The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network
Final Report of the Findings of Questionnaire 15
Quality Assessment of Waived Test Systems

Kathleen M. LaBeau [1], Sharon Granade [2] and Steven J. Steindel [2]

1 Office of Laboratory Quality Assurance
Washington State Department of Health
1610 N.E. 150th Street
Seattle, Washington 98155

2 Centers for Disease Control and Prevention
Public Health Practice Program Office
Division of Laboratory Systems
Laboratory Practice Assessment Branch (MS G-23)
4770 Buford Highway N.E.
Atlanta, Georgia 30341

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BACKGROUND

The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network was created in 1995 to gather ongoing information about practices in hospital, independent and physician office laboratories (POLs) in Alaska, Idaho, Oregon, and Washington. To date, 18 questionnaires have been released to the network, exploring issues related to: testing quality; access to testing services; laboratory-related problems and errors; personnel training and changes; proficiency testing participation; point of care testing; and waived testing.

[Final reports of the findings of each questionnaire and references to journal articles based on these studies can be found on the Centers for Disease Control and Prevention (CDC) Website: http://www.phppo.cdc.gov/dls/mlp/pnlmsmn.asp]

Questionnaire 15

The intent of this questionnaire was to evaluate quality assessment activities used by moderate and high complexity laboratories on test systems categorized as "waived" under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program.

Questionnaire 15 was mailed to 366 network participants in October 2000. One hundred sixteen laboratories returned a completed questionnaire in time for analysis, a 32% response rate. Tests of significance were performed using Student's t-test, at 95% confidence limits ($p=0.05$).

Demographic characteristics of the respondents are summarized in the following table.

Demographic characteristics of respondents (N=116)

Demographic characteristic	Percent of laboratories
STATE	
Washington *	56
Oregon **	18
Idaho **	17
Alaska **	9
CENSUS BUREAU DESIGNATION	
Urban	57
Rural	43
LABORATORY TYPE	
Physician office ***	61
Hospital	29
Independent	10
ACCREDITED	
Yes	33
No	67
TESTING PERSONNEL	
At least one medical technologist or technician	80
No medical technologist or technician	20

* Laboratories are regulated under a CLIA-exempt state program.
** Laboratories are regulated under CLIA.
*** Includes: Physician office laboratories (POLs), clinics, community health centers, rural health centers, health departments/districts, student health centers and health maintenance organizations (HMOs).

FINDINGS

Ten percent of the 116 respondents did not perform any waived testing. Twenty-three tests were listed that were not waived tests: Six were provider-performed microscopic procedures (PPMP) [nasal smear for eosinophils, KOH preparation, wet mount examination], which were not the focus of this questionnaire; 17 were moderate or high complexity tests (Chlamydia, serum pregnancy test, urine drug screen, urine culture, complete blood count, prostate specific antigen, sperm analysis, total eosinophil count, and non-waived test systems for urinalysis, Strep antigen and *Helicobacter pylori*). A total of 331 waived tests were evaluated for 19 waived test analytes.

Quality assessment activities

Network participants were asked to select two qualitative and two quantitative waived tests that they performed on-site for the purpose of completing this questionnaire. For each of the waived tests selected, they were asked if they performed any of the following quality assessment activities:

- Test liquid controls
- Observe procedural controls
- Test electronic controls
- Test proficiency testing samples

For each of the activities where they answered "Yes", they were asked how often they performed the activity and whether they kept records of the results of the activity.

Test liquid controls

External liquid controls are reference solutions that are not built into the testing device (test pack, cartridge, cassette or strip) and are added in liquid form to the test reagent device in the same manner as the patient sample.

Overall, liquid controls were tested with 67% of the 331 waived tests performed. We did not find significant differences between laboratories based on location, type, accreditation status or testing personnel.

Liquid controls were tested most commonly with quantitative tests (glucose, glycohemoglobin, lipid profile, prothrombin time) and urinalysis testing. They were also tested commonly with qualitative tests where controls are either included in the kit or readily available (Strep antigen, mononucleosis, *Helicobacter pylori*, and pregnancy testing). Liquid controls were less commonly tested with tests where there is no "kit" and controls must be purchased separately (erythrocyte sedimentation rate, occult blood, hematocrit.).

