

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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Proficiency Testing for 2017

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 2017. Page seven contains a list of the approved PT agencies. Call the programs for a free copy of their 2017 PT brochure or see their websites. Your PT provider has likely already sent you a PT order form and catalog for 2017. Early enrollment guarantees that you will receive samples for the first testing event that occurs between January and March 2017.

- 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 2017 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 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.
- The [LQA website](#) has a listing of the regulated analytes.

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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	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 2017, cont'd from page 1

- 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.

LQA website: The [LQA 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.

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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Changes to Washington State DOH Surveillance for Antibiotic Resistant Organisms — Effective January 2017

The Washington State Department of Health Public Health Laboratories (PHL) is a proud recipient of funding from U.S. Centers for Disease Control and Prevention (CDC) to serve as a regional laboratory within the new [Antibiotic Resistance Laboratory Network](#) (ARLN) CDC established in fall 2016. The ARLN will provide infrastructure and lab capacity for seven regional labs across the US to detect and support response to resistant organisms recovered from human samples. As part of the ARLN, PHL will perform testing for the western US, including Alaska, California, Hawaii, Nevada, Oregon, and Washington.

In addition to ongoing surveillance for carbapenem-resistant Enterobacteriaceae, beginning January 2017, DOH will expand state surveillance and testing for multidrug resistant organisms (MDRO) to include carbapenem-resistant *Pseudomonas* species, carbapenem-resistant *Acinetobacter* species, drug-resistant *Neisseria gonorrhoeae*, and certain *Candida* species. Detailed submission and testing information for each organism will be available on the [PHL Microbiology Laboratory Test Menu](#). The ARLN will cover shipping costs associated with MDRO submission. Contact Kelly Kauber at 206-418-5589 or by [e-mail](#) for information.

Statewide Surveillance for Carbapenem-resistant Enterobacteriaceae

DOH has performed statewide surveillance for carbapenem-resistant Enterobacteriaceae (CRE) since October 2012. PHL performs multiplex polymerase chain reaction (PCR) to detect the five most common plasmid-mediated carbapenemases in the U.S.:

- *Klebsiella pneumoniae* carbapenemase (KPC)
- New Delhi metallo- β -lactamase (NDM)
- Oxacillin-hydrolyzing β -lactamase-48 (OXA-48)
- Verona integron-encoded metallo- β -lactamase (VIM)
- Imipenem-hydrolyzing β -lactamase (IMP)

The current CRE surveillance case definition (updated in May 2015) is:

E. coli, *Klebsiella* spp., and *Enterobacter* spp. resistant to any carbapenem, according to Clinical Laboratory Standards Institute breakpoints: minimum inhibitory concentrations of ≥ 4 mcg/ml for meropenem, imipenem, and doripenem or ≥ 2 mcg/ml for ertapenem; Kirby-Bauer zone of inhibition diameter ≤ 19 mm for meropenem, imipenem, and doripenem or ≤ 18 mm for ertapenem.

The PHL receives about 15-30 CRE isolates per month, and almost 12 percent are found by PCR testing to produce a carbapenemase. Detailed CRE surveillance summary data are available on the [DOH CRE Surveillance](#) webpage.

CRE isolates meeting the CRE surveillance case definition (above) should be submitted to PHL accompanied by a PHL microbiology submission form and local antimicrobial susceptibility test (AST) result. Please refer to the [PHL Microbiology Laboratory Test Menu](#) for details on specimen collection and submission. PHL will perform confirmation of identification by MALDI-TOF, AST by microbroth dilution, and testing for presence of carbapenemase by PCR.

Please contact Kelly Kauber at 206-418-5589 or by [e-mail](#) for suspected or confirmed carbapenemase production in other Enterobacteriaceae isolates not subject to routine surveillance (i.e., not *E. coli*, *Klebsiella*, or *Enterobacter*).

Sentinel Surveillance for Carbapenem-resistant *Pseudomonas* and Carbapenem-resistant *Acinetobacter*

Carbapenem-resistant (CR) *Pseudomonas* and CR-*Acinetobacter* are concerning causes of healthcare-associated infections. Multidrug-resistant *P. aeruginosa* and *Acinetobacter* have been deemed “serious threats” by CDC. Similar to CRE, these bacteria can produce carbapenemases; in fact, since surveillance for CRE began in 2012, PHL has identified four patients with carbapenemase-producing *Pseudomonas* and/or *Acinetobacter*. Two of the patients had only in-Washington healthcare, raising concern that these organisms are circulating in our state.

