

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume XII Issue 3

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News You Can Use!

by Leonard Kargacin, DOH/LQA

The following information contains late-breaking news that may affect several of the laboratories operating in Washington State. Website information is provided for those who wish to obtain detailed information about the various topics.

Hospital Regulations – Confirmation of Verbal Orders:

The new hospital Conditions of Participation (COPs) (42 CFR 482) have a requirement that verbal orders must be authenticated within 48 hours. As you recall, CLIA requires 30 days for the laboratory to obtain written authorization. In cases where a laboratory is in a facility that is subject to the hospital COPs, the laboratory must meet the more stringent requirement. Information about this update can be found at the Centers for Medicare & Medicaid Services (CMS) at <http://www.cms.hhs.gov/home/regsguidance.asp>. The CMS memorandum to State Survey Agency Directors dated January 26, 2007 (revised February 23, 2007) can be found at <http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter07-13.pdf>.

Multivariate Index Assays: The Food & Drug Administration (FDA) issued draft guidance on September 7, 2006 titled "In Vitro Diagnostic Multivariate Index Assays" (IVDMIA). These tests use laboratory data and an algorithm (analytic tool) to generate a result for the purpose of diagnosing, treating, or preventing disease. Examples of IVDMIA tests include those used to diagnose and guide treatment decisions for breast cancer, prostate cancer recurrence, cardiovascular disease, and Alzheimer's disease. The draft guidance document can be reviewed at

the following website: <http://www.fda.gov/cdrh/oivd/guidance/1610.pdf>

"Pod" or "Condo" Laboratories: The *G-2 Compliance Report for Hospitals, Laboratories, and Physician Practices* is published by G-2 Reports. The April 2007 issue contains an in-depth analysis of "pod" or "condo" laboratories in an article called "What's Next With Pod Laboratories?" Access the following website for further information: <http://www.g2reports.com>.

Lab-Developed Tests (LDTs) or Home-Brew Tests: The March 26, 2007 issue of the *National Intelligence Report*, published by G-2 Reports, contains an article on the expansion of the FDA regulation of LDTs or home-brew tests. Despite opposition from laboratory and professional groups, a bill to "fast track" the increased regulation of LDTs by the FDA has been introduced by Senator Edward Kennedy. The article can be viewed on the following website under the "Breaking News" tab: <http://www.g2reports.com>.

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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

Laboratory Quality Assurance Website

by Leonard Kargacin, DOH/LQA

The Office of Laboratory Quality Assurance (LQA) has many resources available through its website. All of the materials listed in this article can be accessed by going to the LQA website at <http://www.doh.wa.gov/lqa.htm> and scrolling down the listing on the left hand side of the screen to **Links and Extras**.

Supplemental Material (Select the sidebar "Supplemental Material"):

Educational materials:

- Biannual Verification of Accuracy Suggestions
- Calibration & Calibration Verification Compliance Guide
- Good Laboratory Practices with Waived Test Systems
- Instrument Validation Requirements
- Medical Test Site Survey Checklist (All Specialties)
- Pre-Inspection Self-Assessment Checklists
 - Aerobic Cultures
 - Chemistry Testing – Moderate Complexity Only
 - Dermatology Testing
 - Gram Stains
 - Hematology Testing – Moderate Complexity Only
 - Microscopic Examinations
 - Moderate Complexity Testing Kits
 - Proficiency Testing or Biannual Verification of Accuracy

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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 (206) 418-5416
Circulation: Leonard Kargacin (206) 418-5416

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

ELABORATIONS
Washington State Public Health Labs
1610 NE 150th Street
Shoreline, WA 98155

e-mail address: 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>

Quality Assurance Plan Development

Forms (Select the sidebar "Supplemental Material"): Forms to notify LQA of changes in personnel and test menus are found under the "Forms" portion of this tab.

Newsletters: (Select the sidebar "Newsletters"): Copies of the Elaborations newsletter from the past three years can be found here.

Practice Guidelines (Select the sidebar "Practice Guidelines"): Copies of all practice guidelines developed by the Clinical Laboratory Advisory Council are located here.

