Washington State Department of Health

# ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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# Electronic Reporting of Laboratory Results for Notifiable Conditions

by Department of Health Laboratory Reporting Business Team

Electronic reporting of laboratory test results for notifiable conditions is increasing in Washington State. Reporting of notifiable conditions to the Washington State Department of Health allows programs to improve the health of Washington State residents by investigating and containing disease outbreaks, and by using data to inform public health intervention strategies. High-quality lab reporting has had a dramatic effect on human health in Washington State, as was seen recently during the April to August salmonella outbreak investigation that led to the recall of more than 500,000 pounds of infected pork products.

To improve human health, the department has created a workgroup to manage and improve lab reporting in Washington State. This workgroup, the Laboratory Reporting Business Team (LRBT), gives the public health programs that work directly with communities the opportunity to team up with IT staff members and other partners to improve the quality of data received from labs and hospitals. Working together, this group aims to create a process to resolve lab reporting issues, as well as allow programs to communicate their needs for complete and timely lab reporting.

**Why is electronic reporting better for hospitals and laboratories?** One electronic report is adequate to meet most reporting requirements for both local and state public health, and may be integrated into the Lab Information Management System (LIMS), although a phone call is still required for conditions notifiable within 24 hours. Two paperless methods are available for reporting notifiable laboratory results to public health; by Health Level Seven (HL7) messaging, or by a Web Submitter application (an easily implemented solution for low volume reporters). Lab reports submitted to the department through either method are made available to local health jurisdictions, thereby replacing the need for manual paper reporting. Seventeen labs take advantage of this streamlined reporting option, with several others at various stages of developing their capability to submit electronic reports.

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## Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the LQA website.

Acute Diarrhea
Anemia
ANA
Bioterrorism Event Mgmt
Bleeding Disorders
Chlamydia
Diabetes
Group A Strep Pharyngitis
Group B Streptococcus
Hepatitis
HIV
Infectious Diarrhea
Intestinal Parasites
Lipid Screening
PAP Smear Referral
Point-of-Care Testing
PSA
Rash Illness
Red Cell Transfusion
Renal Disease
STD
Thyroid
Tuberculosis
Urinalysis
Wellness

# Records Needed For Your MTS Inspection

by Linda Parisi, Department of Health/LQA

When preparing for your medical test site initial or regular inspection, you should remember that any documentation from the past two years is subject to review. The laboratory surveyor will typically ask to see the laboratory and testing area. Then, the surveyor will ask if any new tests or personnel were added in the past two years. New tests should not be an issue because the laboratory is required to submit to the Department of Health-Laboratory Quality Assurance Program a "Change of Test Menu" form whenever tests are added or deleted. The following general documents should be available for review by the surveyor:

**Technical Procedures**

- Quality Control Policies
- Quality Assurance Plan
- Delegation of Authority (if appropriate)
- Individual Quality Control Plans (IQCP) if applicable
- Safety Policies
- Evidence of Personnel Qualifications, Training, and Experience
- Evidence of Competency Assessment (using the six modes of competency assessment)

**For the past two years, the following documents should be available:**

- Patient test orders or requisitions
- Accession logs
- Test results logs or worksheets
- Instrument printouts or tapes
- Records of quality control, calibration, calibration verification (if applicable), equipment function checks, maintenance activities, temperature checks, humidity monitoring, etc.
- Documentation of quality assurance activities, problem resolution, corrective actions (when applicable)
- Proficiency testing results and all pertinent documentation for proficiency testing such as signed attestation statements, instrument printouts, final reports, etc.
- Patient test reports or charted results

During the survey, the surveyor will point out any concerns or deficiencies as they are found and give the staff or management an opportunity to clarify any misunderstandings or provide records as required. If records are not available or incomplete, the laboratory will be cited for record retention.

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# Ungraded Proficiency Testing Results

by Linda Parisi, Department of Health/LQA

Your proficiency testing (PT) provider occasionally will not be able to grade a PT result. The reasons may range from not being able to analyze a sample because of the instrument was not in use, specimen problems, educational samples, lack of participants or referee consensus, etc. Even though the PT company did not grade the results that does not exclude the laboratory from evaluating the results. In most cases, the proficiency testing provider will provide a summary of test results usually on its website, so the laboratory can perform a self-evaluation. Document the self-evaluation by comparing the laboratory-reported results with the statistics the PT company provides. If the result does not meet the acceptable range or majority of all users, the laboratory may need to perform an investigation and document corrective action. Remember that ungraded proficiency testing results do not equal unevaluated proficiency test results. You must evaluate them if the statistics are provided.

# Proficiency Test Result Scored 80 Percent - Now What?

by Linda Parisi, Department of Health/LQA

Although 80 percent is considered passing in all specialties except for some of the blood bank tests, there should be some sort of evaluation of the test that failed to meet acceptable limits. Keep in mind that you would not accept one out of five patients' samples to be reported incorrectly; therefore, you should not accept one out of five proficiency test results.

**What shall I do?** These are some of the areas you can investigate.

**Review the documentation** on the day of testing and check the quality control results for that test.

**Were the quality control results acceptable?** If so, look at calibration.

**Is the calibration current?** If so, look at peer review quality control results.

**Are the peer review quality control results acceptable?** If so, look at the maintenance records.

**Has maintenance on the instrument been performed regularly?** If so, look at the storage requirements for the proficiency testing samples and reagents. If these are acceptable, you can look at the testing personnel.

**Are the testing personnel competent to perform this test and are they following the PT company's procedure for performance?**

**Clerical Errors:** Remember that many times the failure is because of a clerical error, so check that and figure out a way to avoid this type of error.

The laboratory manager can most likely define more items to be verified before a conclusion can be determined. Record all of this investigation and document any corrective action as appropriate. Be sure that the laboratory director is aware of any proficiency test failures as the laboratory director is ultimately responsible for all patient testing.

# Electronic Reporting of Lab Tests, cont'd from page 1

LRBT membership voted unanimously to forward a recommendation to the Washington State Board of Health to consider a mandate for electronic reporting of conditions notifiable under WAC (Washington Administrative Code 246-101). While a long lead time is necessary before global electronic reporting would be realized, epidemiologists look forward to improvements in reporting speed, accuracy of lab reports, and therefore faster outbreak investigation and containment.

For more information and a list of labs reporting electronically, please see our **ELR Status webpage**. More information will be made available in the coming months.

# 23rd Annual Clinical Laboratory Conference

**What?**
The 23rd Annual Clinical Laboratory Conference

**When?**
Monday, November 14, 2016

**Where?**
Foster Links Golf Course
Tukwila, WA

**Plan to attend.**
**Mark your calendars now!!!**

## Calendar of Events

**Training Classes:**

**2016 ASCLS-WA Spring Meeting**
April 14-16 Renton

**2016 Northwest Medical Laboratory Symposium**
October 12-15 Portland

23rd Annual Clinical Laboratory Conference
November 14, 2016 Tukwila

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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