

**The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network
Inventory of CLIA-Waived Tests Performed in Washington State**

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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, 21 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: www.phppo.cdc.gov/dls/mlp/phlmsmn.asp

Database of all waived tests performed by all testing sites licensed in Washington State

In Washington State, all laboratories are licensed and regulated by the Office of Laboratory Quality Assurance (LQA), under a Clinical Laboratory Improvement Amendments of 1988 (CLIA)-exempt state program known as the Medical Test Site (MTS) rules. Prior to this project, information about the waived tests performed in laboratories in Washington State was available only in a hard copy format on individual MTS licensure application forms. (Appendix A)

While information about specific waived tests and test systems was available for each testing site, it was not present in a format that could be readily retrieved or manipulated for practical uses. For example, a study was conducted in August 2000 by the Washington Department of Health and the Foundation for Health Care Quality to identify the use of standardized methods for the measurement of glycohemoglobin. To provide data about the numbers and types of laboratories performing glycohemoglobins using one of the waived test methodologies, LQA had to perform manual reviews of licensure application forms.

In another instance, LQA wanted to provide testing sites with an update on quality control requirements for a specific waived coagulation test system. LQA staff were unable to target just those laboratories using the specific waived test system and so the information was shared with all laboratories in the state.

The intent of this project was to:

- Create a computer database of all waived tests by brand name and manufacturer for all licensed testing sites.
 - Summarize according to demographic categories of interest
 - Allow for rapid retrieval and manipulation of data for practical uses
- Identify targeted training needs on good laboratory practices with waived test systems, based on the inventory of waived tests performed in Washington State.
 - Develop handout materials
 - Write articles for the Washington Department of Health *ELaborations* newsletter
 - Conduct training classes
 - Provide technical assistance
 - Develop resources on the LQA website
- Share information with all laboratories in Washington State, CDC and other interested parties.
 - Information about specific waived tests and devices is currently unavailable in the CLIA database. The general usage patterns of waived tests identified in Washington State may be used as a surrogate for those nationwide, and may be used as a reference by a variety of interest groups for a variety of purposes.

PROJECT DESIGN

For this project, hard copy files were pulled for every testing site licensed in Washington State (waived, provider-performed microscopic procedures [PPMP], moderate complexity, high complexity, and accredited) and each waived test listed on the application form was entered into a computer database. All testing sites in Washington are required to complete an application for relicensure every two years. Therefore, the majority of the information gathered about waived tests for this project was based on relicensure application forms processed between August and October 2000. Information for the remaining testing sites was gathered from new applications for licensure, received between November 2000 and March 2002.

FINDINGS

As of March 2002, there were 2771 active laboratories listed in the Washington MTS database. Tables 1 and 2 show the distribution of laboratories by license category and site type.

Table 1 - Laboratories by license category

Category (Annual test volume)	Number	Percent	Category (Annual test volume)	Number	Percent
Waiver	1134	41	E (25001-50000)	23	<1
PPMP	921	33	F (50001-75000)	13	<1
Limited testing (<750)	162	6	G (75001-100000)	8	<1
Low volume (751-2000)	120	4	H (100001-500000)	15	<1
A/B (2001-10000)	139	5	I (500001-1000000)	3	<1
C/D (10001-25000)	52	2	Accredited	181	7

Table 2 - Laboratories by site type

Site type	Number	Site type	Number
Ambulatory surgery center	47	Mobile	19
Community clinic	67	Pharmacy	136
Ancillary site	17	Student health center	17
CORF	2	Skilled nursing facility	238
End stage renal disease facility	24	Physician office	1387
Health fair	10	Other practice	57
Health maintenance organization	26	Blood bank	5
Home health	55	Rural health clinic	26
Hospice	1	Drug treatment	5
Hospital	141	Clinic	189
Independent	96	Health department	33
Industrial	12	Other	158
ICFMR	3		

CORF=Comprehensive Outpatient Rehabilitation Facility
 ICFMR=Institutional Care Facility for Mentally Retarded

Using United States Census Bureau designations, 81% are in urban locations and 19% are in rural locations.

