

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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14th Annual Clinical Laboratory Conference

by Leonard Kargacin, DOH LQA

The 14th Annual Clinical Laboratory Conference will be held on November 12, 2007 at the Doubletree Hotel near SeaTac International Airport. This is an excellent opportunity to hear about the current status of health care from a variety of experts.

Dennis Weissman, President of Dennis Weissman & Associates, LLC in Washington, D.C., will present the keynote address for the conference titled **“Reimbursement & Regulatory Update For Labs & Pathologists: Telling It Like It Really Is!”** The speaker will present late-breaking legislative and regulatory developments affecting laboratory and pathology interests including: the Medicare competitive bidding demonstration project for clinical laboratory services, how Medicare payment rates for laboratories and pathologists will be modified in 2008, and an analysis of how changes in the Stark self-referral regulations will impact current business arrangements.

“Despite Success, Health Workforce Shortages Continue and Will Worsen.” In this portion of the program, Troy Hutson, RN, JD, Director of the Health Work Force Institute, will focus on results of the recent hospital and health center workforce surveys, describe successes in expanding education capacity, and discuss why this is insufficient to meet future demand. He will discuss the need to innovate the delivery of both health care education and practice to improve quality and efficiency in order to better meet current and future demand for services. Examples will include Lean, Work Based Learning, and Health Career Academies. Information and examples presented will highlight clinical laboratories.

Mary Lampe, PhD, Director of the University of Washington CLS/MT Program, will present information from all of the Washington laboratory training programs including: current enrollment, capacity, clinical site concerns, where graduates are employed, and what some employers are doing to insure they have adequate staff.

“We Lost Waste with Lean – So What’s Happening Now??” Lee Darrow, Laboratory Administrative Director at Virginia Mason Medical Center in Seattle; Anna Franklin, Quality Assurance Manager at Pathology Associates Medical Laboratories in Spokane; and Joanne Simpson, Laboratory Director at Children’s Hospital and Regional Medical Center in Seattle, will present an update to their talk presented at the 2005 Laboratory Conference. These presentations describe the successes, failures, and knowledge gained from applying Lean practices in three laboratory settings, and discuss the next level of Lean.

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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

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

Tips for Quality Waived Test Performance

by Kathy LaBeau, DOH/LQA

This article continues a series of tips for performing quality waived testing in your laboratory.

Waived tests are generally easy to perform, but problems can occur if you do not perform the test properly, read the manufacturer's package insert, or follow good laboratory practices when testing patient samples. These tips are designed to assist you in providing quality test results for your patients.

In the last two issues of Elaborations, we discussed good laboratory practices when performing waived tests and things to consider when you plan to add new waived tests. Here are more tips.

Getting Prepared to Perform Waived Testing

- Clean the work surface and remove any clutter or trash.
- Assure you have adequate lighting.
- Check and record the temperature of the testing environment and refrigerator where kits, reagents, and controls are stored.
- Check the product insert to assure it is current and there are no changes by the manufacturer.

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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>

- Check the expiration date on the kit and reagents – do not use expired kits or reagents.
- Check the lot number to assure it has been checked out with external controls – do not interchange reagents from different products or lot numbers.
- Visually inspect reagents and vials for damage, discoloration, or contamination.
- Prepare reagents according to instructions – if new, write the date opened on vial or kit.
- Conduct calibration or self-checks, if applicable, prior to testing patient samples.
- Allow refrigerated reagents and patient samples to reach room temperature before testing if specified in the instructions.

Quality Control and Waived Tests: Quality control testing is designed to detect problems that may arise due to operator error, reagent or test kit deterioration, instrument malfunction, or improper environmental conditions. Three types of controls that may be used with waived test systems:

External controls are reference solutions or materials that are added to the test device like patient samples. These may be included with the test kit or may have to be purchased separately.

Internal, built-in, procedural controls are built in to the test reagent device of most qualitative tests to ensure reagents are active, reagents and samples are added correctly, and the test performs according to specifications. They usually appear as a colored dot, line or bar in a control region of the device, and/or as an expected appearance of the device background.

Electronic controls are inert, reusable devices (test strips, cartridges, cassettes) that check instrument performance specifications for some quantitative tests.

Follow the manufacturer's instructions for testing controls. At a minimum you should:

- Test external controls with each new lot of kits, reagents, or testing devices to detect problems during manufacturing or shipment,
- Observe internal controls with each patient test (to assure proper test performance and reagent integrity), and

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Quality Waived Test Performance, continued from page 2

- Test electronic controls, if applicable, at the frequency recommended by the manufacturer.

Assure that the results of external, internal, and electronic controls give the expected results, or do not report patient results. Consult with your director and the manufacturer to resolve any problems before resuming patient testing.

Some test systems have two versions of quality control requirements: one if you are to use it as a waived device; another if you are to use it as a moderate-complexity device. The quality control requirements are usually more stringent when using it as a waived device (e.g., test external controls with each new lot *and each new operator*) since there will be no routine oversight activities (inspection or proficiency testing monitoring) by regulatory agencies. You are required to follow the manufacturer's instructions for performing waived tests, so be sure that you follow the quality control protocol outlined for use as a waived test if there are two sets of instructions.

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Using examples and reflections on the pro's and con's of how Lean processes have impacted their laboratory's operations, the presenters will share their knowledge with those who may be considering implementing Lean, or who are in the early stages of Lean implementation in their institutions.

“Washington Industrial Safety & Health Act (WISHA): Responsibilities & Enforcement” John Furman, MN, is an Occupational Nurse Consultant with the Washington State Department of Labor & Industries, Division of Occupational Safety and Health. He will present an overview of the Washington Industrial Safety & Health Act, RCW 49.17, and Washington's relationship to OSHA. Specific regulatory application to clinical laboratories will be discussed along with compliance strategies and enforcement tools.

WHO SHOULD ATTEND?

Laboratory Directors
Laboratory / Office Managers
Department Supervisors
Bench Personnel
Billing Personnel
Compliance Officer

The conference offers something pertinent for everyone whether you work in a physician office laboratory, an independent laboratory, or a small or large hospital.

LOCATION

The conference will be held at the Doubletree Hotel near SeaTac International Airport. There is easy access from Interstate 5 and the airport. Conference programs and registration information will be mailed in mid-September. If you do not receive your conference registration flyer or have questions, contact information is found on page 2. The registration fee will be \$95.00 per person and will include a continental breakfast, breaks and lunch.

MAKE YOUR PLANS TO ATTEND TODAY!!

Tips for Quality Waived Test Performance

This issue of Elaborations contains the final installment in the series of tips for performing quality waived tests in your laboratory. The article on pages 2 and 3 contains information on quality control and things to consider in the work area where waived testing will be performed.

Refer to the July and August editions of the *Elaborations* newsletter on the following website: <http://www.doh.wa.gov/lqa.htm>

Calendar of Events

PHL Training Classes:
(<http://www.doh.wa.gov/ehspl/phl/training/train.htm>)

Basic Course in Urine Sediments
October 10 OR 11 Shoreline

Northwest Medical Laboratory Symposium
October 24-27 Seattle

14th Annual Clinical Laboratory Conference
November 12 Seattle

2008 WSSCLS/NWSSAMT Spring Meeting
April 24-26, 2008 Lynnwood

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.