

COLA laboratories 34 million tests. Among the Certificate of Compliance laboratories, POLs and laboratories under the classification as "Other" tend to have low annual test volumes, while Hospital and Independent laboratories have higher test volumes (Table 5).

This final rule will affect some aspect of these laboratories differently depending upon their annual test volume and the number of different test procedures they perform. Generally, laboratories performing a limited number of different tests will be impacted less than laboratories performing a greater number of tests. The low volume laboratories, POLs and Others, will be less impacted because they tend to have more limited test menus than those in Hospitals and Independent laboratories. However, the

proportionate costs of testing are greater in low volume laboratories (Tershakovec, Brannon, Bennett, and Shannon, 1995) because of the overhead cost, including those related to CLIA.

Another major determinate of the impact of this final rule that correlates with test volume is the extent of quantitative testing performed using moderate complexity instrumentation. A CDC survey of laboratories found, for example, that among Certificate of Compliance laboratories, the use of quantitative testing instrumentation was extremely variable. Use of hematology analyzers varied from a low of 36 percent among Independent laboratories to a high of 77 percent among Hospital laboratories; for chemistry analyzers, the lowest frequency (20 percent) was among POLs, while Hospital

laboratories had the highest use (83 percent) (Steindel, Rauch, Simon, and Handsfield, 2000). This survey was an unbiased on-site inventory of test systems and sampling was weighted to reflect the composition of U.S. laboratories.

We also anticipate that among Certificate of Compliance POLs, the practice size will affect the magnitude of the impact. Studies also show that practice size correlates directly with the extent of on-site testing (Ambulatory Sentinel Practitioner Network, 1996). Therefore, we expect the aggregate impact of this final rule to be less among solo practices since they perform less testing. However, solo practices have fewer employees and financial resources to execute aspects of this final rule, which may increase burden.

TABLE 5.—ANNUAL TEST VOLUMES BY LABORATORY TYPE, CERTIFICATE OF COMPLIANCE LABORATORIES ONLY, OSCAR, APRIL 2001

Laboratory type <sup>1</sup>	Total number of laboratories	Total number of tests <sup>2</sup>	Average number of tests per laboratory	Number and percent of laboratories grouped by annual test volume							
				≤2,00 tests/yr		2,000–10,000 tests/yr		10,000–25,000 tests/yr		>25,000 tests/yr	
				N <sup>3</sup>	% <sup>4</sup>	N	%	N	%	N	%
Hospital	1,392	354	254,310	444	32	56	4	148	11	744	53
Independent ...	2,593	307	118,396	572	22	481	18	433	17	1,107	43
Physician Office ....	14,687	147	10,008	6,899	47	4,681	32	1,617	11	1,490	10
Other ....	4,048	183	45,207	1,614	40	968	24	578	14	888	22
All ..	22,720	991	43,618	9,529	42	6,186	27	2,776	12	4,229	19

<sup>1</sup> Self-reported.

<sup>2</sup> In millions.

<sup>3</sup> Number of laboratories.

<sup>4</sup> Column percent.

## 2. Specific Changes Associated with Completion of the QC Phase-in Period

### a. Procedure Manuals

#### Rationale

During the QC phase-in period, laboratories performing commercial, unmodified moderate complexity testing must "have a procedure manual describing the processes for testing and reporting patient test results." With the completion of the phase-in, laboratories performing this type of testing will now be subject to more specific, comprehensive procedure manual requirements. Some laboratories may need to augment their current procedure manuals to meet the new requirements. Although we are unable to estimate the number of laboratories and the specific procedure manual changes they will need to make, we estimate that all Certificate of Compliance and COLA

laboratories will require changes to their procedure manual.

In addition, laboratories must now document the dates of initial use and discontinuance for each procedure; and all procedures and procedural changes must be approved, signed, and dated by the current laboratory director before use.

#### Benefits

A comprehensive and up-to-date procedure manual is essential to ensure reliable and reproducible performance among individuals and is considered one hallmark of good laboratory practice and a necessary component of quality management.

#### Costs

For those Certificate of Compliance and COLA laboratories that need to amend procedure manual instructions, the cost will vary depending on the

extent to which they may need to create procedural elements and the number of procedures performed in each laboratory. The cost for each laboratory will be the cost of the labor to augment documentation and the laboratory director's time in reviewing, signing, and dating procedures. We estimate that these costs will be minimal since most Certificate of Compliance and COLA laboratories do not perform a large number of test procedures and many may already have the documentation. We are unable to estimate the total cost for this requirement since we have no estimate on the extent to which procedure documentation will be necessary.