Practice Patterns of Testing Waived Under the Clinical Laboratory Improvement Amendments

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• ***Objectives.*—To determine operational practices in laboratories operating under a Certificate of Wavier (waived laboratories), or equivalent, under the Clinical Laboratory Improvements Amendments (CLIA) of 1988 when performing tests designated as having an insignificant risk of an erroneous result (ie, waived tests).**

***Methods.*—Waived laboratories that were part of the Centers for Disease Control and Prevention Laboratory Sentinel Monitoring Network project in the states of Arkansas, New York, and Washington were surveyed about their quality control (QC) and quality assurances (QA) practices when performing waived testing. Arkansas and Washington sent out similar questionnaires, whereas onsite surveys were conducted in New York. The survey in Arkansas and Washington also included nonwaived laboratories. The New York visits were designed to pilot test a regulatory inspection program for limited testing sites, which, in New York, are roughly equivalent to laboratories operating under a CLIA Certificate of Wavier and/or Provider-Performed Microscopy but are generally not located in physicians' offices. Laboratories visited in New York were selected from a list of limited testing sites and were representative of that population.**

***Results.*—Arkansas received responses from 211 facilities (37% response rate), of which 38% had Certificates of Waiver. Washington received responses from 190 waived laboratories (71% response rate) and from 116 nonwaived laboratories (32% response rate). In New York, 607 of the 2751 limited testing laboratories were visited. Reporting laboratories in all 3 states most frequently performed testing for glucose, urinalysis, urine human chorionic gonadotropin, occult blood, and group A *Streptococcus* antigen, although other waived tests were performed less frequently. Washington found that 57% of waived laboratories followed manufacturers' QC requirements. Arkansas found that 58% of laboratories doing waived tests that required liquid controls performed these controls, and 59% performing waived testing requiring electronic controls used these controls. In New York, 68% of the laboratories complied with the manufacturer's QC requirements for a variety of tests. Being accredited by an external organization or affiliated with a more complex laboratory improved compliance. Nonwaived laboratories in Washington and Arkansas complied with manufacturer's instructions at a higher rate than did waived laboratories. Similar deficiencies in following CLIA requirements were found in other areas of laboratory operation.**

***Conclusions.*—Just more than half of waived laboratories in 3 diverse states follow manufacturer's instructions for recommended QC and QA. These instructions help ensure that the test will produce results that have an insignificant chance of an error. Although we did not study the impact of this and other findings on patient care, the results show that imposing good laboratory practices by regulation alone was insufficient to ensure quality laboratory results in any location evaluated. A system that can continually provide accessible education on laboratory practices, coupled with new thoughts on the regulatory environment, is in order.**

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Throughout history, laboratory medicine has provided caregivers with essential information about patient status that is not available by other means. It was not until the 1920s, however, that the American College of Surgeons required laboratory services in the US hospitals that it certified.[1,2] In 1927, the American Medical Association reported on clinical laboratory services and called for standardization and some form of laboratory accreditation.[3] Since those early days, the medical community has tried various methods to ensure that quality laboratory services are delivered uniformly. In 1965, the Medicare Act[4] extended federal oversight to those laboratories providing testing for Medicare patients not located in physician's offices. The 1967 Clinical Laboratory Improvement Act[5] explicitly extended this to cover all laboratories engaging in interstate commerce. Paralleling these federal laws and regulations were local efforts in many states that regulated

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laboratory testing by licensing laboratory operation and/or testing personnel.[6]

A key feature of the 1970s and 1980s was the existence of a dual laboratory regulatory structure. Under Medicare, hospitals and independent laboratories were regulated, but physicians performing tests on their own patients were exempt. The philosophy behind this approach was that when physicians used a hospital or independent laboratory, they were viewed as the customer for laboratory tests, and regulations protecting this customer were appropriate.[7] Between 1965 and 1988, the nature of a physician office laboratory became more complex as technologic advances allowed more tests to be performed in an office environment.[8,9] By 1989, an estimated 6700 hospitals and 12 000 independent laboratories were under regulation, and ''several hundred thousand'' physician office laboratories were exempt.[10] In 1987, the news media reported on errors in laboratory testing, focusing on cholesterol testing[11] and gynecologic cytology.[12] The next year, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) of 1988[13] and changed the nature of laboratory regulations.

