

3. Changes in Specialty and Subspecialty QC Requirements

a. Changes to Specific Microbiology QC Rationale

We are changing the requirements for some specific QC practices in microbiology in response to public comments, including recommendations made by the American Society for Microbiology (ASM). The changes affect the subspecialties of microbiology, including bacteriology, mycobacteriology, and mycology.

In 1996, the ASM (ASM, 1996) reported to the CLIAC a study of QC failures for 304 laboratories and nearly 15,000 commercial reagent lots representing 21 different bacteriology and mycology tests. QC failure rates for the reagents studied were 0.3 percent overall. The individual failure rate for

each reagent was less than 2 percent, except for X factor strips/disks, which was 2.13 percent. The results of this study prompted the ASM to propose that reagent QC be required only with each new lot for commercial microbiology reagents having a 98 percent or greater success rate. On the basis of these study results and ASM's recommendations, in this regulation, we are lowering the required frequency for reagent QC for several bacteriology tests and two mycology tests (Table 9).

For mycobacteriology, we are increasing some QC requirements based on public comments, making them equivalent with standards that already exist (Table 9). False positive results have been reported in testing for *M. tuberculosis* (Burman, Stone, Reeves, et al, 1997). At the same time, the incidence of infection caused by other

mycobacteria requiring additional testing for accurate identification is increasing significantly. To some extent, false positive results leading to inaccurate diagnoses and unnecessary or inappropriate therapy could be reduced by including a negative reagent control with biochemical identification tests. Therefore, in this regulation, negative controls are now required in addition to positive controls each day of use for mycobacteriology reagents. In addition, positive and negative controls are now required each day of use for acid-fast stains, and each time of use for fluorochrome stains. The revised requirements are justified by the important public health consequences of accurate and timely identification of mycobacteria, including *M. tuberculosis*.

TABLE 9.—CHANGES TO MICROBIOLOGY QC REQUIREMENTS

Existing regulations	New regulations (specified in this rule)
Bacteriology	
Each day of use, check catalase, coagulase, beta-lactamase and oxidase reagents and DNA probes using a positive and negative control.	(NC) Each day of use, check beta-lactamase, (other than cefinase (D)) and DNA probes using a positive and negative control.
Each week of use check bacitracin, optochin, ONPG, X, and V discs or strips using a positive and negative control.	(D) Check each batch, lot number and shipment of reagents (catalase, coagulase, and oxidase), disks (bacitracin, optochin, ONPG, X, V and XV), stains, antisera and identification systems for positive and negative reactivity, and graded reactivity if applicable.
Each month of use check antisera using a positive and negative control	(D) Check each batch, lot number and shipment of antisera when prepared or opened and once every 6 months thereafter using a positive and negative control.
Mycobacteriology	
Each day of use, check iron uptake test using a positive and negative acid-fast organism and check all other reagents or test procedures using a positive acid-fast organism.	(I) Each day of use, check all mycobacteriology reagents ((NC) iron uptake test) using a positive and negative acid-fast organism.
Each week of use check acid-fast stains using positive control	(I) Each day of use, check acid fast stains using a positive and negative controls.
Each week of use, check fluorochrome acid-fast stains using positive and negative controls.	(I) Each time of use, check fluorochrome stains using positive and negative controls.
Mycology	
Each day of use, test staining materials (lactophenol cotton blue) for intended reactivity.	(D) Check each batch, lot number and shipment of lactophenol cotton blue when prepared or opened for intended reactivity.
Each week of use, check biochemical tests and mycological identification tests (germ tube) with a positive control.	(D) Check each batch, lot number and shipment of reagents, disks, stains, antisera and identification systems for positive and negative reactivity.

D = Decreased QC Testing.

I = Increased QC Testing.

NC = No change.

Methodology

The number of laboratories impacted by the QC changes for the microbiology subspecialties of bacteriology, mycobacteriology, and mycology includes laboratories issued a Certificate of Compliance or a Certificate of Accreditation performing testing in the applicable subspecialties of microbiology according to the CMS OSCAR (2001) database. The number also includes the 1,448 laboratories performing testing in bacteriology, mycobacteriology, and mycology laboratories in the exempt States.

In estimating the cost of materials for changes to the microbiology QC requirements, we used information from several different microbiology reagent manufacturers and distributors (Remel, Becton Dickinson, and Fisher), including average list prices or suggested retail prices for reagents and supplies (we acknowledge some laboratories receive lower prices through negotiated discounts or purchasing agreements). We estimated the time and amount of reagent needed to perform QC testing and maintain records for the affected tests in the

applicable subspecialties, through discussions with experts in microbiology.

For the tests the QC changes will affect, the cost of QC organisms was considered negligible since organisms may be preserved and recultivated on an ongoing basis. Although the cost of maintaining cultures, including media and supplies, and the time spent in preservation and recultivation may be considerable, the changes in this final rule will not cause complete elimination of QC organism testing; therefore, the cost of culture maintenance will not