

**The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network
Final Report of the Findings of Questionnaire 4 - Waived and PPMP Sites
Utilization of Referral Laboratories**

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EXECUTIVE SUMMARY

This study evaluated how waived and provider-performed microscopic procedures (PPMP) sites utilize reference laboratories and the types of problems they encounter with send-out testing.

In February 2001, a questionnaire was mailed to 264 waived and PPMP testing sites that participate in a data-gathering network in Washington State. Participants were asked to provide the following information:

- The number of reference laboratories used for send-out testing
- The type of reference laboratory used for the majority of their send-out tests
- The distance from their primary reference laboratory
- The most important factors in choosing a reference laboratory
- Recent changes in reference laboratories
- Problems with send-out tests

We found that waived and PPMP sites used an average of 1.8 referral laboratories, with a range of 0 to 20.

Fifty-three percent used an independent laboratory for the majority of their send-out tests and 68% of the sites using this type of referral laboratory sent their work within 25 miles. Sixty-nine percent of urban sites were within 10 miles of their referral laboratory and only 3% had to send testing more than 100 miles away. Thirty-nine percent of rural sites were within 10 miles, with 26% sending tests more than 100 miles away.

The most important factors in choosing a reference laboratory were:

- Reputation of the laboratory
- Turnaround times for test results
- Courier services
- Proximity
- On-site computer or printer for test results

Ten percent of the respondents had changed to another reference laboratory in the past two years, with 7% of all respondents doing so due to problems or quality issues.

When specifically asked about send-out tests with which they had the most problems, 38% of the respondents listed 93 tests or types of tests and 109 types of problems. The most problematic send-out tests were chemistries, PAP smears, esoteric testing, cultures, hepatitis and HIV testing. The most commonly listed problems related to turnaround times, compromised specimens, incorrect testing performed, and courier issues. Concerns about testing quality and accuracy were low.

BACKGROUND

Clinical Laboratory Improvement Amendments (CLIA) and test categorization

To improve the quality of clinical laboratory testing in all sites conducting the testing of human specimens for the assessment of health or the prevention, diagnosis or treatment of disease, the United States Congress passed the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Implemented in 1992, the CLIA regulations set minimum standards for clinical laboratory testing, taking into account different levels of testing technology complexity.

Tests categorized by CLIA as “moderate” or “high” complexity are subject to standards for: personnel qualifications and responsibilities; quality control; quality assurance; and record keeping. Laboratories that perform moderate and/or high complexity testing must undergo on-site inspections and participate in an approved proficiency testing program.

Under CLIA, a “waived” test is a simple laboratory examination or procedure that has an insignificant risk of an erroneous result. Testing sites that perform only waived tests must obtain a Certificate of Waiver and 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 Pacific Northwest Laboratory Medicine Sentinel Monitoring Network

With the passage of the CLIA regulations, studies were mandated to assess the quality, accuracy and reliability of laboratory testing results and the extent and nature of laboratory-related problems and errors. In 1995, in response to this mandate, the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network was created, through a cooperative agreement between the Washington State Department of Health and the Centers for Disease Control and Prevention (CDC), to gather information about clinical laboratory practices in hospital, independent and physician office laboratories. As of February 2001, the network comprised 633 clinical testing sites performing waived, provider-performed microscopic procedures (PPMP), moderate- and high-complexity testing. To date, 19 questionnaires have been released to the network. The network has provided interest groups (physicians, laboratorians, manufacturers, educators, consumers) and regulators with information on trends in the practice of laboratory medicine.

[Full text reports of the findings of these studies and references to journal articles can be found on the CDC Website at: <http://www.phppo.cdc.gov/dls/mlp/pnlmsmn.asp>].

METHODOLOGY

To evaluate how waived and PPMP sites utilize reference laboratories and the type of problems they encounter with send-out testing, a questionnaire was sent to the 264 network participants categorized as waived or PPMP. One hundred ninety-one participants returned a completed questionnaire in time for analysis, a 72% response rate.