Regulatory oversight was extended to cover all testing sites, regardless of location. All of those testing sites are now required to follow the same standards for quality control (QC), quality assurance (QA), proficiency testing, personnel, documentation, and other aspects of practice.[14,15] Four years later, regulations defining laboratory operation were published in final form.[16] A key feature of the CLIA, which were detailed in the regulations, was the recognition that a subset of laboratory tests were simple to perform and ''have an insignificant risk of an erroneous result.'' Laboratories performing only those tests, designated as waived tests, require a Certificate of Waiver and are exempt from proficiency testing, personnel, and QA standards and inspection, but they are required to follow manufacturer's instructions in performing tests. Authority was granted to inspect subsets of these laboratories to gauge compliance. Shortly after the regulations were published, another subset of tests received special treatment. These tests were microscopy procedures that were performed by the provider immediately after obtaining a sample because of limited specimen stability and had no QC materials available to monitor the entire process. As long as these tests, designated as Provider-Performed Microscopy procedures (PPMP), were performed by the provider, they were exempt from biennial inspections. If these and waived tests were the only tests performed, inspection was still not required.[17]

The 1992 regulations noted 8 tests designated for a Certificate of Waiver: dipstick or tablet urinalysis (nonautomated), fecal occult blood, ovulation and urine pregnancy tests by visual color comparison, nonautomated erythrocyte sedimentation rate, hemoglobin measurement by copper sulfate (nonautomated) method, spun microhematocrit, and blood glucose determined by monitoring devices approved by the Food and Drug Administration (FDA) for home use. As happened from 1965 to 1988, technologic changes have extended the original list to include specific test kits or devices for common tests such as cholesterol, prothrombin time, and group A *Streptococcus* antigen (Strep antigen) tests and less common tests such as bladder tumor antigen and hemoglobin A_{1c}. As this list grows, it is desirable to know how laboratories implement these tests and methods, and to verify that they are meeting both the intent and requirements of CLIA. In 1996, the National Inventory of Clinical Laboratory Testing Services[18] estimated that 500 million waived tests were performed, approximately half for measurement of blood glucose levels, representing about 7% of all laboratory testing.

The Centers for Disease Control and Prevention (CDC), as part of its monitoring program under CLIA, established a Laboratory Sentinel Monitoring Network now operating in 3 states: Arkansas, New York, and Washington. The CDC asked each state to provide information on QC and QA practices of laboratories performing waived and PPMP tests in its specific network. In Arkansas and Washington, the responding laboratories consisted of those operating under a Certificate of Wavier and those that were full service. New York investigated laboratories not located in physician offices that limited their tests to those that were waived and PPMP tests. Washington has already reported on the QC procedures used by full-service laboratories for waived tests.[19] This report extends that study to waived laboratories in Washington and the other 2 states.

MATERIALS AND METHODS

The Arkansas Department of Health mailed surveys to 571 waived, moderate- and high-complexity laboratories located both within the state and in counties bordering the state. The survey requested the complete name of the waived test including analyte and manufacturer, and asked if external liquid controls were used and how often, if the results of built-in procedural controls were observed and how often, if proficiency testing was performed and how often, and if the waived test results correlated with patient information and how often. A column was provided to give other information. Statistical review of the data consisted of descriptive statistics, particularly frequency distributions, and comparative tests.

The New York State Department of Health selected a sample of laboratories performing on-site testing limited to PPMP and/or procedures that are included in the Department of Health and Human Services category of waived tests. An initial list of laboratories was generated from the Centers for Medicare & Medicaid Services (formerly the Health Care Finance Administration) database of all active CLIA numbers in New York State registered as any facility other than a physician office laboratory. After eliminating all laboratories holding a full-service New York State permit, a database was established containing 2751 sites designated as limited testing laboratories. Of these, 607 (22%) were surveyed in time for this report. These sites provided geographic diversity within the state and included high- and low-volume testing sites as well as most types of Centers for Medicare & Medicaid Services facility types. This subset also represented the overall ratio of sites that were either affiliated with a full-service licensed laboratory or that lacked such an affiliation (ie, nonaffiliated sites). The survey was extensive, containing questions concerning general laboratory operation as well as specific, analyte-appropriate questions for the waived tests and PPMP tests. Statistical review of the data consisted of descriptive statistics, particularly frequency distributions.

