

by reducing the QC frequency for these tests. Since we estimate that these changes will affect 50 percent of mycology laboratories, the total annual cost savings in mycology will be the annual savings per laboratory multiplied by half the number of mycology laboratories (9,059), an estimated total cost savings of \$1.4 million the first year.

Costs

Mycobacteriology

We estimated the cost for the changes to mycobacteriology QC testing in the same manner as we estimated savings for bacteriology (Table 11). However, in mycobacteriology, not all laboratories will be affected for every test, since no

more than 35.4 percent of laboratories perform organism identification. Therefore, when estimating the overall costs of increasing the mycobacteriology QC requirements, we considered the difference in the number of affected laboratories in the calculations.

When calculating costs for the acid-fast and fluorochrome acid-fast stains, we estimated that for each test, mycobacteriology laboratories would test two QC slides on at least a daily basis. Although QC is required each time of use for fluorochrome acid-fast stains (which can differ from each day of use), we assume QC would be performed daily and that each laboratory performs both acid-fast and fluorochrome acid-fast stains daily and

will incur an increase in QC testing costs for both methods. However, some mycobacteriology laboratories use only one method of staining, and some laboratories already check QC slides each time of use. The percentage of laboratories using each type of stain exclusively or already performing QC each time of use is not available. Therefore, our estimate of the cost impact of this increase in QC testing is higher than the actual costs that will be incurred. When calculating the weekly QC testing costs for acid-fast stains, we used 7 days for laboratory operations, taking into account the CDC recommended turnaround time of 24 hours (Huebner, Good and Tokars, 1993) for reporting acid-fast smears.

TABLE 11.—CHANGE IN COST PER TEST FOR REVISED MYCOBACTERIOLOGY QC REQUIREMENTS

	Labor cost	Reagent amount	Reagent cost	Total cost per test	Change in cost per day	Change in cost per week	Change in cost per year
Identification Tests ¹	² \$6.00	Variable	\$20.46	\$26.46	+\$7.56	+\$52.92	+\$2,751.84
Acid-fast Stains	³ 1.80	2–3 mL of 3 solutions	0.61	2.41	+2.41	+14.46	+751.92
Fluorochrome Stains	³ 1.80	2–3 mL of 3 solutions	0.60	2.40	+2.40	+14.40	+748.80
Total	+4,252.56

¹ Estimate includes the following tests: arylsulfatase, 68 degree catalase, semi-quantitative catalase, NaCl tolerance, niacin, nitrate, pyrazinamidase, tellurite reduction, Tween 80 hydrolysis, and urease.
² Combined labor cost estimate for each reagent/test includes one minute to perform QC test and one minute for recording and monitoring QC results.
³ Labor cost estimate for each stain procedure includes five minutes to perform QC test and one minute for recording and monitoring QC results.

For conventional biochemical reagents and identification procedures used on mycobacterial culture isolates, we calculated the potential cost increase for adding a negative control to each test based on 10 biochemical reagents (or tests) used for mycobacterial identification, as listed in Essential Procedures for Clinical Microbiology (Eisenburg, 1998). Although several additional biochemical tests can be used in the conventional scheme of mycobacterial identification, most of these tests were not included in our calculations since they are growth tests on certain selective media, which would not be subject to increased QC requirements. The iron-uptake test was also not included in our calculations since a negative control was previously required for this test. In estimating the change in cost for these identification procedures, the cost of labor for these tests was first calculated for a single test and then multiplied by 10. We assume the same approximate time is required to perform and record each QC test. The total reagent cost was determined by adding the cost of reagents for each individual test. The total cost for all 10 tests is the sum of the labor and reagent

costs. Since in most laboratories these tests are performed less frequently than acid-fast stains or bacteriology identification tests, our estimates assume that each of these tests would be run twice per week. The additional cost for each laboratory per week is equal to twice the total cost for all 10 tests, and the additional annual cost per laboratory is estimated on the basis of this total weekly cost.
To estimate the total annual increase in the cost of QC for mycobacteriology, we multiplied the increased costs for acid-fast and fluorochrome stains by the total 3,185 mycobacteriology laboratories, and multiplied the increased costs for conventional biochemical identification tests by 35.4 percent of the total number of laboratories (1,127), and then added these amounts. We estimated the total cost increase would be \$7.9 million the first year.
Error Rates
Bacteriology
We do not expect increased error rates in patient testing for the QC changes in bacteriology. As reported in the ASM study, the QC failure rates for

laboratories participating in the study translated into one failure for all reagents surveyed every 53 years (ASM, 1996). Since in many cases, a single reagent or test is only a part of a bacterial identification scheme, these rare failures are not likely to lead to errors in organism identification or patient testing.
Mycology
We expect no additional errors as a result of the decreased requirements for QC in mycology.
Scope of Impact
The changes in QC requirements for microbiology laboratories will result in significant cost savings overall, on an annual and 5-year basis, when considering the net effect of the changes being implemented in the subspecialties of bacteriology, mycobacteriology, and mycology. The decreased QC requirements in bacteriology and mycology are expected to impact all U.S. laboratories performing this testing under a Certificate of Compliance, Certificate of Accreditation, or State exemption. We estimate the total cost savings for each microbiology laboratory