Backgrounds of directors in waived testing sites

Under CLIA and the Washington MTS regulations, there are no qualifications specified for directors of sites that perform only waived testing. The following summarizes the backgrounds of directors of the 1134 waived testing sites in Washington State.

Table 3 - Backgrounds of waived test site directors

Background	Number	Percent
Physician (MD, DO, DPM, ND, OD, DDS)	663	59
No qualifications listed	170	15
Pharmacist (RPh or PharmD)	139	12
Registered nurse (RN)	92	8
Nurse practitioner, Physician assistant	21	2
Medical technologist (MT)	13	1
Bachelor degree (BS or BA)	13	1
Other, includes: MS, MSW, PhD, MBA, EdD, JD, MPH, NHA	23	2

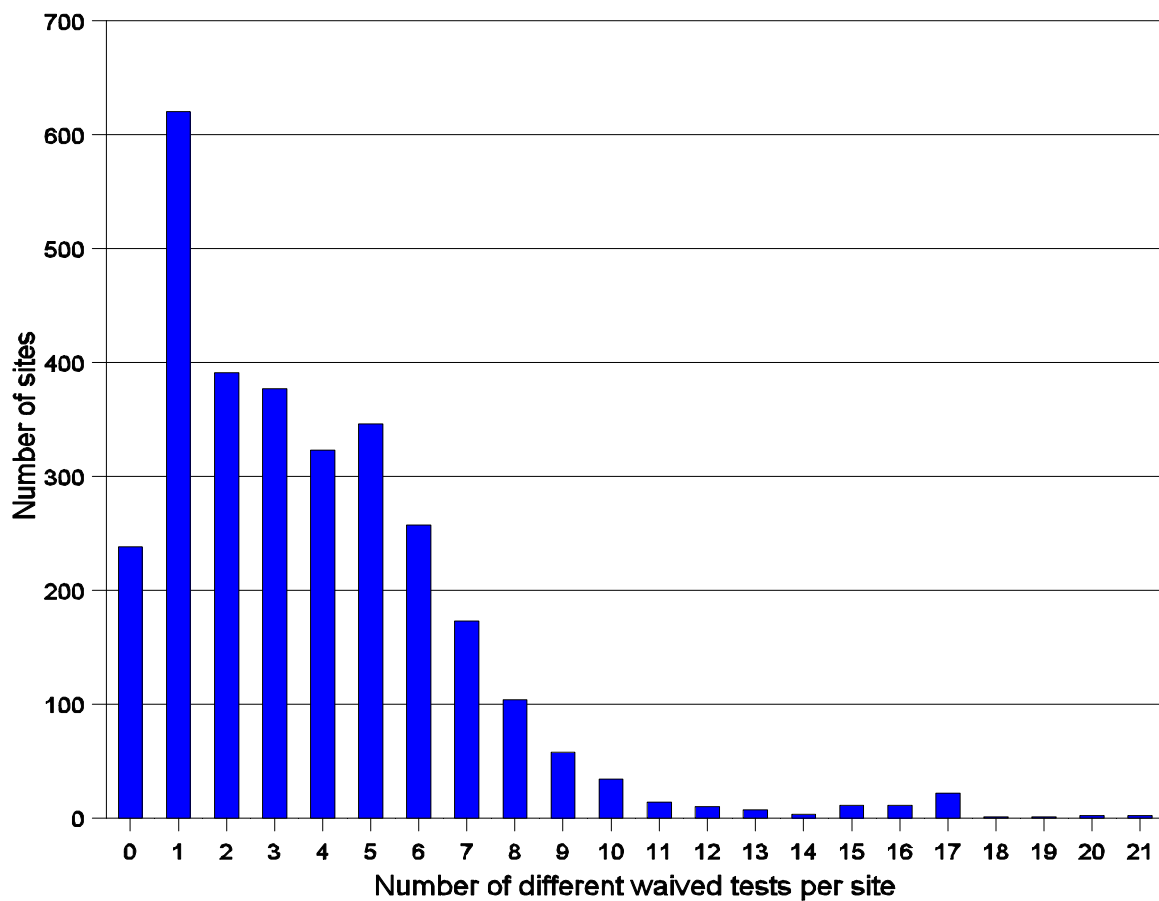
Inventory of waived tests

Of the 2771 active laboratories in the MTS database, 2770 files were available for data entry. Application forms for three sites were completed such that waived tests could not be determined.

