

# ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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## Proficiency Testing for 2012

Proficiency testing (PT), required under Medical Test Site rules WAC-246-338-050, is a source of external quality control. Although labs perform daily internal quality control with their test systems, external quality control provides important interlaboratory comparisons to determine the accuracy and reliability of your testing procedures.

It is time to enroll in PT for 2012. Page four contains a list of the currently approved PT agencies. Call the programs for a free copy of their 2012 PT brochure or visit their websites. Your current PT provider will automatically send you a PT order form and catalog for 2012. Early enrollment guarantees that you will receive samples for the first testing event that occurs between January-March 2012.

- Shop around for prices and test groups.
- In order to cover all tests performed in your laboratory, it may be necessary to enroll in PT with more than one company.

**Urine Culture Growth /No-Growth Reminder:** Does your laboratory perform urine cultures for growth/no-growth only and/or colony count only? If so, participation in a five-sample proficiency testing program applies to you.

**Failure to participate in PT** results in a score of 0% for each analyte. This is a failure, and may jeopardize your ability to continue testing patient specimens.

**Information needed to enroll:** Complete the 2011 Order Form in the PT brochure with the following information:

- Name (use the name exactly as it appears on your MTS license)

- Address
- CLIA ID # (primary means of identifying your lab)
- MTS license number (see your MTS license)
- Select the appropriate program for your lab (you may have to enroll in several modules and/or companies to cover all analytes)

**NOTE:** Authorize the PT agency to send copies of your results to the Washington State Department of Health Office of Laboratory Quality Assurance. Do this for each analyte!

### Regulated analytes:

- Five sample modules shipped three times per year are required for all regulated analytes.
- Visit the LQA website ([www.doh.wa.gov/lqa.htm](http://www.doh.wa.gov/lqa.htm)) for a listing of the regulated analytes.
- PT participation is required for all non-waived tests for Influenza A and B, and Direct Strep Antigen.
- Some manufacturers of waived test kits include in-

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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 following website:  
[www.doh.wa.gov/lqa.htm](http://www.doh.wa.gov/lqa.htm)

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

# Proficiency Testing for 2012, continued from page 1

structions for moderate complexity testing in the same package insert. This allows the laboratory to choose whether they want to perform the test as a waived test following the waived test requirements or as a moderate complexity test following these requirements. If the laboratory chooses to perform the test as a moderate complexity test, it must participate in a five-sample PT program three times per year.

**Non-regulated analytes:** Test all non-waived tests (other than the regulated analytes) using one or a combination of the following:

- A two-sample PT program from one of the proficiency testing providers, or
- Blind samples with known values, or
- Split samples with another lab, or
- Split samples with another instrument or method, or
- Two analysts perform microscopic tests and compare results, or
- Kodachromes of microscopic tests, or
- Correlate patient results with clinical history.

**Adding tests during the year:**

- Notify our office within 30 days.
- Enroll in PT for regulated analytes before you start testing patient samples.

**Deleting tests during the year:**

- Notify our office within 30 days.

**Temporarily discontinuing tests during the year:**

Notify our office if you temporarily discontinue a test.

- Use the appropriate action code from your PT provider if you temporarily discontinue a test at the time of a PT challenge.
- When you reinstate the test, notify our office.

**LQA website:** The LQA website contains additional information regarding proficiency testing, applications, licensing, practice guidelines, surveys and checklists, medical test site rules and much more. The website address is <http://www.doh.wa.gov/lqa.htm>.

If you have other questions regarding proficiency testing, contact Leonard Kargacin at (253) 395-6747.

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Secretary, DOH: Mary Selecky  
Health Officer: Maxine Hayes, MD, MPH  
Director, PHL: Romesh Gautam, PhD  
Program Manager, LQA: Susan Walker  
Editor: Leonard Kargacin (253) 395-6747  
Circulation: Leonard Kargacin (253) 395-6747

Comments, letters to the editor, information for publication, and requests for subscription can be directed to:

*ELABORATIONS*  
Laboratory Quality Assurance  
20435 72nd Ave S Ste 200  
Kent, WA 98032

e-mail address: [leonard.kargacin@doh.wa.gov](mailto:leonard.kargacin@doh.wa.gov)

NOTE: Letters to the editor may be published unless specified otherwise by the author.

