

**Clinical Forum
Editorial Staff**

Dr. Christopher Ball
Robert Voermans
Wendy Loumeau
Amanda Bruesch
Matthew Burns
Vonnita Barton
Erin Peterson

To be added
or removed
from the
Clinical Forum
email list:

statelab@dhw.idaho.gov

TB Year in Review

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in 2016.

IBL worked closely with the California Microbial Disease Laboratory to utilize the National TB DST Reference Center. The National DST Reference Center provides molecular detection of drug resistance (MDDR) testing by request. MDDR testing is a rapid method to detect drug resistance in patients who are at risk of having drug-resistant TB. Patient outcomes are improved with this ability to use MDDR testing to determine whether a person has drug resistant TB; MDDR

testing provides results weeks before traditional drug susceptibilities are complete. IBL requested and sent six samples for the MDDR test in 2016.

Fortunately,

none of the six samples was found to be resistant to rifampin (RIF) or isoniazid (INH). RIF and INH are the primary treatment drugs for TB therapy; resistance to either will result in an escalation of disease consequence.

There is no clear explanation as to why Idaho saw more positive TB cases in 2016 compared to previous years (Figure 2), but partnership between public health (TB Controller's Office and IBL), submitting laboratories, and providers ensured appropriate response to the increase in cases in 2016.

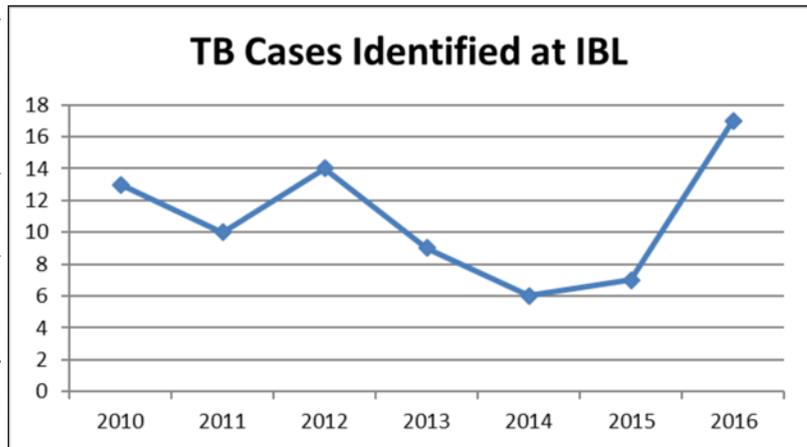


Figure 2. IBL identified 17 positive TB cases for 2016. This is the highest number of cases in recent years.

Check it Out!

Idaho Bureau of Laboratories' (IBL) laboratorians Erin Peterson and Ashley Machado were co-authors on a Mortality and Morbidity Weekly Report (MMWR) article pertaining to last spring's plague identifications in ground squirrels and domestic cats. Get the full story at https://www.cdc.gov/mmwr/volumes/65/wr/mm6548a5.htm?s_cid=mm6548a5_e or <https://goo.gl/B8QjEe>.

Zika Virus Summary

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2004. As a result, there is no recent US data about its prevalence to help determine the impact Zika virus infection may have on microcephaly rates. The Division of Public Health (DPH) initiated a new surveillance program for microcephaly in infants born on or after January 1st, 2016. To support the program, DPH developed a case definition, investigative protocols, and a case investigation form to ensure uniform reporting statewide. During 2016, two confirmed cases of microcephaly were reported in Idaho and neither was associated with Zika virus infection.

Microcephaly is not the only concern for expectant mothers with Zika virus exposures. Infections during pregnancy have also been linked to other adverse outcomes including severe fetal brain defects, pregnancy loss, eye defects, hearing loss, and impaired growth in infants. To better understand the epidemiology of Zika virus and its impact on newborns, the Centers for Disease Control and Prevention (CDC) established the US Zika Pregnancy Registry (USZPR) to collect information about pregnancy and infant outcomes following laboratory evidence of Zika virus infection during pregnancy. Data collected through this registry will be used to update recommendations for clinical care, to plan for services for pregnant women and

families affected by Zika virus, and to improve prevention of Zika virus infection during pregnancy. In Idaho, consent is sought from eligible women or mothers of eligible infants to include them in the USZPR. So far, one eligible Idaho resident who had laboratory evidence of an unspecified flavivirus during pregnancy has consented to participate.

The Idaho Bureau of Laboratories (IBL) forwarded 241 samples to the CDC for Zika IgM Capture EIA testing in 2016. In April 2016, IBL began performing Trioplex RT-PCR, which identifies Dengue, Chikungunya and Zika viruses. IBL reported Trioplex RT-PCR results on 73 samples in 2016. Fortunately, incidence has been low in Idaho despite heightened public health response.

Now, commercially available diagnostic Zika virus testing is available in clinical reference laboratories. Due to the wide availability of Zika testing, IBL will only be accepting Zika virus submissions that are part of active public health district or state epidemiology investigations. Idaho clinical laboratories should refer Zika specimens to their normal commercial reference laboratory. More information is available at the CDC website (<https://www.cdc.gov/zika/laboratories/lab-guidance.html>).