Updates (Select the sidebar "Updates"): This tab will contain any updated information about the Medical Test Site (MTS) licensing program. Currently, the following information can be found here:

- Calibration & Calibration Verification Compliance Guide
- Laboratory Conference Program Flyer
- Revised Medical Test Site Rules
- Who Can Order and Interpret Laboratory Tests
- MTS License Renewal Instructions

Other Links (Select the side-bar "Other Links"): Links to the following are included under this tab:

- Continuing education opportunities
- Laboratory professional organizations
- Laboratory personnel certification
- Laboratory accrediting agencies
- Laboratory training programs
- Proficiency testing companies
- Miscellaneous Links
 - Centers for Disease Control and Prevention (CDC)
 - Centers for Medicare and Medicaid Services (CMS)
 - Clinical and Laboratory Standards Institute (CLSI)
 - Clinical Laboratory Improvement Amendments (CLIA)
 - Clinical Laboratory Initiative
 - Department of Labor & Industries - Safety Information
 - Food and Drug Administration (FDA)
 - Laboratory Model Compliance Plan
 - Hospital Model Compliance Plan
 - NCCLS - see CLSI
 - Office of the Inspector General
 - Washington State Public Health Laboratories

Parasite Identification Tips

by Laura Kentala, DOH PHL Training Program

Parasitology is one of the most unique areas in the field of microbiology. Many laboratories have dropped parasite testing all together because it is costly and takes a well-trained eye to pick them out of the preparations. For the most part, we parasitologists sit at a microscope with our reference books for company and look at stools all day. Hunting for parasites does not have a lot of glamour but we can always find excitement in every slide.

Over the years I have noticed a few common traits in almost all of my students. I have found that students have a tendency to under identify at first and then, as time passes, they see parasites everywhere. With time and practice, they finally expand their skill and train their eyes and brain to a level where they find only the true parasites in a specimen. It doesn't take a long time for this to occur but it does take a lot of reading wet mounts and Trichrome slides for the skill to be developed.

Missing a parasite in a stool specimen may not be life threatening, but it can affect a patient's health especially if they are immunocompromised. Here are some helpful hints for the parasitologist when training a bench microbiologist in the art of reading parasites preparations.

Reading a wet mount is not a rapid method: The slide must be read in a serpentine fashion that will cover the entire 22 X 40 mm coverslip first on 10x and then again on 40x power. There are no shortcuts. If you skip reading on the 10x power, there is a good chance that helminth eggs will be missed. Many species of worms do not produce large numbers of eggs, and one or two eggs on a slide can easily be missed if you only read on the higher power. Even if your laboratory seldom, if ever, finds eggs, it is necessary to read the slides on both powers. *Ascaris*, hookworms, *Strongyloides*, and *Enterobius* are found throughout the world, not just in strange and distant lands. Remember that since people now often travel to strange and distant lands, you have a good chance of identifying such parasites in your laboratory.

Mix the specimen very well: The different parasites tend to layer in the sediment. Remember that you only need a small amount of sediment at the end of processing. To make sure that you end with a small amount of sediment, you need to begin with only about 1 teaspoon of stool. The more stool used at the beginning of the process, the greater chance that the ethyl acetate will be overwhelmed and not all of the debris will be removed. The more debris in the sediment, the greater chance of missing the low number of parasites.

Have your resource material close at hand: Even though reference books are costly, you really need to have the materials right at the bench to make a proper identification. The Centers for Disease Control and Prevention (CDC) book *Morphology of Diagnostic Stages of Intestinal Parasites of Humans* is still the best book for the price. The book is free on cd-rom. Visit the CDC website at <http://www.dpd.cdc.gov/dpdx/HTML/Contactus.htm>. A good tip is to print the eight pages of drawings. Carefully write in the sizes of all the organisms and place the pages in plastic covers or have them laminated. Keep these pages next to the parasite microscope along with your conversion chart for the ocular micrometer. The next best reference book is the *Atlas of Human Parasitology, 4th edition* by Ash & Orihel. The color pages show the organisms in more than one type of stain and include pictures showing the internal structure you need to see to positively identify the parasite. There are also sections that give photographs of the rarely seen parasites and a section of artifacts that can easily be mistaken for parasites. In my opinion it is a "must have" for every laboratory that even thinks of doing parasites. You never know when something unusual is going to walk into your laboratory.