The Washington Department of Health mailed 2 surveys to the members of their Pacific Northwest Laboratory Medicine Sentinel Monitoring Network located in the states of Alaska, Idaho, Oregon, and Washington. The first survey was sent to 267 waived laboratories and was essentially identical to that used by Arkansas. The second survey was sent to 366 moderate- and high-complexity laboratories and focused on their practices in performing waived testing. The first part of this survey was similar to Washington's initial survey. The remainder of the survey was concerned with the frequency of QC testing, the use of proficiency-testing samples, and the frequency of test failure during a 6-month period. Network members were further asked to provide

Table 1. Use of Waived-Test Quality Control Methods in Arkansas*

Test†	No. of Laboratories	Quality Control Methods Used, % of Laboratories				
		External Liquid Controls	Procedural Controls	Electronic Controls	Comparison to Patient History	Proficiency Tests
Glucose	136	86	24	39	59	26
Urine hCG	113	46	76	NA	54	40
Urinalysis	103	53	12	5	56	47
Occult blood	89	19	71	NA	51	37
Strep antigen	63	60	13	NA	54	62
Erythrocyte sedimentation rate	51	8	2	NA	51	43
Hemoglobin	50	42	20	66	54	16
Helicobacter pylori	44	66	86	NA	50	43
Mononucleosis	42	64	93	NA	69	31
Prothrombin time	16	88	13	100	44	44
Hematocrit	14	36	14	0	54	36
Wet mount (PPMP)	13	NA	NA	NA	69	31
Cholesterol	10	80	30	30	60	20

* NA indicates not applicable; hCG, human chorionic gonadotropin; and PPMP, Provider-Performed Microscopy procedures.
† Tests used by 10 or more laboratories.

the number of patient tests, to recall how often, during the same 6-month period, the results did not agree with clinical impression, how often a test was repeated, how many repeated tests were confirmed, and how many were not. The last question asked them to name the single best indicator of an erroneous result for waived testing. Statistical review of the data consisted of descriptive statistics, particularly frequency distributions.

In New York, QC and QA practices were assessed by observations and record reviews conducted by on-site inspectors. Checklist questions included QA and QC practices recommended by the test manufacturers, and it was noted if these practices were not followed. General QA practices were not assessed in Arkansas and Washington. Laboratories in those states were asked about the type and frequency of QC used for the test kits they used, including liquid, electronic, and procedural controls. Manufacturers' requirements, determined from package inserts, for control use were compared against reported use during data analysis. Laboratories were noted as successfully meeting requirements if they performed the required procedure, regardless of frequency. All 3 states determined use of proficiency testing. Arkansas and Washington determined whether test results were correlated with patient history.

RESULTS

Arkansas received responses from 211 laboratories (37% response rate) of which 37% were physician office laboratories, 18% were hospital and independent laboratories, 20% were public health laboratories doing waived testing only, and the rest were a mix of diverse laboratory types known to perform mostly waived testing.[18] Washington received 116 responses for the survey sent to the moderate- and high-complexity laboratories (32% response rate) and 190 responses from the waived laboratories (71% response rate); of the latter, 40% were physician office laboratories and 16% were nursing facilities. All of the 607 laboratories selected for the survey in New York participated (100% response rate). In New York, no physician office laboratories were visited, with nursing facilities (25%) and community clinics (22%) representing the largest groups.

Of the facilities responding in Arkansas, most were waived laboratories (38%), followed closely by moderate-complexity laboratories (34%), high-complexity laboratories (16%), and PPMP laboratories (4%). All laboratories in New York State were limited testing laboratories, which are equivalent in testing services to waived and PPMP laboratories. Of the 306 total responses that Washington received, 62% were from waived laboratories.

Arkansas found an overall accreditation rate by external organizations of 18%. This rate differed significantly according to type of certification ($P < .001$, chi-square test) and showed noticeable differences for those holding a Certificate of Waiver (7% accredited) and those that were high-complexity laboratories (24% accredited) or did not state a certification level (39% accredited). Washington found that 33% of the moderate- or high-complexity laboratories were accredited by an outside organization. New York did not examine an accreditation status for their limited testing laboratories, but 26% were formally affiliated with a New York State–licensed laboratory that offered more complex services.

Arkansas and Washington determined the distribution of tests performed in the waived and moderate- or high-complexity laboratories in their surveys. The top 5 tests performed in the waived laboratories surveyed by Arkansas were glucose test (71% of waived laboratories), urinalysis (41%), urine human chorionic gonadotropin (hCG) test, 40%), occult blood test (35%), and Strep antigen test (20%). In Washington, the top 5 tests were identical, but the order varied: glucose test (73%), urinalysis (72%), occult blood test (60%), urine hCG test (42%), and Strep antigen test (26%). The top 5 waived tests performed in moderate- and high-complexity laboratories in Arkansas were glucose test (65% of moderate- and high-complexity laboratories), urine hCG test (65%), urinalysis (56%), occult blood test (53%), and erythrocyte sedimentation rate (38%). The corresponding list of tests for moderate- and high-complexity laboratories in Washington was urine hCG test (47%), urinalysis (35%), Strep antigen test (34%), glucose test (34%), and occult blood test (28%). For Arkansas, Strep antigen test occupied the sixth position (38%), and for Washington, erythrocyte sedimentation rate was sixth (22%).