Testing external liquid controls

Waived test	**Number of testing sites**	**Percent that test liquid controls**	**Frequency that liquid controls are tested *** (Number of testing sites)								
			ED	W	M	K	KO	QS	A	NS	O
Urine pregnancy test	55	73	5	1	2	29	3				
Urinalysis	41	80	18	8	1	6					
Strep antigen	40	83		2	2	24	3			1	1
Glucose	39	97	32	1		4				1	
Fecal occult blood	32	13	2	1		1					
Erythrocyte sedimentation rate	25	16	1	3							
Mononucleosis	23	83	2	1	2	14					
Helicobacter pylori antibody	15	80			1	10	1				
Prothrombin time	14	79	1	7		3					
Glycohemoglobin (A1C)	10	90	2	1		5					1
Hematocrit	10	30	2					1			
Hemoglobin	9	44	3					1			
Lipid profile	4	100	1			3					
H. pylori gastric tissue	4	25				1					
pH	3	100	2		1						
Gastric occult blood	3	67				2					
Microalbumin	2	100	1	1							
Bladder tumor antigen	1	0									
Ethanol	1	100				1					

* ED=each test or daily; W=weekly; M=monthly; K=each new kit or shipment; KO=each new kit and each new operator; QS=quarterly or semiannually; A=annually; NS=not specified; O=Other frequency.

For many waived test systems, the manufacturer's instructions for test performance include **recommendations** for testing liquid quality control materials (e.g., "Good laboratory practice recommends the use of external controls to assure that the assay is performing properly. It is recommended that controls be tests once for each 25 tests and as otherwise required by your laboratory's standard quality control procedures").

For other waived test systems, the manufacturer's instructions include specific **requirements** for testing liquid controls (e.g., "A positive and negative external control must be tested when opening a new test kit. Each operator performing testing within a test kit must test a positive and negative external control once with each test kit"). Testing sites using waived tests with quality control requirements must perform the quality control as part of following the manufacturer's instructions for performing the test.

We found that liquid controls were tested with 85% of the waived tests where this was required in the manufacturer's instructions.

Waived test systems with required quality control

Waived test system	Manufacturer's requirements	Number of testing sites	Percent that run liquid controls
Glycohemoglobin (A1C) Bayer DCA 2000+	Test a normal and abnormal control with each new lot and 1 liquid control (alternating levels) with each 10 cartridges	10	90
H. pylori antibody Quidel QuickVue One-Step	Test 2 levels of liquid control with each kit and each new operator	9	100
Prothrombin time Roche/Boehringer Manneheim Coagucheck	Each operator must test 2 levels of liquid controls weekly	12	92
Strep antigen test Quidel QuickVue In-Line One-Step	Test 2 levels of liquid control with each kit and each new operator	14	64
Urinalysis Bayer Clinitek 50	Test a positive and negative control each day and each new vial of strips	2	100

Observe procedural controls

Procedural controls are built into each test reagent device to ensure that reagents are active, that reagents and the patient sample are added correctly and that the test system performs according to specifications. Procedural controls are common in qualitative waived test kits (e.g., urine pregnancy, mononucleosis, Strep antigen and *H. pylori* tests).

Respondents observed the results of procedural controls with 91% of the 168 waived tests where procedural controls are part of the test system.

Test electronic controls

Electronic controls are inert, reusable devices (test strips, cartridges, cassettes, etc.) that are used to check instrument performance specifications. Electronic controls are available for use with some quantitative waived test systems (e.g., hemoglobin, lipid profile, prothrombin time, glycohemoglobin).

Respondents tested electronic control devices with 70% of the 33 waived tests where electronic controls are available for quality assurance purposes.

Test proficiency testing samples

Samples from a private proficiency testing company can be obtained and tested to provide a comparison of results with sites performing the same test and using the same test system.

Overall, proficiency testing samples were performed with 52% of the waived tests performed. Proficiency testing samples were tested with a significantly higher proportion of waived tests in laboratories that were located in CLIA-regulated states, in hospital and independent laboratories, accredited laboratories and those employing medical technologists or technicians.

Testing proficiency testing samples (N=331 waived tests)

Laboratory characteristic	**Percent of tests with which proficiency testing samples are performed**
Regulated under CLIA	59
Regulated under Washington State rules	47
Hospital	63
Independent	64
POL	45
Accredited	61
Not accredited	48
Employ at least one medical technologist or medical laboratory technician	57
No medical technologist/technician	36

Proficiency testing samples were tested at relatively high frequencies ($ 65%) with glucose, urinalysis, Strep antigen, mononucleosis and urine pregnancy testing. They were tested at relatively low frequencies (< 30%) for erythrocyte sedimentation rate, occult blood, hemoglobin and hematocrit testing.

