

million the first year and \$34.6 million over the next 5 years.

Laboratories performing testing in syphilis serology (7,634), immunology (20,665), and hematology (32,753) can perform less frequent QC testing. We are unable to estimate the savings because we do not know how often the testing will be performed.

Finally, we are including a number of other changes that we are not considering burdensome. In many cases, we expect these other changes to have positive impacts; however, we are not able to quantify the consequences. Among these changes is the completion of the phase-in period for the laboratory director qualification requirement for high complexity testing that allowed an individual with a doctoral degree and the specified training and experience to qualify as a director of a laboratory performing high complexity testing in lieu of board certification up until December 31, 2002. To ensure a smooth transition to the new provisions for directors of high complexity testing who are not board certified (but who have doctoral degrees), we will not be holding facilities out of compliance

with the provisions of the rule concerning directors who are not board certified until the effective date of this new rule, to the extent the facilities are otherwise in compliance with the requirements for laboratory directors. This means that on and after February 24, 2003, individuals with a doctoral degree who have not been grandfathered in as directors will need to be board certified to serve as directors of laboratories performing high complexity testing. The grandfather provision allows those individuals with a doctoral degree who have served or are currently serving as high complexity laboratory directors and have at least 2 years of training or experience, or both; and 2 years of experience directing or supervising high complexity testing as of December 31, 2002 to continue in this capacity without obtaining board certification. In the absence of this provision, the experienced individuals who have a doctoral degree without board certification and have served or are serving as directors of laboratories performing high complexity testing would be ineligible to continue serving as a director, resulting in costly and

disruptive burdens associated with currently employed individuals obtaining board certification and laboratories replacing currently serving directors.

In summary, in the first year, we estimate the sum of all costs to be \$36.2 to \$45.0 million with savings of \$63.8 million and a net saving of \$18.8 to \$27.6 million the first year. Over the next 5 years, we estimate the sum of all costs to be \$158.7 to \$197.3 million, a total saving of \$279.8 million, and a net saving of \$82.5 to \$121.0 million.

In addition to overall monetary savings, this analysis acknowledges the potential for improvements in test accuracy and lower error rates in patient testing. We expect there to be improvements in the accuracy of patient testing and in accuracy of moderate complexity testing resulting from performance of method verification and calibration verification, and additional QC testing in mycobacteriology. We also expect more timely identification of potential laboratory errors resulting from the grading of more proficiency testing (PT) challenges.

TABLE 1.—IMPACTS DUE TO REGULATORY CHANGES: FIRST YEAR AND 5 YEAR TOTALS

	First year		5 Year total	
	Labs affected	Savings (costs) †	Labs affected	Savings (costs) †
Method Verification .....	11,248	(\$11.3–20.1) .....	29,601	(\$49.6–88.0)
Calibration Verification .....	29,601	(17.0) .....	29,601	(74.5)
Microbiology Changes .....				
Bacteriology .....	27,443	62.4 .....	27,443	273.7
Mycology .....	9,059	1.4 .....	9,059	6.1
Mycobacteriology .....	3,185	(7.9) .....	3,185	(34.6)
Microbiology Total .....		55.9 .....		245.2
Less QC for Other Specialties .....				
Syphilis serology .....	7,634	Unknown savings .....	7,634	Unknown savings
Immunology .....	20,665	Unknown savings .....	20,665	Unknown savings
Hematology .....	32,753	Unknown savings .....	32,753	Unknown savings
Total .....		18.8–27.6 .....		82.5–121.0

†In millions of dollars.

TABLE 2.—IMPACTS DUE TO REGULATORY CHANGES: ANNUAL IMPACTS OVER 5 YEARS

	Savings (costs) †					
	Year 1	Year 2	Year 3	Year 4	Year 5	5-Year total
Method Verification .....	(\$11.3–20.1) .....	(\$10.6–18.8) .....	(\$9.9–17.6) .....	(\$9.2–16.4) .....	(\$8.6–15.3) .....	(\$49.6–88.0)
Calibration Verification .....	(17.0) .....	(15.9) .....	(14.8) .....	(13.9) .....	(13.0) .....	(74.5)
Microbiology Changes:						
Bacteriology .....	62.4 .....	58.3 .....	54.5 .....	50.9 .....	47.6 .....	273.7
Mycology .....	1.4 .....	1.3 .....	1.2 .....	1.1 .....	1.1 .....	6.1
Mycobacteriology .....	(7.9) .....	(7.4) .....	(6.9) .....	(6.4) .....	(6.0) .....	(34.6)
Microbiology Total .....	55.9 .....	52.2 .....	48.8 .....	45.6 .....	42.7 .....	245.2
Less QC for Other Specialties:						
Syphilis serology ..	Unknown .....	Unknown .....	Unknown .....	Unknown .....	Unknown .....	Unknown
Immunology .....	Unknown .....	Unknown .....	Unknown .....	Unknown .....	Unknown .....	Unknown