Changes - DOH Antibiotic Resistant Organisms Surveillance, cont'd from page 3

Beginning in 2017, DOH will conduct sentinel surveillance for CR-*Pseudomonas* and CR-*Acinetobacter* from select labs across the state. Participation by laboratories in this effort is encouraged, but is voluntary. Participating labs should submit non-mucoid CR-*Pseudomonas* isolates (minimum inhibitory concentration ≥ 8 $\mu\text{g/mL}$ or Kirby-Bauer zone of inhibition diameter ≤ 15 mm for any carbapenem) and CR-*Acinetobacter* isolates (minimum inhibitory concentration ≥ 8 $\mu\text{g/mL}$ for any carbapenem or Kirby-Bauer zone of inhibition diameter ≤ 14 mm for doripenem and meropenem or ≤ 18 mm for imipenem) accompanied by a PHL microbiology submission form and local AST result. Please refer to the [PHL Microbiology Laboratory Test Menu](#) for details on specimen collection and submission. At PHL, submitted CR-*Pseudomonas* and CR-*Acinetobacter* isolates will undergo the same testing as for CRE.

We will contact laboratory directors in December to inquire about interest in participation. A benefit associated with participation is that labs will access advanced laboratory testing for their patients, and the ARLN will pay all shipping costs associated with MDRO surveillance. Contact Kelly Kauber at 206-418-5589 or by [e-mail](#) for information.

Surveillance for Plasmid-Mediated Colistin Resistance (mcr-1)

Over the past year, plasmid-mediated colistin resistance (mcr-1) has been identified in Enterobacteriaceae in humans and animals in many countries and continents, including in the U.S. (see the [CDC mcr-1 Health Advisory](#) for details). Plasmid-mediated colistin-resistance is particularly worrisome because of concern that, in combination with plasmid-mediated carbapenem-resistance, untreatable bacteria may emerge. As of November 2016, mcr-1 has not been identified in Washington. CDC, FDA and USDA perform national surveillance for mcr-1 in *E. coli* and *Salmonella* via the National Antibiotic Resistance Monitoring System (NARMS).

Laboratories that perform AST to determine whether colistin can be used clinically are asked to submit to PHL any *E. coli*, *Klebsiella*, *Enterobacter*, *Pseudomonas*, or *Acinetobacter* isolates with a minimum inhibitory concentration to colistin of 4 $\mu\text{g/ml}$ or higher accompanied by a PHL microbiology submission form and local AST result. Please refer to the [PHL Microbiology Laboratory Test Menu](#) for details on specimen collection and submission.

At this time, colistin-resistant isolates will be forwarded to CDC for testing for mcr-1. PHL will begin testing colistin-resistant Enterobacteriaceae for mcr-1 in the near future. If colistin resistance is found in an isolate not subject to routine surveillance (i.e., not *E. coli*, *Klebsiella*, *Enterobacter*, *Pseudomonas*, or *Acinetobacter*), please contact the [ARLN](#) for guidance.

Drug-resistant *Neisseria gonorrhoeae*

As part of ARLN, in 2017 PHL will perform antimicrobial susceptibility determination of confirmed *N. gonorrhoeae* isolates in addition to identification confirmation.

Statewide Surveillance for Drug-resistant *Candida*

In recent years, multidrug resistant *Candida auris* has emerged as a cause of invasive infections with high potential to cause outbreaks in healthcare facilities, including in the U.S. (see the [CDC Clinical Alert to US Healthcare Facilities](#) for details). *C. auris* is difficult to identify with standard laboratory methods. It is often misidentified as other *Candida* species.

Any laboratory that identifies *C. auris*, *C. haemulonii*, or *C. glabrata* should submit these isolates to PHL accompanied by a microbiology submission form and local AST, if available. *Candida* species that cannot be identified by the lab after performing species identification (i.e. species not in the database) should also be submitted. If labs experience a high volume of *C. glabrata* isolates and cannot send them all, every third or fifth isolate is acceptable. Please refer to the [PHL Microbiology Laboratory Test Menu](#) for details on specimen collection and submission. All shipping costs associated with MDRO surveillance will be paid by the ARLN. Contact Kelly Kauber at 206-418-5589 or by [e-mail](#) for information.