Review of quality control and proficiency testing results

For the waived tests monitored for this questionnaire, participants were asked to review their previous six months of records for the following:

- Number of times controls (liquid, electronic, procedural) were tested/observed
- Number of times controls (liquid, electronic, procedural) failed or exceeded expected limits

- Number of proficiency testing samples performed
- Number of times proficiency testing results exceeded expected limits

If they did not keep records of these activities, they were instructed to indicate “not recorded”.

Failure rates for controls and proficiency testing samples were very low.

Failures on controls, proficiency testing samples

	Liquid controls	Procedural controls	Electronic controls	Proficiency testing samples
Total number tested	67514	10313	2309	1867
Number with results that exceeded expected limits	1231	6	33	20
Average failure rate	1.8%	0.06%	1.4%	1.1%

Review of patient test results

For the waived tests monitored for this questionnaire, participants were asked to review their previous six months of records for the following:

• Number of patient tests performed
• Number of times patient results did not match clinical impression, patient history, diagnosis

• Number of times patient tests had to be repeated on-site or by another laboratory
For the total number of times that patient tests had to be repeated:
- A tally of each according to the reason for the repeat testing
- Number of times where the original result was confirmed on repeat
- Number of times where the original result was not confirmed on repeat

If participants did not keep records of a particular item, they were instructed to indicate "not recorded". If their record keeping system did not allow them to readily track a particular item, they were to indicate "cannot track".

Patient testing records

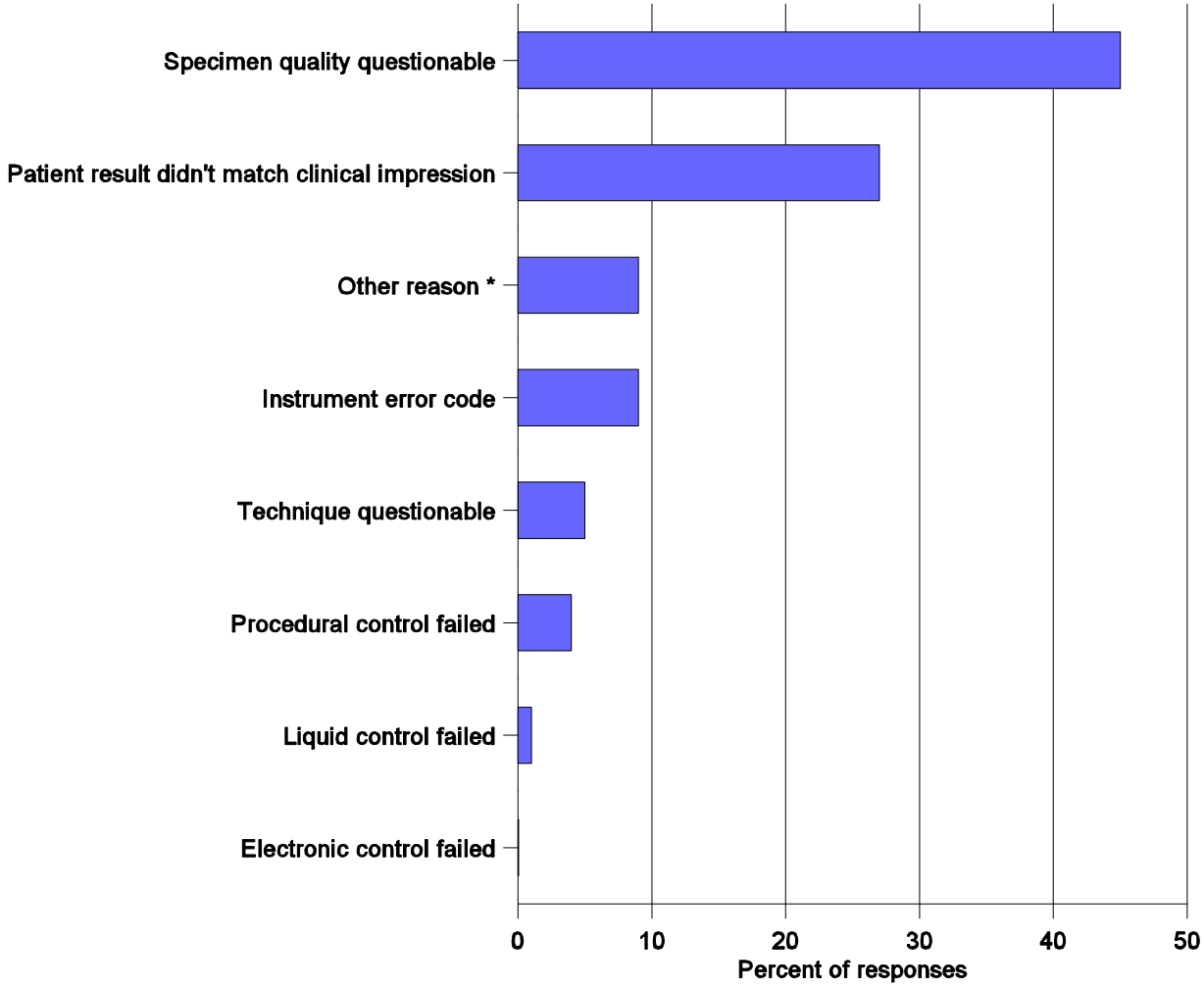
	Number of tests (percent)		
	Yes	**Cannot track**	**Not recorded**
Keep records of number of patient tests performed	263 (80%)	51 (15%)	16 (5%)
Correlate patient result to history, presentation, diagnosis	111 (36%)	139 (45%)	61 (20%)
Keep records of patient repeats	180 (59%)	70 (23%)	57 (18%)