Be prepared for just about anything: Recently a most interesting case came into the Washington State Public Health Laboratories (WA PHL) parasite laboratory. A county health worker called to say that they had a case of *Trichinella sp.* in a hunter. Our first thought was that it must be from bear meat, but it turned out to be from an unexpected source. The hunter says that he was in the forest hunting deer when he awoke to see a cougar stalking him. He promptly shot it and then fixed himself raw cougar on a cracker. Within a few weeks, he started to experience typical symptoms of Trichinellosis infection. A serum test confirmed the diagnosis and he was prescribed medicines. The cougar meat was sent to the WA PHL to be processed for the worm. *Trichinella sp.* is rare in Washington and we had never seen a positive specimen before. We were fortunate that reference material was available to aid in our identification.

It is very easy to keep a parasitologist content. All we need is a good microscope, a very comfortable chair, excellent reference materials, and we can be happy for a long time. It is important to get good training when first beginning to read parasites. Whenever possible take a refresher course every few years. The National Laboratory Training Network (NLTN) and WA PHL Training Program both offer a variety of parasitology courses every year. Remember to keep your skills up-to-date by building a good reference library of positive specimens, read numerous slides, and make sure to measure, measure and then re-measure everything you see.

This article was previously published in the February 2007 edition of the NLTN Newsletter.

PHL Training Course List and Registration Form

The PHL Training Program offers a variety of training courses during the year for laboratorians. A list of the courses offered for the remainder of 2007 are listed below. Refer to the PHL Training Program website at <http://www.doh.wa.gov/ehsphl/phl/training/train.htm> for a complete description of the courses listed.

Class List Preference (check as many as applicable):

- Basic Course in Urine Sediments, May 9 OR 10, 2007** (\$115 before 5/02/07 & \$125 after 5/02/07)
- Parasitology Part III: Trichromes, May 24 & 25, 2007** (\$220 before 5/17/07 & \$240 after 5/17/07)
- Packaging & Shipping of Infectious Substances (in Mt. Vernon), June 29, 2007**
(\$95 before 6/22/07 & \$105 after 6/22/07)
- Parasitology Part IV: Blood Parasites, July 10 & 11, 2007** (\$220 before 7/02/07 & \$240 after 7/02/07)
- Basic Microscopy, August 8 OR 9, 2007** (\$95 before 8/01/07 & \$105 after 8/01/07)
- Venipuncture, September 10, 2007** (Register through the University of Washington)
- Basic Blood Cell Morphology, September 13, 2007** (\$115 before 9/06/07 & 125 after 9/06/07)
- Basic Course in Urine Sediments, October 10 OR 11, 2007** (\$115 before 10/03/07 & \$125 after 10/03/07)
- Packaging & Shipping of Infectious Substances (Eastern WA location to be determined), October 25, 2007**
(\$95 before 10/18/07 & \$105 after 10/18/07)
- Packaging & Shipping of Infectious Substances, November 29, 2007** (\$95 before 11/22/07 & \$105 after 11/22/07)
- Gram Stain Techniques, December 12, 2007** (\$115 before 12/05/07 & \$125 after 12/05/07)

Course Registration Form:

Name: _____

Employer: _____

Employer Address: _____

City: _____ State: _____ Zip: _____

Work Phone: _____ FAX: _____

E-mail: _____ Message Phone: _____

Complete the registration form and mail to :
Department of Health, PHL Training Program
1610 NE 150th Street
PO Box 550501
Shoreline, WA 98155-9701

Complete the registration and fax or e-mail to:
Fax to: (206) 418-5445
E-mail to: phl.training@doh.wa.gov

A registration form is also available on our website at: <http://www.doh.wa.gov/ehsphl/phl/training/train.htm>. A confirmation packet containing payment instructions and a map to the course location will be mailed to you. Please **do not** send money with your registration form.