**IBL Update: CLIA
Inspector**

Liz Parent, Clinical Laboratory Inspector at Idaho Bureau of Laboratories, has accepted a position in a Northern Idaho laboratory. She expressed appreciation for her time at IBL and has enjoyed working with laboratorians across the state. We wish Liz the best in her new adventure!




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Ask the CLIA Auditor: Competency Assessments

Elizabeth Parent, MLS (ASCP), CG and Amanda J. Bruesch, MS

What is a competency assessment? A competency assessment is a method of evaluation used to determine how well a laboratory employee is performing the required job skills in relation to specific regulatory requirements. It is used to ensure effective training among laboratory personnel and can identify procedural errors resulting from training gaps or procedure drift.

Competency assessments are required by CLIA six months after completion of training for a new employee and annually thereafter or any time a test system is changed or a new procedure is put into place. They are required for testing personnel for each test that the individual is approved to perform. Figure 1 shows the six required elements for competency assessments. These elements must be performed for every competency assessment.

The Laboratory Director is also responsible for completing competency assessments on General Supervisors, Technical Supervisors, and Technical Consultants to ensure their CLIA responsibilities are being met and that they are competent to fill these important roles in the laboratory. Competency assessments must be completed on all testing personnel, even those that don't work in the laboratory on a daily basis but are completing testing under the laboratory's CLIA certificate (e.g., respiratory therapist).



Figure 1. Six required elements for competency assessments.

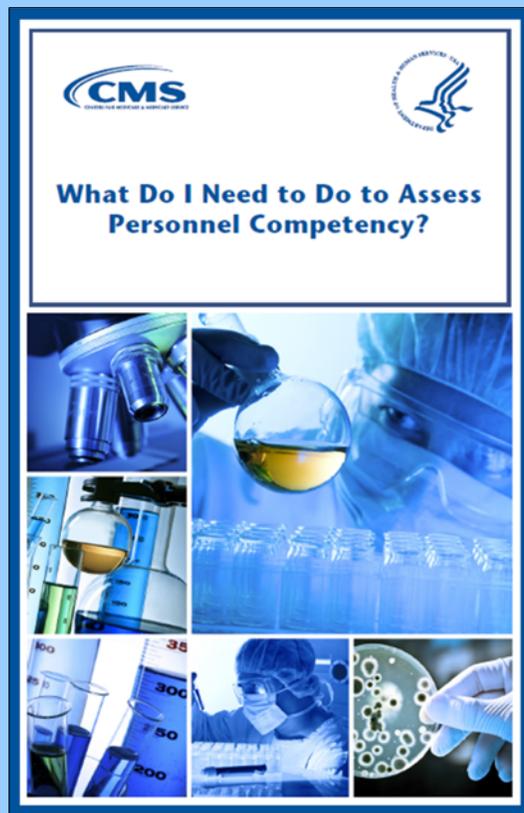


Figure 2. CLIA Brochure #10 can be accessed from the CLIA site at https://www.cms.gov/regulations-and-guidance/legislation/clia/clia_brochures.html.

Laboratories performing microscopic testing under a Provider Performed Microscopy (PPM) CLIA certificate must also ensure that competency assessments are completed on any mid-level practitioners performing testing.

Contact the Idaho Bureau of Laboratories (IBL) Lab Improvement section at LabImprovement@dhw.idaho.gov or 208-334-0528 with questions about competency assessment requirements.

Resources:

- CLIA Brochure #10 – What Do I Need to Do to Assess Personnel Competency? (Figure 2): https://www.cms.gov/regulations-and-guidance/legislation/clia/clia_brochures.html

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Have You Heard?



An isolate of *Klebsiella pneumoniae* resistant to all USA treatment options was isolated from a patient in Nevada.

<https://www.cdc.gov/mmwr/volumes/66/wr/mm6601a7.htm>

The FDA has banned powdered surgical and exam gloves.

<https://www.federalregister.gov/documents/2016/12/19/2016-30382/banned-devices-powdered-surgeons-gloves-powdered-patient-examination-gloves-and-absorbable-powder>



The Department of Health and Human Services released the final version of the “Common Rule” (45 CFR 46) regulating research use of human subjects and tissues.

<https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-01058.pdf>

CLIA civil penalties have increased to \$5,936/day for labs not meeting requirements but not posing immediate jeopardy.