**Website addresses:**

**DOH home page:** <http://www.doh.wa.gov>  
**LQA home page:** <http://www.doh.wa.gov/lqa.htm>  
**PHL home page:**  
<http://www.doh.wa.gov/EHSPHL/PHL/default.htm>

## TIPS for Proficiency Testing Success

Improve your chances for successful participation in PT by considering the following suggestions:

- ✓ **Release Results:** Notify the PT provider to send copies of PT results for each analyte to the Office of Laboratory Quality Assurance.
- ✓ **Handle PT samples like patient samples, but DO NOT** refer them to your reference laboratory for further study. Do not run them multiple times.
- ✓ **Retain all raw data:** Save data showing the workup of PT samples, instrument printouts, worksheets, and log sheets.
- ✓ **Make sure all testing personnel perform PT during the year:** Share or rotate the samples among all staff who perform the test.
- ✓ **Be timely:** Always be sure to meet the deadline for returning your results.
- ✓ **Review your graded results:** Review your graded PT results with your lab director. Document corrective action for scores below 80%. Evaluate ungraded results.

# CDC Free Online Waived Testing Training Course

The Centers for Disease Control and Prevention (CDC), Division of Laboratory Science and Standards (DLSS), is now offering a free online laboratory testing training module. The module is entitled **“READY? SET? TEST! Patient Testing is Important. Get the right results.”** To take this training module visit <http://wwwn.cdc.gov/dls/waivedtests/>.

The CDC DLSS developed this training to supplement other free educational materials already available from CDC to promote good laboratory practices and ensure the quality of patient testing, especially in physician office laboratories and other sites that perform testing waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It includes practice exercises, job aids, and real-life testing scenarios to reinforce the learning process. After completing the module, participants may print out a Certificate of Completion and obtain continuing education credits offered to physicians, nurses, pharmacists, laboratory professionals, and others.

## **Background**

CLIA regulates all facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease. Waived tests include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria. Although CLIA requires that waived tests must be simple and have a low risk for erroneous results, this does not mean that waived tests are completely error-proof. Errors can occur anywhere in the testing process, particularly when the manufacturer’s instructions are not followed and when testing personnel are not familiar with all aspects of the test system.

**Some waived tests have potential for serious health impacts if performed incorrectly.** For example, results from waived tests can be used to adjust medication dosages, such as prothrombin time testing in patients undergoing anticoagulant therapy and glucose monitoring in diabetics. In addition, erroneous results from diagnostic tests, such as those for human immunodeficiency virus (HIV) antibody, can have unintended consequences. To decrease the risk of erroneous results, the test needs to be performed correctly, by trained personnel, and in an environment where good laboratory practices are followed.

## **Additional Resource**

In 2005, the CDC DLSS published the Morbidity and Mortality Weekly Report (MMWR) Recommendations and Reports on “Good Laboratory Practices for Waived Testing Sites.” Physicians, nurses, and others who performed waived tests in sites holding a MTS/CLIA Certificate of Waiver license, can use these recommendations as a resource. The DLSS published the recommendations to promote quality testing, reduce testing errors, and enhance patient safety.

We encourage you to share this information broadly with colleagues who are concerned with promoting good laboratory practices, especially in waived testing sites. In addition, if possible, we would appreciate your organization or facility’s inclusion of an electronic link to the training and other educational materials at the following CDC website location: <http://wwwn.cdc.gov/dls/waivedtests/>

## Approved PT Providers

- Accutest** (800) 356-6788  
<http://www.digitalpt.com>
- Amer. Acad. of Family Physicians** (800) 274-7911  
<http://www.aafp.org/pt.xml>
- Amer. Assoc. of Bioanalysts** (800) 234-5315  
<http://www.aab.org/>
- American Proficiency Institute** (800) 333-0958  
<http://www.api-pt.com/>
- ASIM Medical Lab Evaluation** (800) 338-2746  
<http://www.acponline.org/mle/>
- California Thoracic Society** (714) 730-1944  
<http://www.thoracic.org/sections/chapters/ca/pt-program.html>
- College of American Pathologists/EXCEL**  
(800) 323-4040  
<http://www.cap.org/apps/cap.portal>
- WSLH** (800) 462-5261  
<http://www.slh.wisc.edu/pt/>

For answers to your PT questions, go to the LQA website at [www.doh.wa.gov/lqa.htm](http://www.doh.wa.gov/lqa.htm) or call Leonard Kargacin at (253) 395-6747.

## Calendar of Events

### Training Classes:

#### 2012 ASCLS-WA Spring Meeting

April 26-28                      Kennewick

#### Northwest Medical Laboratory Symposium

October 2012                      Portland

#### 19th Annual Clinical Laboratory Conference

November 2012                      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.

For persons with disabilities, this document is available upon request in other formats. To submit a request, please call 1-800-525-0127 (TTY/TDD 1-800-833-6388).



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