Respondents

Using U.S. Census Bureau designations, 74% were characterized as urban and 26% as rural. The following types of clinical settings were represented: Physician office laboratories (POLs), clinics, nursing homes, pharmacies, hospital ancillary services, home health agencies, rehabilitation centers, health departments, occupational health programs, family planning clinics, community health clinics, student health clinics, dental offices, and Women, Infant and Children (WIC) programs.

FINDINGS

Number of reference laboratories used

Participants were asked “How many different reference laboratories do you use for your send-out tests?” The network respondents used an average of 1.8 reference laboratories, with a range of 0 to 20.

Primary reference laboratory

Participants were asked for the type of reference laboratory they used for the majority of their send-out tests and the distance of that reference laboratory from their facility. Overall, 53% of the network respondents used an independent laboratory for the majority of their send-out tests and 68% of the sites using this type of referral laboratory sent their work within 25 miles away.

Twenty-eight percent sent their referral work to a hospital laboratory. Ninety-two percent using this type of reference laboratory sent the work within 10 miles away.

Overall, 61% of the respondents sent their work to reference laboratories within 10 miles of their facility and 9% sent their referral work more than 100 miles away.

Tables 1 and 2 summarize the types of reference laboratories used and the distances from the network respondents.

Table 1 - Type of primary reference laboratory used

Type of reference laboratory used	Percent of respondents
Independent	53
Hospital	28
Clinic	10
Hospital and independent	3
Public health	3
Other: research, dialysis, hospital-based independent	2

Table 2 - Distance to primary reference laboratory

Distance to reference lab (miles)	Percent of respondents			Respondents using as their reference lab:		
	All	Urban	Rural	Independent	Hospital	Clinic
< 10	61	69	39	45	92	56
11 to 25	14	18	4	23	6	6
26 to 50	9	7	15	14	2	11
51 to 100	6	3	15	7	0	11
> 100	9	3	26	11	0	17

Factors in choosing a reference laboratory

Participants were asked to rank their top three factors in choosing their primary reference laboratory (the one used for the majority of their send-out tests).

The factors that were ranked in the top three by the highest percentage of respondents were: Reputation of the laboratory; turnaround times for test reports; courier services; proximity to my facility; and on-site computer or printer for test results.