Two hundred thirty-eight sites (9%) performed no waived testing. Dermatology practices and laboratories performing only histopathology and/or cytology services comprise the largest category of sites that do not perform any waived tests. Other types of sites that do not perform waived testing include those specializing in cancer treatment, pulmonary or respiratory care, fertility services, or molecular genetic testing.

A total of 11,005 waived test analytes were recorded, averaging four different waived tests per site. Figure 1 shows a distribution of the number of waived tests per site, as listed by the 2767 sites that correctly completed an application for licensure.

Figure 1 - Number of different waived tests per site



The following table shows the number and percentage of sites (in descending order) that perform the listed analytes by one or more waived test methods.

Table 4 - Waived analytes - All site types

Analyte	Number of sites	Percent	Analyte	Number of sites	Percent
Urinalysis	1859	67	Microalbumin, urine	173	6
Glucose	1612	58	Gastric occult blood	122	4
Fecal occult blood	1540	56	Glycohemoglobin	108	4
Urine pregnancy	1185	43	Fructosamine	53	2
Strep antigen	755	27	<i>H. pylori</i> gastric tissue	38	1
Hematocrit	580	21	Ovulation	23	<1
pH, body fluid	403	15	Influenza	15	<1
ESR	322	12	Ketones	14	<1
Cholesterol	265	10	Creatinine, urine	11	<1
<i>Helicobacter pylori</i> antibody	258	9	Ethanol, saliva	8	<1
Mononucleosis	230	8	Bladder tumor antigen	8	<1
Hemoglobin	228	8	ALT	7	<1
Prothrombin time	214	8	Drugs of abuse	7	<1
Lipid profile	196	7	Collagen type 1 crosslink	1	<1
HDL cholesterol	181	7	Catalase	1	<1
Triglycerides	178	6			
ESR=Erythrocyte sedimentation rate ALT=Alanine amino transferase					

Six of the top ten tests are analytes that were defined as waived in the original CLIA regulations published in 1992 - urinalysis, glucose, fecal occult blood, urine pregnancy, hematocrit and erythrocyte sedimentation rate.

The following table shows the top ten waived tests according to the most common site types - POLs, skilled nursing facilities, clinics, hospitals, pharmacies and independent laboratories.

Table 5 - Top ten waived tests by site type

Rank order	POL (N=1387 sites)	SNF (N=238 sites)	Clinic (N=189 sites)	Hospital (N=141 sites)	Pharmacy (N=136 sites)	IL (N=96 sites)
1	Urinalysis	Glucose	Urinalysis	Fecal occult blood	Glucose	Urinalysis
2	Fecal occult blood	Fecal occult blood	Fecal occult blood	Urinalysis	Cholesterol	No waived tests
3	Glucose	Urinalysis	Glucose	Glucose	Triglycerides	ESR
4	Pregnancy test	Gastric occult blood	Pregnancy test	Pregnancy test	Lipid profile	Fecal occult blood
5	Strep antigen	pH, body fluid	Strep antigen	ESR	HDL cholesterol	Strep antigen
6	Hematocrit	Ketones	Hematocrit	Strep antigen	H. pylori antibody	Pregnancy test
7	pH, body fluid	Prothrombin time	ESR	Hematocrit	Glyco-hemoglobin	Hematocrit
8	H. pylori antibody	Microalbumin	pH, body fluid	Gastric occult blood	Urinalysis	Prothrombin time
9	ESR	Cholesterol	Mononucleosis	No waived tests	Hemoglobin	Mononucleosis
10	Microalbumin	Creatinine, urine	H. pylori antibody	pH, body fluid	Fructosamine	Glucose
POL=Physician office laboratory; SNF=Skilled nursing facility; IL=Independent laboratory ESR = Erythrocyte sedimentation rate						

For a detailed listing of waived tests by all site types and by manufacturer and brand name, see Appendices B and C.