Use of liquid, electronic, or procedural controls did not vary significantly with certification type in Arkansas ($P > .5$, Kendall τ-b test). Table 1 displays the percentage of Arkansas laboratories using various QC methods for tests that were used in 10 or more laboratories. Of the accredited laboratories in Arkansas, 50.3% performed proficiency testing compared with 37.0% of the nonaccredited labo-

Table 2. Use of Liquid Control and Proficiency Testing by Laboratory Certification Level in Washington*

Test	No. of Respondents		% That Tested: External Liquid Controls		% That Tested: Proficiency Testing Samples	
	W or PPMP	M or H	W or PPMP	M or H	W or PPMP	M or H
Urine hCG	68	55	29	73	10	65
Urinalysis	118	41	20	80	8	68
Strep antigen	44	40	64	83	21	65
Glucose	124	39	69	97	18	69
Fecal occult blood	90	32	23	13	4	19
Erythrocyte sedimentation rate	9	25	11	16	22	28
Mononucleosis	10	23	60	83	40	70
Helicobacter pylori antibody	13	15	46	80	31	40
Prothrombin time	8	14	75	79	25	43
Glycohemoglobin (Hb A_{1C})	3	10	67	90	33	60
Hematocrit	38	10	21	30	11	20
Hemoglobin	18	9	22	44	11	22
Lipids	17	4	76	100	47	0
Gastric occult blood	20	3	8	67	0	33
pH	12	3	20	100	5	33

* W indicates waived; PPMP, Provider-Performed Microscopy procedures; M, moderate complexity; H, high complexity; and hCG, human chorionic gonadotropin.

Table 3. Use of Quality Control Methods by Laboratory Certification Level in Washington*

Quality Control Method	Moderate- or High-Complexity Laboratories, %	Waived or PPMP Laboratories, %
Liquid controls	67	38
Procedural controls	91	60
Electronic controls	70	77
Proficiency testing	52	13
Comparison to patient history	26	72

* PPMP indicates Provider-Performed Microscopy procedures.

Table 4. Selected Deficiencies in New York Limited Testing Sites*

	Affiliated (n = 155)	Nonaffiliated (n = 452)
QA deficiency		
Staff qualification documentation	6	18
Testing out of certification level	3	3
Staff competency checks	10	40
Assay validation policies	22	71
Monitoring QC data	8	36
Procedure manual review by director	19	69
QA/QC oversight by director	10	34
Proficiency testing	39	88
Safety deficiency		
Personal protective equipment	2	1
Eating/drinking/smoking	0	1
Sharps disposal	3	7
Regulated medical waste	1	1

* Values are percentages of laboratories with the deficiency. QA indicates quality assurance; QC, quality control.

ratories ($P = .003$, chi-square test). Table 2 shows the extent of external liquid control use and proficiency testing use by laboratory certification level in Washington, and Table 3 summarizes that information along with the other QA methods used in the Washington sample. New York determined QA and safety deficiencies (Table 4) and test-specific deficiencies (Table 5) in the laboratories they visited and related each to the laboratory's affiliation status. Note that Table 4 shows a lower rate of deficiencies in those sites that were affiliated with facilities that had more extensive laboratory operations, but this difference was not so striking for safety-related deficiencies. Table 5 also shows the percentage of New York laboratories that had deficiencies in following the manufacturer's recommended QC procedures. Table 6 gives the percentage of laboratories with QA deficiencies among limited testing laboratories in New York that were doing PPMP.

In Washington, 85% of the moderate- or high-complexity laboratories followed manufacturer's QC requirements as determined by matching reported practice to requirements, and 57% of the waived or PPMP laboratories did so. In Arkansas, 59% of those performing tests using electronic controls when available used these controls, 82% observed procedural controls when part of the test, and 58% of those performing tests requiring liquid control testing did this testing. For those tests requiring liquid controls performed in Arkansas, 49% of nonaccredited laboratories and 90% of the accredited laboratories performed the required QC ($P = .001$, chi-square test). Neither accreditation status nor certification type was significantly associated with whether the manufacturer's recommendations were followed for the use of other controls.

Washington determined the frequency of control failures in their moderate- and high-complexity laboratories for the waived tests. Liquid controls failed 1.8% of the time, followed by electronic controls (1.4%), proficiency testing (1.1%), and procedural controls (0.06%). Of these laboratories, 80% kept records on the number of waived patient tests performed, 59% kept records of repeated waived tests, and 36% could correlate the result with history, presentation, and/or diagnosis. The average rate at which a result did not match clinical information was 0.8%. Waived tests were repeated at the same rate, 0.8%, most commonly for reasons of questionable specimen quality or discrepancy between test results and clinical presentation. These laboratories believed that the best indicators of a questionable waived test result were failure of the procedural control, discrepancy between the result and the clinical information, and questionable specimen quality.

