened, and once every six months thereafter

For antimicrobial susceptibility tests, you are required to check each batch of media and each lot number and shipment of antimicrobial agent(s) before or concurrent with initial use using approved control organisms.

- Each day tests are performed, you must use the appropriate control organism(s) to check the procedure



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- Your laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results

Mycobacteriology

Each day of use, you should 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.

For antimycobacterial susceptibility tests, you 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).

- Your laboratory must establish limits for acceptable control results.
- Each week tests are performed, your laboratory must use the appropriate control organism(s) to check the procedure.
- The results for the control organism(s) must be within established limits before reporting patient results.

Mycology

You are required to check each batch (prepared in-house), lot number (commercially prepared), and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control

organism(s). For antifungal susceptibility tests, you need to check each batch of media and each lot number and shipment of antifungal agent(s) before or concurrent with initial use using an appropriate control organism(s).

- Your laboratory must establish limits for acceptable control results.
- Each day tests are performed, you must use the appropriate control organism(s) to check the procedure.
- The results for the control organism(s) must be within established limits before reporting patient results.

Parasitology

Your laboratory should have a reference collection of slides or photographs and, if available, gross specimens for identification of parasites to use for appropriate comparison with diagnostic specimens. You need to calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is critical for identification.

Each month of use, you must check permanent stains using a fecal sample control material that will demonstrate staining characteristics.

Virology

When using cell culture to isolate or identify viruses, you need to simultaneously incubate a cell substrate control or uninoculated cells as a negative control.