By combining this database with our MTS database, we are now able to create customized lists according to a variety of characteristics, including:

- Locations
 - Zipcode
 - City
 - County
 - Region
 - Census Bureau Urban/Rural Designation
- Site types
- License categories
 - Waived
 - PPMP
 - Regulated
 - Accredited
 - Annual test volume
- Other tests, specialties
- Personnel

DISCUSSION

Waived testing represents a large segment of all clinical laboratory testing. More than 800 waived test systems are currently available for 40 different analytes. In Washington State, 91% of all licensed sites perform one or more waived tests, with 41% performing waived tests exclusively. Routine on-site inspections and proficiency testing participation are not required in 74% of Washington's licensed sites because only waived and/or PPMP tests are performed.

At the federal level, there is much concern and debate over the criteria to categorize tests as waived and the degree of oversight necessary to assess that laboratories are using waived test systems correctly.

In 1999, the Office of the Inspector General (OIG) conducted a study based on interviews and written surveys of the Centers for Medicare and Medicaid Services (CMS) state agencies, accrediting organizations, the CDC and the Food and Drug Administration (FDA). They also performed a secondary analysis of the results of the studies conducted by CLIA surveyors in Colorado and Ohio. In their findings (released in August 2001), they concluded that "significant vulnerabilities exist in CLIA's oversight of waived and PPMP laboratories" due in part to the lack of on-site visits in those sites and that "despite safeguards, some vulnerabilities also exist for moderate and high complexity laboratories" because surveys of those laboratories do not include reviews of waived and PPMP testing.

In response to the vulnerabilities identified by the OIG study, the following recommendations

were made to CMS. These were also reiterated by the Clinical Laboratory Improvement Advisory Committee (CLIAC) during their May 2001 meeting:

- For moderate and high complexity laboratories
 - Review the waived and PPMP tests conducted in moderate and high complexity laboratories during routine surveys.
- For waived and PPMP laboratories
 - Require laboratories applying for waived and PPMP certificates to identify which tests they plan to conduct and which test systems they will use.
 - Provide educational outreach to laboratory directors of waived and PPMP laboratories.
 - Use periodic paper self-assessment tools to help ensure compliance for laboratories that are not routinely visited.
 - Survey a percentage of waived and PPMP laboratories annually.

CMS has challenged professional organizations, accrediting organizations, state programs, and other federal agencies to develop educational programs about waived testing practices. In April 2002, state agencies started conducting on-site reviews in 2% of waived and PPMP sites.

The data we gathered about general usage patterns of waived tests for Washington State laboratories likely reflect the patterns nationwide and may be used as a reference by a variety of interest groups for a variety of purposes.

By developing this list of waived tests for all sites licensed in Washington, we can target our efforts in providing technical assistance, preparing handouts, developing educational resources on our website and conducting training courses. Some of these activities have already been accomplished:

- Our newsletter *ELaborations* has a new section called “Waived Testing Helpful Hints,” in which we feature a new hint each month. *ELaborations* is mailed to all testing sites licensed in Washington.
- We have posted a self-study slide show, called “Good Laboratory Practices with Waived Tests”, on our website.
 - www.doh.wa.gov/hsqa/fsl/LQA_home.htm
 - Click on “Updates”
- “Good Laboratory Practices with Waived Tests” is also sent as a handout to sites seeking an initial application for licensure. We also plan to mail a copy of this handout to all of our sites during relicensing in October 2002.
- I serve on a CMS Region X workgroup that is developing a training course and handout

materials on good laboratory practices for urinalysis testing. All waived testing sites in Washington have been invited to a waived test seminar and product show, scheduled for June 21, 2002 in Seattle.

- As part of this CDC grant, we are conducting on-site reviews of quality assurance activities with waived test systems in 150 moderate- and high-complexity laboratories during routine surveys for compliance with the MTS rules. Results of this study will be shared in a separate report due for completion in September 2002.