COMMENT

Is the glass half empty or half full? This question arises frequently when discussing the controversial subject of CLIA. Fischer[20] raised the question when commenting on studies by Stull et al[21] and Hurst et al[22] concerning results of physician office laboratories when first exposed to proficiency testing. Both reports showed statistically significant differences in proficiency-testing failures between physician office laboratories and previously regulated laboratories. Stull et al reported that hospital laboratories passed proficiency testing 97% of the time compared with 91% for physician office laboratories, and Hurst et al noted that physician office laboratories passed 96% to 98% of the time. Both studies called for physician office laboratories to improve analytic performance.

Laboratory practice described by the surveys in Arkansas, New York, and Washington shows greater diversity than that found for the aforementioned proficiency-testing studies. A general impression is that many waived laboratories are doing QC and proficiency testing and many are not. The data, however, show that the same statement can be made for the nonwaived laboratories surveyed in Arkansas and Washington. New York data show that affiliated laboratories, which represent an active oversight relationship, had fewer deficiencies in performing waived tests than did those that were not affiliated. Accreditation, which is a weaker form of oversight relationship, did not have the same significant impact noted in the other states. Clearly, waived testing practices in all sites are not uniform and in many cases are not conforming to regulations.

The 3 states show sampling differences in the distribution of sites that relate to how their networks were constructed and surveyed. The Arkansas network is located in the state public health laboratory and actively recruited the local public health laboratories. New York focused on the limited testing laboratories, excluding physician office laboratories. When Washington recruited the moderate- and high-complexity laboratories for their survey, participants were assured that the data would not be linked to regulatory information, and only limited category information was obtained. A common characteristic of many of these waived and PPMP sites is that they are not traditional laboratories and were unregulated before the CLIA regulations. LaBeau et al[23] reported on the qualifications of testing personnel in the moderate- and high-complexity laboratories in the 4-state Pacific Northwest network and found that 73% had professional training in laboratory medicine, whereas less than 5% had similar training in waived laboratories.[24]

Several studies, reviewed by Boone,[25] have shown that in nontraditional testing sites, the use of laboratory trained personnel reduces the number of process-oriented deficiencies that now form the basis of our evaluation of laboratory quality. Crawley et al[6] found that in Idaho, 70% of technologist-supervised physician office laboratories maintained acceptable QC programs compared with 26% of those supervised by nurses and 42% of those supervised by those who were trained on the job. Hurst et al[22] showed that the subset of physician office laboratories that had laboratory-trained personnel passed more of their proficiency-testing challenges than those that did not have such personnel, but physician office laboratories overall still failed proficiency testing more frequently than did the traditional laboratories. LaBeau[26] found a mean total number of deficiencies during the first inspection cycle in laboratories new to regulation that used laboratory-trained personnel of 3.0 compared with 4.5 for those laboratories that did not have personnel with laboratory training. She also reported that in the second inspection cycle, the mean number of deficiencies dropped to 2.1 in those laboratories that used personnel with laboratory training and to 1.6 in those that did not.

Of the 3 states, New York was the only one to investigate laboratory operation outside of QC practices (Table 4). All practices listed in Table 4 are necessary for continually successful laboratory performance. Many of the limited testing laboratories that were nonaffiliated could not show a procedure manual reviewed by the laboratory director. About half did not check the ability of their staff to do the test. One third did not have QC and QA practices reviewed by the director. Three quarters did not validate if the assay they were using could produce the results in accordance with manufacturer's directions, a requirement in New York. It is not known if these deficiencies had an impact on patient care; however, adherence to these aspects of good laboratory practice helps achieve more consistent delivery of laboratory medicine and is required of laboratories performing testing in New York. It is interesting to contrast the quality assurance and safety deficiencies noted in Table 4. Limited testing laboratories are generally part of larger facilities that are also governed by safety requirements. The low number of safety deficiencies perhaps reflects this institutional awareness.

Waived tests are simple, and the philosophical intent is that they either produce an acceptable result or fail to produce a result if performed according to manufacturer's instructions. Hence, many, but not all, of these instructions contain procedures to verify proper operation of testers and test systems. Electronic controls are simulated test samples, either built into the device or introduced externally, that test if the device's electronics react correctly to the test signal expected from a true sample. Liquid controls are QC samples that laboratories use to mimic patient samples that have predetermined results that must be achieved to indicate proper operation. Manufacturers require or recommend a frequency for testing of electronic or liquid controls, usually using the words ''must'' or ''should,'' respectively. In New York, laboratories are required to follow these instructions regardless of wording; in Arkansas and Washington, the distinction between a recommendation and a requirement depends on the wording of the instructions.

