

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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24th Annual WA Clinical Lab Conference

The 24th annual WA Clinical Laboratory Conference will be held on November 13 at Foster Links Golf Course in Tukwila. This is an excellent opportunity to hear about the status of health care from a variety of experts.

Dennis Weissman, president of Dennis Weissman & Associates, LLC, in Washington, D.C., is the keynote speaker for the conference. He is presenting “**Hard Realities for Healthcare Policy in the Trump Era: What’s In Store for Labs in the Year Ahead?**” The Trump Administration and the Republican controlled Congress have sent a series of mixed policy signals to healthcare providers, including labs, during a first year of unified leadership in the nation’s capital: partisan battle to repeal, replace, or fix the Affordable Care Act; administrative actions related to ACA health exchanges; potential changes in the Medicaid program; budgetary standoff over health care priorities and programs; fraud and abuse enforcement; and efforts to reduce regulatory burdens on industry.

For the clinical laboratory and pathology sectors, 2017 has been marked by slow, uneven movement in several key policy and legislative areas. This presentation will examine the latest regulatory developments for the startup of a new Medicare market-based national lab fee schedule under PAMA, discuss the status of laboratory-developed test oversight by the FDA and Congress, and provide an update on the implementation of MACRA (Medicare Access and CHIP Reauthorization Act of 2015) and its effect on Medicare stakeholders. Finally, the speaker will frame the policy and practice climate that labs and pathologists can anticipate.

Inside This Issue

- 2 24th Annual Lab Conference, cont’d
- 2-3 Proficiency Testing for 2018
- 4 Approved Proficiency Testing Providers/Calendar of Events

John D. Thompson, PhD, MPA, MPH, is the Newborn Screening Office Director at the WA State Public Health Laboratories in Shoreline. He will present “**Saving Lives Through Newborn Screening: Making the Most of a Simple Blood Test.**” This presentation will cover the basics of newborn screening as a public health program, and will provide a series of case studies of the complexities of population-based screening for heritable disorders. The presentation will also include what is on the horizon as new technologies and treatments become available and an overview of how policy decisions are made about the newborn screening panel.

Geoffrey Baird, MD, PhD, is the Chairman of the UW Department of Laboratory Medicine. He will present “**Autopsy of a Unicorn: What We Can Learn from the Theranos Debacle.**” In this talk, Dr. Baird will describe the timeline of the story of Theranos, a Bay Area laboratory that was recently in the news for highly public qual-

continued on page 2

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	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	

24th Annual Clinical Lab Conference, cont'd from page 1

ity problems. The issues surrounding Theranos will be discussed in the framework of biomedical ethics.

Siu Kei “Jacky” Chow, PhD, D(ABMM), is the Technical Director of Infectious Diseases Diagnostics at MultiCare Health System in Tacoma. He will present “**The Latest in Microbiology – Magic or Madness?**” The clinical microbiology field is evolving at a rapid pace. Emerging technologies are influencing practices and improving patient care. The speaker will provide an overview of the latest technologies and practices for the clinical microbiology lab. Recent highlights from the literature that may affect laboratory function will be reviewed.

Scott Lindquist, MD, MPH, is the WA State Epidemiologist for Communicable Diseases and Deputy Health Officer. He will present “**Notifiable Conditions Update and the Current Status of Electronic Lab Reporting (ELR).**” Dr. Lindquist will present an update to the current notifiable conditions reporting requirements for labs. This will be an opportunity for labs to understand the current requirements and any changes proposed for rule making updates in 2018-19. In addition, an update on the current status of electronic lab reporting in Washington State will be provided. There will be representatives at the conference from the DOH ELR program as well as WA State Board of Health rule making staff who will allow time for questions and feedback.

Who Should Attend?

- Laboratory directors
- Laboratory and office managers
- Department supervisors
- Bench personnel
- Billing personnel
- Compliance officers

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

Location

The conference is held at the Foster Links Golf Course with easy access from Interstate 5 and the airport. See the [Laboratory Quality Assurance](#) website for information and a registration form for the 2017 conference or contact Leonard Kargacin at leonard.kargacin@doh.wa.gov. The \$95 per-person registration fee includes a continental breakfast, breaks and lunch. Make your plans to attend today. You still have time to register.

Tips for Proficiency Testing Success

Improve your chances for successful participation in PT:

- Release results: Notify the PT provider to send copies of PT results for each analyte to LQA.
- Handle PT samples like patient samples, but do not refer them to your reference/main lab 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.
- Attestation statement: Keep a copy of the form signed by the director and personnel who tested the samples.
- Make sure all testing personnel perform PT during the year.
- Be timely: Always be sure to meet the deadline for returning your results.
- Review your graded results: Review the graded PT results with your lab director. Document corrective action for scores below 80 percent. Evaluate ungraded results.

Note: Anything less than a score of 100 percent is considered a failure for some immunohematology (blood bank) tests. Document corrective action for scores below 100 percent.

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Website access:

- [Department of Health](#)
- [Laboratory Quality Assurance](#)
- [Public Health Laboratories](#)

Proficiency Testing for 2018

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 inter-laboratory comparisons to determine the accuracy and reliability of your testing procedures.

It is time to enroll in PT for 2018. Page four contains a list of the approved PT providers. Your PT provider has likely already sent you a PT order form and catalog for 2018. Early enrollment guarantees you will receive samples for the first testing event that occurs between January and March 2018.

- 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 percent for each analyte. This is a failure and may jeopardize your ability to continue testing patient specimens.

Information needed to enroll: Complete the 2018 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 number (primary means of identifying your lab)
- MTS license number (see your MTS license)
- Select the appropriate program (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.
- The [LOA website](#) has 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 instructions for moderate complexity testing in the same package insert. This allows the laboratory to choose whether it wants 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.

Discontinuing tests during the year:

- Notify our office within 30 days of discontinuing the tests.

Temporarily discontinuing tests during the year:

- Notify our office within 30 days 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.

The [LOA website](#) contains additional information regarding proficiency testing, applications, licensing, practice guidelines, surveys and checklists, MTS rules and much more. If you have other questions regarding proficiency testing, contact Veronica Bush at 253-395-6782.

Approved PT Providers

[Amer. Acad. of Family Physicians](#) (800) 274-7911

[Amer. Assoc. of Bioanalysts](#) (800) 234-5315

[American Proficiency Institute](#) (800) 333-0958

[ACP Medical Lab Evaluation](#) (800) 338-2746

[California Thoracic Society](#) (415) 536-0287

[College of American Pathologists/EXCEL](#)
(800) 323-4040

[WSLH](#) (800) 462-5261

For answers to your PT questions, go to the [LQA web-site](#) or call Veronica Bush at (253) 395-6782.

Calendar of Events

Training Classes:

[2017 Northwest Medical Laboratory Symposium](#)

October 18-21 Lynnwood

[24th Annual Clinical Laboratory Conference](#)

November 13 Tukwila

[2018 ASCLS-WA Spring Meeting](#)

April 26-27, 2018 Renton

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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