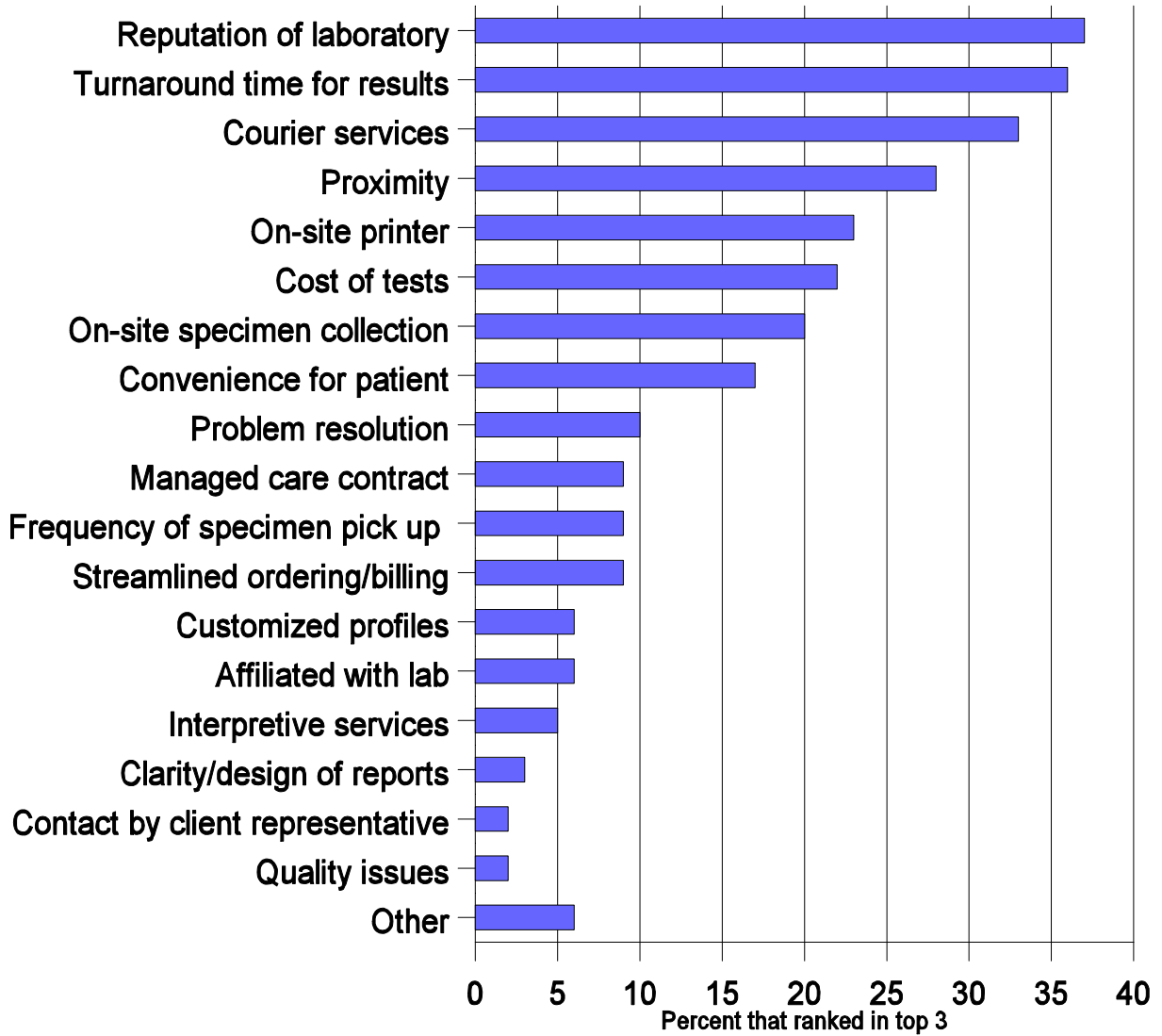
Figure - Factors in choosing a reference laboratory - All respondents

Table 3 - Factors in choosing a reference laboratory - Urban and rural differences

Factor in choosing a reference laboratory	Percent of respondents ranking the factor in top 3	
	Urban (N=118)	Rural (N=45)
Reputation of the laboratory	42	27
Turnaround time for test reports	31	49 *
Courier services	28	47 *
Proximity to my facility	27	31
On-site computer or printer for test results	25	20
Cost of tests	21	24
On-site specimen collection services	20	20
Convenience for patients	19	11
Accessibility of staff for problem resolution	6	20 *
Mandated by a managed care or insurance contract	11	4
Frequency of specimen pick up	11	4
Streamlined systems for ordering and billing	11	2
Customized profiles to suit the needs of my practice	8	0
Availability of interpretation of test results	5	4
Clarity or design of test reports	4	0
Frequent contact by client representative	2	2
* significant difference using Student's t-test at 95% confidence limits		

Changing reference laboratories

Participants were asked “In the past two years, have you changed your primary reference laboratory?” Ten percent of all respondents stated they had changed to another reference laboratory, with 7% of all respondents doing so due to problems or quality issues. Table 4 shows a summary of the 20 reasons given by the 17 respondents who changed reference laboratories in the past two years.

Table 4 - Reasons for changing reference laboratories

Reason for changing reference labs	Number of responses	Percent
For fewer problems	9	45
For better quality	3	15
Due to managed care or insurance contract	3	15
For better pricing	2	10
Other	3	15

Problem send-out tests

Participants were asked to write the name of up to five tests or types of tests that they send to a reference laboratory, with which they have had the most problems and to describe the type of problem encountered.

Seventy-two respondents (38%) listed a total of 109 problems for 93 tests or types of tests. Sixty-two percent of respondents did not list any tests or stated they had no problems.