Among the 110 tests where there were records of the number of patient tests done and the number where results did not match the clinical impression, 25296 patient tests were recorded with 195 that didn't match the clinical impression (0.8%).

Among the 174 tests where there were records of the number of patient tests done and the number of patient tests that had to be repeated, there were 907 repeats out of 114827 patient tests (0.8%).

For 73% of repeats, the original results were confirmed on repeat. The most common reasons for repeat testing were because the specimen quality was questionable and because the patient result did not match the clinical impression.

Reasons for repeat testing of patient samples (N=854 responses)



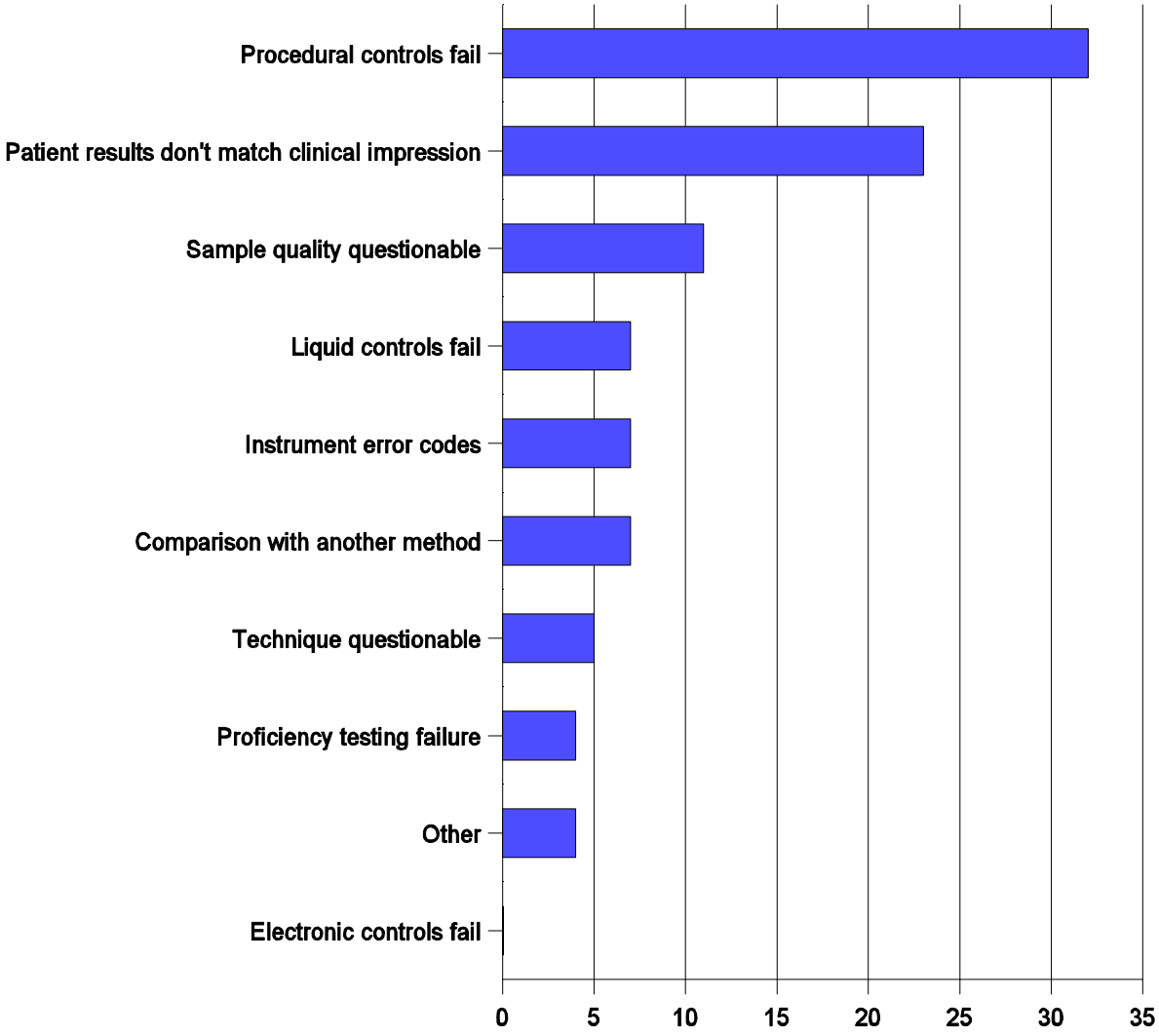
* Other reasons included: Specimen unlabeled or mislabeled; Test result exceeded instrument linearity; Patient result was extremely high; Patient tests were repeated to confirm a high or low value; Patient stated her result was lower on her own instrument; Back up cultures for Strep antigen testing.

