

with regard to the frequency of testing the disks, media, and overall procedure. The commenter felt that there is a contradiction between §§ 493.1227(c) and (c)(2) and that one of these statements should be deleted.

Response: In the former regulation, antimicrobial susceptibility testing requires that whenever a new batch of media or a new lot number and shipment of antimicrobial agents (disks) are put into use, the laboratory must verify that the media and agents perform within acceptable control parameters for testing. Following this initial verification that the test components (that is, media and antimicrobial agents) are working appropriately, the test procedure must be checked routinely with appropriate control strains to ensure that it is being performed accurately and all components of the procedure continue to work properly. This routine control procedure must be performed each day of patient testing or can be performed weekly. The weekly QC testing will be deemed to meet CLIA requirements, if performed as specified in the approved procedure providing equivalent quality testing in Appendix C of the State Operations Manual (CMS Pub. 7). The control organisms must be within established control limits before patient results can be reported.

Although we did not intend for the requirements at §§ 493.1227(c) and (c)(2) to appear contradictory, we are revising the language now at § 493.1261(b) for clarification of these requirements. In addition, we are making conforming changes to the language pertaining to the requirements for antimycobacterial and antifungal susceptibility testing for consistency and to be current with testing performed in these subspecialties. These requirements, formerly at §§ 493.1229(d) and 493.1231(d), are now at §§ 493.1262(b) and 493.1263(b).

Comment: A number of commenters stated the control requirements for identification procedures used in mycobacteriology at § 493.1229(a) should not selectively require positive and negative acid-fast control organisms to check the iron-uptake test each day of use while requiring only a positive acid-fast control for all other procedures. The commenters recommended that all identification procedures used in mycobacteriology be tested each day of use with an acid-fast organism that produces a positive result, and an acid-fast organism that produces a negative result.

Response: We agree with these commenters and because the incidence of infection caused by a variety of mycobacteria is increasing significantly,

it is important for laboratories to accurately identify individual species within this genus. This results in increasing numbers and types of identification procedures being performed and it is critical that the accuracy of each of these tests be verified each day of use. This can best be ensured each day of use by including both an acid-fast control organism that produces a positive reaction and an acid-fast control organism that produces a negative reaction for each test. We are revising the requirement formerly at § 493.1229(a) (now at § 493.1262(a)) to reflect this change.

Comment: One commenter expressed concerns regarding the expense of testing controls and stated that the frequency for checking positive and negative reactivity of the BACTEC NAP test used to identify *M. tuberculosis* should be changed from each day of use to each week of use. This commenter suggested the requirement for testing a positive control each day of use could be satisfied by subculturing the growth from the BACTEC bottle to a solid media to detect appropriate colony and microscopic morphology.

Response: The control requirements were written to address test complexity and specialties or subspecialties of testing, not specific test systems or procedures. Test-specific CLIA regulations are only developed when tests are not adequately addressed in the general or specialty or subspecialty requirements. The commenter requested a change in CLIA regulation because of the expense of performing controls each time the BACTEC NAP test is set up. The alternative method that the commenter suggests for a positive control is not actually a control on the ability of the NAP test to inhibit growth of *M. tuberculosis*, but is a confirmatory test for the presence of this organism.

Although we agree with confirming results of the NAP test, it is not the same as using positive and negative control organisms to check the NAP vials for their ability to inhibit growth of *M. tuberculosis* and to allow growth of other mycobacteria. However, we understand the financial concerns associated with running positive and negative controls each day of use for this test. Since the test has a growth control included as part of each test, and the manufacturer indicates the media is stable and does not recommend testing positive and negative organisms as frequently as each day of use, we agree with the commenter that laboratories should only be required to check positive and negative control organisms each week of use. In addition, we are specifying this

requirement as provided at § 493.1256 as an alternative procedure in Appendix C of the State Operations Manual (CMS Pub. 7).

Comment: One commenter stated positive and negative reactivity should be checked each day of use for all acid-fast staining procedures, rather than each week of use.

Response: We agree with the commenter that both fluorochrome and conventional acid-fast stains should be tested more frequently than each week of use and that both positive and negative control organisms should be tested. Nonpathogenic mycobacteria in water supplies have been found to contaminate buffers, rinse water, or other reagents, producing false positive staining results. Given the widespread use of acid-fast stains with the increasing incidence of mycobacterial disease, it is critical that the accuracy of these tests be verified each day of use. Therefore, we are deleting the requirements formerly at §§ 493.1229(b) through 493.1229(c) for testing fluorochrome and conventional acid-fast stains each week of use. The requirement for testing conventional acid-fast stains will now default to the general control requirement for stains formerly at § 493.1218(f)(2) (now at § 493.1256(e)(2)) that requires testing staining materials for intended reactivity each day of use. For stains that provide positive and negative reactivity (intended reactivity), we are revising the language to clarify that stains must be tested with positive and negative controls each day of use. By eliminating the subspecialty requirement for fluorochrome acid-fast stains, the general control requirement for fluorescent stains formerly at § 493.1218(f)(3) (now at § 493.1256(e)(3)) becomes applicable to these procedures. This general requirement specifies testing for positive and negative reactivity each time of use. It is appropriate to require the same control testing for fluorochrome acid-fast stains as are required for all other fluorescent stains.

Comment: One commenter recommended the deletion in bacteriology of testing positive and negative organisms each week of use for acid-fast stains as required in § 493.1227(a)(2) and replacement of the mycology term "acid-fast stain" at § 493.1231(c), with "modified acid-fast stain." This commenter emphasized that acid-fast stains are used in mycobacteriology rather than bacteriology, and that the procedure for staining used in mycology is a modification of the acid-fast stains performed in mycobacteriology.