Table 3 shows the differences in QC practices between laboratories in Washington that were and were not operating under a Certificate of Waiver. Moderate- and high-complexity laboratories tended to perform liquid controls at twice the rate of those holding a Certificate of Waiver, although some of that testing may be excessive.[19] Table 2 shows the percentage of laboratories using liquid controls in Washington for both groups of laboratories by specific test. The Arkansas data did not separate liquid control use by type of laboratory, but the rate of use by specific test is shown in Table 1. Although the types and proportions of laboratories in the 2 states differ, the rate of liquid control use in Arkansas by test is approximately the average rate of the use of the 2 laboratory types in Washington, thus giving an indication of the commonality of practices across the country.

A procedural control, when provided, is an integral

Table 5. Selected Test-Specific Deficiencies in New York Limited Testing Sites*

Deficiency	Glucose		Urinalysis	
	Affiliated (n = 124)	Nonaffiliated (n = 381)	Affiliated (n = 125)	Nonaffiliated (n = 252)
Specimen collection and/or labeling	3	4	1	6
Reagent kit storage	10	21	15	19
Lot no. and expiration date assessment	15	52	18	60
Recommended calibration	5	14	NA	NA
Recommended QC	3	39	9	65
Test time limitations	NA	NA	1	7
Interpretation of internal QC	NA	NA	NA	NA
Lot identifiers	12	54	20	62
Policy for failed QC	10	53	14	60
Supervisory QC review	NA	NA	14	50
Corrective action (reports)	15	41	18	46

* Values are percentages of laboratories with the deficiency. hCG indicates human chorionic gonadotropin; NA, not applicable; and QC, quality control.

part of the test process and is used to verify proper test performance. Manufacturers' instructions describe how to interpret the control and state that the test result is invalid if the control fails. Routine use of a procedural control, when available, should be 100%. Tables 1 and 3 and show that this is not the case. For this study, procedural controls were defined as ''controls that are built into each testing device to ensure that reagents are active and added correctly, and the system performs according to specification,'' and laboratories were asked if the procedural controls were observed. Although Table 1 indicates a 41% overall use of procedural controls in Arkansas, we noted that for tests that provided these controls, they were observed in 82% of laboratories. Hence, the low rate of use of procedural controls may have reflected laboratories responding that they did not use procedural controls when in fact the test did not provide one, indicating a possible misinterpretation of the question.

All 3 states provide information on whether the laboratories were doing what the manufacturer required for waived testing. New York provided the most specific data by test (Table 5). For the 5 analytes studied, approximately one third to three quarters of the nonaffiliated limited testing laboratories did not comply with the manufacturers' recommended QC, whereas affiliated laboratories performed considerably better. Of the other items in Table 5, a large percentage of nonaffiliated laboratories did not review or record lot number information or expiration dates. Without an adequate tracking mechanism for lot numbers and expiration dates, it is difficult to determine, when testers are questioned, if a test performed in the past used reagents within the manufacturers' acceptable performance periods.

Table 6 shows similar data for PPMP testing in New York. Although the percentage of nonaffiliated laboratories with deficiencies is still higher than that for affiliated laboratories, it is generally lower than those noted in Table 5. Competency assessment, however, can be viewed differently from the other deficiencies. Perhaps the provider does not understand the need to validate ongoing performance when it is either himself/herself or someone within the practice performing the test. An interesting observation is how does one do competency assessment on oneself? In an affiliated laboratory, someone from the other laboratory can do the assessment, but in a nonaffiliated laboratory, an external peer must be located.

Washington found that 57% of waived and PPMP laboratories followed manufacturers' QC requirements. Arkansas found that 58% of laboratories doing tests that required liquid controls used these controls. These values compare favorably with the average of 54% of nonaffiliated laboratories in New York who also followed recommendations. Arkansas observed that 59% of laboratories used electronic controls when they were available. A study of waived hemoglobin testing in California in 1995 showed a similar compliance rate.[27] Quality control is a fundamental procedure that laboratories perform to ensure that the test system and the tester are capable of producing acceptable and accurate results. Performing QC testing and understanding the need for it are learned behaviors. Although it is encouraging to observe that just over half of the waived or PPMP laboratories in 3 states have learned these behaviors, it is disturbing to observe that the other half have not. Failure to perform required or recommended QC testing to verify test performance makes detection of test failures difficult.