Best indicator of erroneous or questionable patient test results

Given nine possible choices, participants were asked "From your experience with any waived test, what is the best indicator that patient test results are erroneous or questionable and warrant repeat testing?". If none of the choices applied, they were able to describe their response under "Other".

The top choices for the best indicator of erroneous or questionable patient test results were procedural controls fail or appear atypical and patient test results do not match the clinical impression.

Best indicator that test results are erroneous or questionable (N=110 responses)



DISCUSSION

Under CLIA, a "waived" test is a simple laboratory examination or procedure that has an insignificant risk of an erroneous result. To be considered a waived test, it must: be approved by the CDC or the Food and Drug Administration (FDA), following a waiver review process; be approved by the FDA for home use; or be one of the original tests designated in the CLIA regulations to be a waived test. Under CLIA and the CLIA-exempt Washington State rules, laboratories must follow the manufacturer's instructions for performing the waived test, but are otherwise relieved of the regulatory requirements associated with tests of higher complexity. The quality control and quality assurance standards set by private accrediting organizations for CLIA-waived tests differ from government regulations and vary between agencies.

According to this study, quality assessment activities were relatively high in moderate and high complexity laboratories and these laboratories tested most types of reference materials at significantly higher rates than we found in a study of 190 waived and PPMP testing sites in Washington State in October 2000.

Quality assessment activity	Percent of tests where activity is performed	
	Moderate/high complexity sites	**Waived/ PPMP sites**
Test liquid controls	67	38
Test liquid controls where required by manufacturer	85	57
Observe procedural controls for tests where applicable	91	60
Test electronic controls for tests where applicable	70	77
Test proficiency testing samples	52	13

Failure rates on controls were very low. Rates were also very low for patient test results that did not match clinical information and for repeat patient testing.

The overall response rate for this questionnaire was low compared to the average response rate on previous questionnaires (69%). Network participants were asked to collect data over a specified time period, which may be too difficult or time-consuming for the majority of participants.

Two separate studies are currently being conducted in other parts of the United States to assess quality assurance activities with waived test systems. Representatives of the Health Care Financing Administration (HCFA) are conducting on-site visits in a sampling of waived and PPMP sites in ten selected states in the country. Individuals from the New York State

Department of Health are also conducting on-site visits, as part of a cooperative agreement with CDC to monitor laboratory practices in that state.

Data gathered from our Pacific Northwest network will allow for a comparison with these on-site studies to determine if our self-reported data are comparable to that collected through on-site record review by an outside entity.

While most of the laboratories in our network kept records of the number of patient tests performed, records of comparisons of patient values to clinical information and repeat testing were relatively low. This diminished our efforts to collect data on failure rates of waived test systems and may make efforts to collect similar data through on-site visits difficult as well.