Medical Test Site (MTS) License Renewal

Current Medical Test Site (MTS) licenses expire on June 30, 2007. License renewal application packets were mailed out in mid-March. If you have not received a renewal packet, contact the LQA office at (206) 418-5600.

Didn't I just renew my MTS license in 2006? Yes. MTS licenses were renewed last fall for an eight-month period. The eight-month license renewal was done to comply with the Washington State Department of Health (DOH) request that the Office of Laboratory Quality Assurance (LQA) change the MTS licensing cycle to correspond with the Washington State biennial budget.

Didn't I pay the full two-year fee when I renewed my MTS license last fall even though I only received an eight-month license? No. The 2006 MTS license renewal fees were prorated for the eight-month period.

What does this mean for MTS license renewal this year? Your MTS license will be renewed for the two-year period from July 1, 2007, through June 30, 2009. Your two-year license fee will be assessed based upon the category of your MTS license.

Will you collect the same information this year as you have in the past? The information included on the MTS renewal application is largely the same; however, there is some additional information needed this year such as the facility Unified Business Identifier (UBI), and Washington State professional license numbers, if applicable, for the key personnel.

What is a UBI? The UBI is the Unified Business Identifier that your facility received from the Washington State Department of Revenue when you opened your business. It is a 9-digit number generally beginning with the number 6.

Why is this additional information necessary? The MTS program is part of the Health Services Quality Assurance (HSQA) division of the DOH. HSQA is in the process of upgrading to a new comprehensive licensing computer system that will integrate the facility licensing and the professional licensing functions. The new information requested on the MTS renewal application will link the professional and facility licensing information.

MTS License Renewal Process: The renewal process is different this year depending upon the type of license a facility holds. See the explanation below for your category of license.

Certificate of Waiver/Provider Performed Microscopic Procedures (PPMP): You received a full MTS license renewal application packet. Follow the printed instructions and return the updated application by **April 16, 2007**. LQA will review and process your application and send you a fee letter for the applicable two-year license fee. **DO NOT SEND MONEY** with your renewal application.

It is essential that the information on the pre-printed renewal application be checked closely for accuracy. The information on the renewal form is entered into the MTS computer system and the Centers for Medicare & Medicaid Services (CMS) computer system. The information in the CMS database is accessed by government reimbursement agencies, such as Medicare and Medicaid, who use the information to reimburse medical claims to providers.

Accredited and MTS-Inspected: If your facility is inspected by a private accrediting agency or inspected by the LQA staff, **you only received a renewal fee letter.** The two-year license fee for the renewal of your current MTS license is for the period of July 1, 2007 through June 30, 2009. The fee was generated from the information that is currently in the MTS database. Fee letters will be mailed in mid-March. Return your payment to the Tumwater address at the bottom of the fee letter by **April 30, 2007**.

If you have not received your renewal information or have questions:

Call (206) 418-5600.

Visit our website at <http://www.doh.wa.gov/lqa.htm>.

Click on the "Updates" sidebar.

Scroll to "MTS License Renewal Instructions" and click on the applicable license category.

NOTE: If you have not received your license renewal packet, please contact the Office of Laboratory Quality Assurance at (206) 418-5600.

MTS Relicensing

Current MTS licenses will expire on June 30, 2007.

Relicensing applications were mailed in March. If you have not received your renewal information, contact the LQA Office at (206) 418-5600.

For more information about relicensing, see page 5 of this issue of Elaborations.

Calendar of Events

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

Basic Course in Urine Sediments
May 9 OR 10 Shoreline

Parasitology Training Course: Trichromes
May 24 & 25 Shoreline

Northwest Medical Laboratory Symposium
October 24-27 Seattle

14th Annual Clinical Laboratory Conference
November 12 Seattle

2008 WSSCLS/NWSSAMT Spring Meeting
April Seattle

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.