42 CFR 493.1834(d)(2)(ii) 42 CFR 493.1834(d)(2)(ii) <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.html>

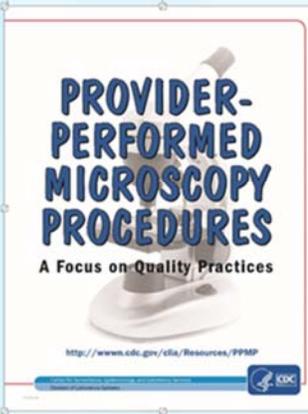


Ask the CLIA Auditor

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- Provider Performed Microscopy Procedures booklet (Figure 3): <https://wwwn.cdc.gov/clia/Resources/PPMP/>
- Personnel Competency Assessment Form: www.statelab.idaho.gov => Clinical Lab Certification => Resources

Provider-Performed Microscopy Procedures Educational Booklet



PROVIDER-PERFORMED MICROSCOPY PROCEDURES
A Focus on Quality Practices

<http://wwwn.cdc.gov/clia/Resources/PPMP>

- Describes recommended practices under a CLIA Certificate for PPM procedures for
 - physicians,
 - midlevel practitioners (nurse midwife, nurse practitioner, or physician assistant), and
 - dentists.
- Contains an overview of
 - the regulatory requirements,
 - resources including forms and examples, and
 - images of common microscopic findings for the nine specific microscopic examinations that may be performed under a Certificate of PPM Procedures.
- Request hardcopies of the booklet through email at PPMP@cdc.gov or online at <http://wwwn.cdc.gov/clia/Resources/PPMP>

<http://wwwn.cdc.gov/clia/Resources/PPMP>

Figure 3. The Provider-Performed Microscopy Procedures booklet is available on the CDC website at <https://wwwn.cdc.gov/clia/Resources/PPMP/>.

Upcoming Trainings and Webinars

Laboratory Safety Outreach Workshop

April 2017 in Eastern Idaho

May 2017 in Lewiston and Hayden

More information to come!



Previous attendees tell us what they liked about the course:

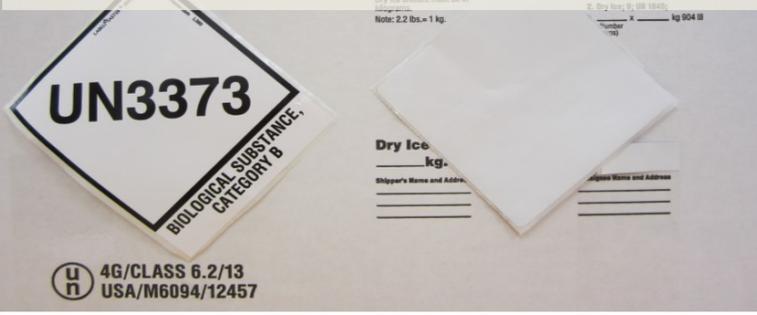
- Everything! Well done! I was not bored or distracted once.
- Nice agenda, good mix.
- Instructors were very knowledgeable/passionate about what they do
- Good variety, applicable topics

Packaging and Shipping Division 6.2 Materials Training

Monday, June 19th in Boise

Thursday, June 22nd in Lewiston

Register online at www.aphl.org/courses/Pages/019-17.aspx.



Webinars

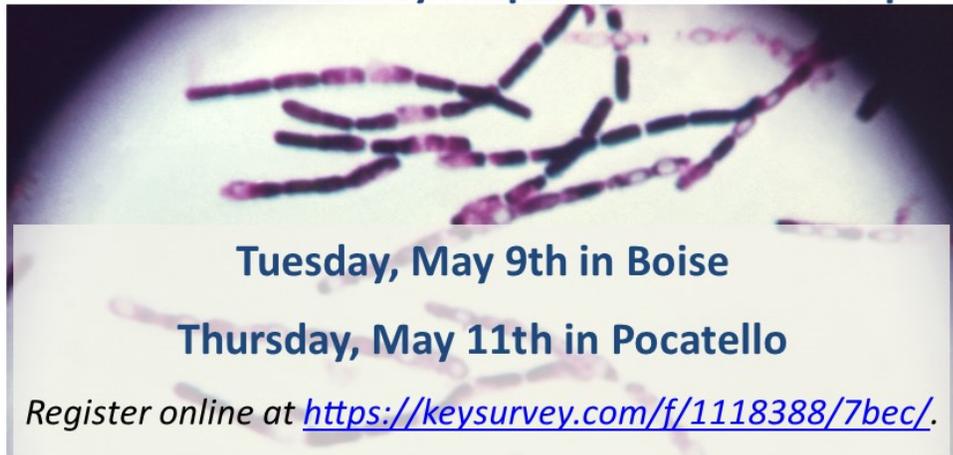
April 18, 2017; 11:00 am Mountain Time
Antimicrobial Resistance Mechanism: A
Primer for Bench Technologists

April 25, 2017; 11:00 am Mountain Time
Emerging and Resurging Infectious
Diseases: 2017

May 2, 2017; 11:00 am Mountain Time
Detection of Contaminated Material
from Outside the Lab

Contact Wendy Loumeau at
wendy.loumeau@dhw.idaho.gov to
register.

Sentinel Laboratory Preparedness Workshop



Tuesday, May 9th in Boise

Thursday, May 11th in Pocatello

Register online at <https://keysurvey.com/f/1118388/7bec/>.