A wide variety of tests were recorded, from very common to very exotic. The following were mentioned most frequently as problematic send-out tests:

- **Chemistry tests (23)**
Compromised specimens, incorrect test done, turnaround times.
- **PAP smears, cytology, pathology, biopsies (15)**
Turnaround time was the primary concern.

- **Esoteric tests (12)**
Examples included: viral load, CA125, ferritin saturation, CD4, HLA B27, lupus panel, maternal triple screen, n-teleopeptides.
The first reference laboratory has to send specimen onto a second reference laboratory, delaying testing and complicating the handling.
Specimens get lost, incorrect tests are done, unsure what specimen requirements are.
- **Cultures (11)**
Turnaround times, no weekend pick up of specimens, false negatives, false positives, culture results do not match urinalysis findings.
- **Hepatitis and HIV testing (8)**
Examples included: hepatitis C PCR-quantitative, hepatitis C RNA PCR, hepatitis panel, hepatitis profile, HIV, HIV-1 IgM.
It is difficult to know what to order and what you will get.
Instructions for ordering are confusing.
- **Frozen specimens (4)**
Not frozen on arrival.
- **Prothrombin times (4)**
Turnaround times, courier pick up is not timely.
- **Complete blood counts (CBC) (4)**
Compromised specimens, hemolysis, specimen stability.

Overall, the most frequent problems reported were: Turnaround times were too long; compromised specimens; not getting all tests or the correct tests performed; and courier services. When individual problems were combined according to categories of interest, test reporting issues and specimen handling issues ranked highest. The following gives an overview of all responses, with some specific examples of the types of tests and problems.

Reporting results	Number of responses	Percent	Examples
	49	45	
Turnaround time for test reports	40	37	PAP smears, cultures, protimes
Concerns about accuracy	7	6	GC/Chlamydia, PSA, urine cultures
Lost reports	2	2	

Specimen handling	35	32	
Compromised specimens	12	11	Frozen specimens arrive thawed Hemolysis
Wrong test performed Did not perform all tests	12	11	Missed orders, discarded specimens before correction could be made
Handling requirements are difficult	7	6	
Lost specimen	3	3	
Labeling problem	1	1	

Courier services	11	10	
			Specimens not picked up Problems on weekends No courier services offered

Billing / Costs	8	7	
			Billing mix-ups Coding problems Rejected codes High costs

Ordering tests	3	3	
			Unsure what to order Given two sets of instructions for specimen requirements Difficult instructions

Miscellaneous	3	3	
			Confidentiality Testing schedule is difficult Problems created by our own lab

DISCUSSION

The results gathered from this study compare closely with studies of moderate and high complexity laboratories, with a few exceptions. More waived and PPMP respondents are located closer to their primary referral laboratory and these sites had fewer problems with send-out tests than the higher complexity laboratories. Table 5 shows a comparison of the results of these studies.

Table 5 - Utilization of referral laboratories

	Waived/PPMP labs	Moderate/high labs	Moderate/high labs
Date of study	2/01	6/00	3/96
Number of respondents	191	257	216
Average number of reference labs used	1.8	2.2 *	
<u>Type of referral lab used:</u> Independent Hospital Clinic Hospital-based independent	53% 28% 10% <1%	53% * 29% 5% 10%	
<u>Distance from referral lab:</u> < 10 miles 11 to 25 miles 26 to 50 miles 51 to 100 miles > 100 miles	61% 14% 9% 6% 9%	47% * 14% 9% 9% 21%	46% * 20% 10% 8% 14%
Top factors in choosing a reference lab	Reputation Turnaround times Courier services Proximity Onsite printer		Turnaround times * Reputation Cost of tests Courier services Problem resolution
Changed referral lab in previous 2 years	10%	14%	
Listed problematic tests	38%	86%	
Problems most frequently encountered	Turnaround times Compromised specimens Incorrect tests performed Courier services	Turnaround times Compromised specimens Ordering information Incorrect tests performed	
* Results are for respondents categorized as POLs, which included: physician offices, clinics, community health centers, rural health centers, health departments, student health centers and health maintenance organizations (HMOs).			