This study illustrates the complex relationship between affiliation, accreditation, and waived and PPMP laboratories. Affiliation signifies oversight of the operations of a waived or PPMP laboratory by another licensed, more complex laboratory and, as the New York data show, results in better but not complete adherence to regulations. Accreditation represents a laboratory's willingness to accept the standards of an organization, such as the Joint Commission on Accreditation of Healthcare Organizations, the College of American Pathologists, or the Commission on Laboratory Accreditation, for the operation of its facility. Accreditation agencies seek to have standards equivalent to or exceeding those of CLIA regulations. Laboratories that are accredited by these organizations are exempt from routine CLIA inspections but must meet accreditation requirements through an accreditation inspection. Accreditation agencies, in general, do not recognize waived tests and require some level of QC and proficiency testing. Results from Washington and Arkansas reflect the influence of accreditation on the performance of proficiency testing for waived testing. Results from 116 moderate- and high-complexity laboratories in Washington show that

Table 5. Extended					
Occult Blood		Urine hCG		Strep Antigen	
Affiliated (n = 87)	Nonaffiliated (n = 204)	Affiliated (n = 94)	Nonaffiliated (n = 145)	Affiliated (n = 62)	Nonaffiliated (n = 75)
2	7	1	3	5	3
13	12	15	15	15	19
37	55	12	50	13	37
NA	NA	NA	NA	NA	NA
14	31	5	39	5	32
2	3	1	6	0	1
NA	NA	NA	NA	3	8
37	59	15	52	19	36
16	50	14	57	11	44
14	39	14	39	11	24
17	40	22	37	21	27

Table 6. Selected Deficiencies in New York Limited Testing Sites Doing Provider-Performed Microscopy Procedures*

	KOH		Wet Mounts	
Deficiency	Affiliated (n = 44)	Nonaffiliated (n = 66)	Affiliated (n = 78)	Nonaffiliated (n = 104)
Written collection procedure	21	23	15	21
Microscope maintenance	9	21	8	14
Written testing procedure	23	24	17	22
Written reporting policy	23	21	17	22
Supervisory review (results)	25	23	24	23
Corrective action (reports)	36	44	32	42
Competency assessment	32	59	33	59

* Values are percentages of laboratories with the deficiency. KOH indicates potassium hydroxide.

those that were accredited performed proficiency testing at a significantly higher rate (61%) than those that were not (48%). In Arkansas, an average of 37% of laboratories performed proficiency testing, but the actual rate was test dependent (Table 1), and those that did this testing were more likely to be accredited, although about one third of nonaccredited laboratories also performed proficiency testing. In both states, about 30% of the nonwaived laboratories were accredited. In Washington, about half of the nonwaived laboratories performed proficiency testing compared with about 10% for waived laboratories (Table 3). In New York, 61% of the affiliated laboratories performed proficiency testing compared with 12% of the nonaffiliated laboratories (Table 4).

Data presented here clearly outline a lack of conformance among those laboratories that are part of the Laboratory Sentinel Network monitoring project to the CLIA regulations regarding waived testing independent of certificate types. No attempt was made within the project to obtain an unbiased sample of laboratories, and it is clear that many types of bias exist within the sample presented. New York used the survey mentioned earlier of limited testing sites not to determine compliance with regulations, but as a validation tool for future inspections. Recruitment to the networks in Washington and Arkansas was by solicitation letters requesting voluntary participation. Neither network has formally determined whether a selection bias existed. Finally, the response rates in Arkansas and Washington were low, and potential response bias was not investigated. Despite these obvious shortcomings, the data from 3 different areas of the country, using 3 different samples and sampling methods, are remarkably consistent. It can be concluded that inferences drawn concerning waived-test implementation are indicative of what is actually happening in the nation's laboratories. Other surveys involving point-of-care testing also support the results presented here,[28] and similar voluntary survey programs are known to give results that represent general laboratory performance.[29]

The implications of results presented are not known. Process deficiencies are evident, but the impact on patient care is not known. Washington determined that the QC and proficiency-testing failure rates and rates of repeated patient testing for waived testing in nonwaived or PPMP laboratories were around 1% and were similar to the rate found for nonwaived testing.[30,31] Waived testing, however, tends to be performed at the point of care, and the result can be readily correlated to what is clinically observed. Correlation with patient history was a common QC tool used in Arkansas (Table 1), and in Washington, more waived or PPMP laboratories use it as a QC tool than did nonwaived laboratories (Table 3). Goldschmidt and Lent[32] investigated the physician's ability to predict laboratory results in a limited study and found that prediction did not fit actual results 57% of the time. They did note, however, that the ability to predict a result is very dependent on placing the patient in the proper clinical context of monitoring, screening, or diagnosis, with adequate history to provide statistical boundaries for the result. Their study was conducted in a hospital setting, and they noted that in an office setting, the ability to provide a proper context improves.