Changes - DOH Antibiotic Resistant Organisms Surveillance, cont'd from page 4

Table 1. Resistance Criteria for Washington State MDRO Surveillance

Family/Genus	Antibiotic Susceptibility Criteria
CR-Enterobacteriaceae: <i>E. coli</i> <i>Klebsiella</i> spp. <i>Enterobacter</i> spp.	Resistant to ≥ 1 carbapenem: -Minimum inhibitory concentrations ≥ 4 mcg/ml for meropenem, imipenem, and doripenem -Minimum inhibitory concentrations ≥ 2 mcg/ml for ertapenem -Kirby-Bauer zone of inhibition diameter ≤ 19 mm for meropenem, imipenem, and doripenem -Kirby-Bauer zone of inhibition diameter ≤ 18 mm for ertapenem AND/OR Resistant to colistin: -Minimum inhibitory concentration ≥ 4 μ g/ml
CR- <i>Pseudomonas</i> spp.	Resistant to ≥ 1 carbapenem: -Minimum inhibitory concentration ≥ 8 μ g/mL for any carbapenem -Kirby-Bauer zone of inhibition diameter ≤ 15 mm for any carbapenem AND/OR Resistant to colistin: -Minimum inhibitory concentration ≥ 4 μ g/ml
CR- <i>Acinetobacter</i> spp.	Resistant to ≥ 1 carbapenem: -Minimum inhibitory concentration ≥ 8 μ g/mL for any carbapenem -Kirby-Bauer zone of inhibition diameter ≤ 14 mm for doripenem and meropenem -Kirby-Bauer zone of inhibition diameter ≤ 18 mm for imipenem AND/OR Resistant to colistin: -Minimum inhibitory concentration ≥ 4 μ g/ml

*In addition to requested surveillance above, all providers, laboratories, and facilities should report to local public health bacteria in any family or genus (e.g., Enterobacteriaceae, *Pseudomonas*, *Acinetobacter*) suspected of producing a carbapenemase. If an organism not listed is colistin-resistant, please contact the [ARLN](#) for guidance.

Changes - DOH Antibiotic Resistant Organisms Surveillance, cont'd from page 5

Table 2. Washington State Surveillance for Unusual *Candida* Species Isolates

Species for Submission
All <i>C. auris</i>
All <i>C. haemulonii</i>
All <i>C. glabrata</i> *
Any <i>Candida</i> species that is not identified after species identification is performed (i.e. not in database)

*If labs experience a high volume of *C. glabrata* isolates and cannot send them all, every third or fifth isolate is acceptable.

We sincerely thank laboratories for their diligence in reporting and submitting antibiotic resistant organisms to public health. The Healthcare Associated Infections Program is available for consultation on any aspect of MDRO surveillance and infection prevention or to answer questions about ARLN. Please contact Kelly Kauber at 206-418-5589 or by [e-mail](#) with questions or comments.

FDA Delays LDT Guidance

On November 18, 2016, the FDA announced they will delay the release of its pending laboratory developed test (LDT) guidance until the next administration. This is the statement FDA recently released in this regard:

“The FDA believes that patients and health care providers need accurate, reliable, and clinically valid tests to make good health care decisions—inaccurate or false test results can harm individual patients. We have been working to develop a new oversight policy for laboratory developed tests, one that balances patient protection with continued access and innovation, and realize just how important it is that we continue to work with stakeholders, our new administration, and Congress to get our approach right. We plan to outline our view of an appropriate risk-based approach in the near future. It is our hope that such an approach will help guide continued discussions.

Parallel legislative approaches driven by industry and patient groups which would charge CLIA to bear some of the burden of LDT regulation continue to be discussed at the congressional level. Congressional Quarterly reports this could be included in the medical device user fee legislation that is due for reauthorization next year. FDA will continue to advise Congress on aspects of their legislative approaches.”

We will provide updates through Elaborations as they become available.

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 ASCLS-WA Spring Meeting](#)

April 27-28, 2017 Kennewick

[2017 Northwest Medical Laboratory Symposium](#)

October 18-21, 2017 Lynnwood

[24th Annual Clinical Laboratory Conference](#)

November 2017 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.



ELABORATIONS

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