In an editorial accompanying Boone's review[25] on research related to factors affecting the quality of laboratory

medicine, Neff and Speicher[33] wondered if the changes introduced in 1988 would lead to improved quality and if so, whether we could determine so. Questions concerning the impact of the 1988 amendments and the 1992 regulations have not lessened. We find editorials pointing toward the success of CLIA in making physicians more aware of good laboratory practice in their office testing[34] and the value of proficiency testing in the office setting, despite ''the problems associated with CLIA . . . .''[35] Although research by Hurst et al[22] and Stull et al[21] focused on physician offices new to the proficiency-testing process, other studies have shown that these laboratories improve with repeated proficiency-testing exposure.[36–38] Articles that are critical of CLIA note that those laboratories that stay the course, generally the larger practices, show improvement in quality as determined by process measures, but the studies also note how many laboratories have decreased test menus, ceased testing, or converted to solely waived testing, raising questions about access to testing or delays in treatment due to increased test turnaround time.[39,40] A government study on the impact of CLIA, however, did not reach the same conclusions.[41]

Manufacturers have responded to physician's concerns regarding the impact of CLIA on office testing by simplifying tests, thereby increasing the number of waived tests now available from the original 8 found in the 1992 regulations to the extensive lists of tests found in Arkansas (Table 1), New York (Table 5), and Washington (Table 2). Ehrmeyer and Laessig[42] describe the subjective nature of the requirement that waived-tests ''have an insignificant risk of an erroneous result''[13] and discuss the difficulties involved in implementing it using a proposed CDC protocol. In that discussion, they note that the FDA's approval process can serve as a basis for much of the waiver approval process; a recent description of this process has been published.[43] Levine et al[44] have commented on the FDA premarket approval process, noting that 98% of the in vitro diagnostic products now marketed are approved as being ''substantially equivalent'' to an existing product. Consequently, few devices undergo scientific and clinical studies that show effectiveness, and several products were cited as examples of unreliable diagnostic devices approved as substantially equivalent. The results that we present here show that a large percentage of all laboratory types performing waived testing fail to follow manufacturers' instructions and do not monitor the ongoing ability of their testing environment to produce a quality result through QC or proficiency testing. Hence, an increased burden is required of manufacturers to produce reliable waived test kits that show adequate performance in an unmonitored environment as well as on the FDA to validate that those products continue to perform as first approved.

Laboratories performing waived testing must share in the burden of producing a quality result for their patients. Moderate- and high-complexity laboratories know what good laboratory practice requires and are periodically inspected to verify compliance. At a minimum, these laboratories must have policies in place for moderate- and high-complexity testing that meet the minimal requirements of either CLIA or their accreditation agency and periodically, at least semiannually, verify that testers adhere to these policies and can adequately perform the tests. Additionally, if these laboratories perform waived testing, the same philosophies and practices for higher-complexity testing may carry over.

In waived laboratories, the situation is more complex. It cannot be assumed that testers, or even laboratory directors, in those facilities know what good laboratory practice entails, and the turnover of testing personnel may be great. Failure to follow even minimal requirements may be a result of not knowing what the requirements are. Studies have shown that results improve when testers are continually educated in good laboratory practices, especially as they relate to their test.[38,45] LaBeau's study[26] on conformance on second-cycle inspections showing that laboratories operated by nonlaboratorians had fewer deficiencies than those run by trained laboratorians also illustrates the success of education on a new audience, while showing the overall complexity of continually implementing good laboratory practices. These results show the great need for a coordinated continual-education program such as increased manufacturer's training programs and a more active role by nonlaboratory professional organizations in education of laboratory practices, enhanced perhaps by greater use of Internet-based training materials. Discussions among manufacturers, regulators, and the testing community are needed to shape this program.

Is the glass half empty or half full? Both the optimist and pessimist can interpret our results to support his/her position. Peddecord and Hammond[7] have noted that the process started by the CLIA amendments of 1988 represents a philosophical change. Establishing site-independent requirements for testing requires laboratories, independent of testing location, to now view the patient (not the physician) as the customer. The results presented here are not unexpected and may represent the difficulties that laboratories encounter in accommodating this change. As with many studies about the delivery and impact of laboratory medicine, the answer is not clear. Nevalainen et al[46] have noted that the total testing process in laboratory medicine has not significantly improved in 10 years and requires investigations that will redesign and improve the system. Similarly, the ongoing inability to ensure that waived testing continually meets patients' needs regardless of where performed, as defined by the manufacturer's instructions, indicates that this process also requires thoughtful redesign.

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