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# Idaho Bureau of Laboratories Clinical Forum

Volume 9, Issue 1

Spring 2016

## Tuberculosis (TB) Timeliness: What You Can Do

Steve Gregoire

Healthy People 2020 is not a new diet or exercise plan, but rather a national science-based initiative with multiple objectives intended to improve the health of all Americans. Objective IID-32<sup>1</sup> is to “Increase the proportion of culture-confirmed TB patients with a positive nucleic acid amplification test (NAAT) result reported within 2 days of specimen collection.”

In order to meet this objective and improve patient care in Idaho for all TB testing, the Idaho Bureau of Laboratories (IBL), in partnership with the Idaho TB program and the Centers for Disease Control and Prevention (CDC), has set a goal to receive all TB samples at IBL for testing within 24 hours of sample collection. This goal decreases turna-

round time for reporting results and ensures that the quality of the sample is maintained, as long transit or holding times increase general bacterial presence in the sample and reduce the chance of recovering TB. Figure 1 shows the percentage of TB samples received at IBL within 24 hours of sample collection; IBL has set a benchmark of 67%.

This goal can be a challenge, as IBL receives TB samples Monday through Friday between 8:00 AM and 5:00 PM and is closed on weekends and 10 holidays throughout the year. This limited schedule shrinks the “receiving window,” making goal achievement difficult before any samples are even collected or sent. Other challenges include the cost of

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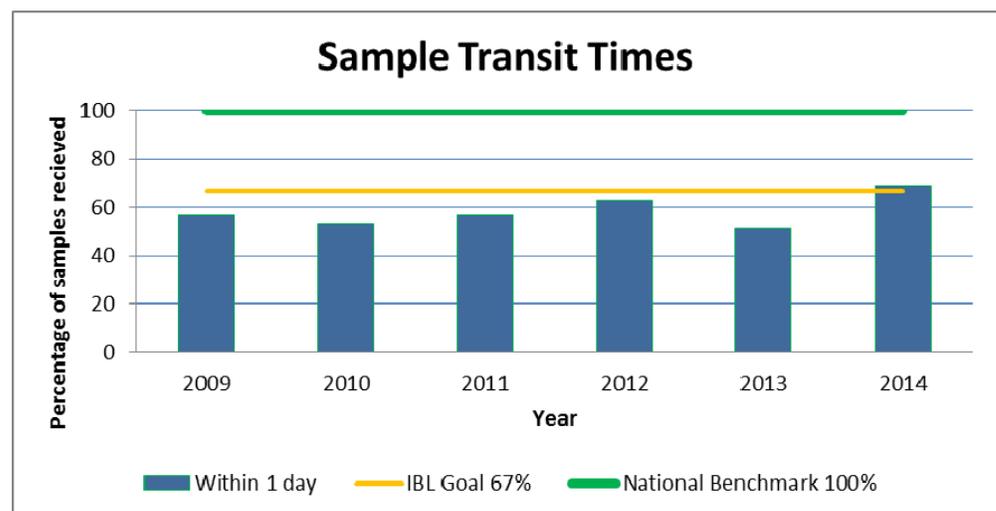


Figure 1. Sample transit times for TB samples sent to IBL, 2009-2014. IBL's goal is 67% received within one day.



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## TB Timeliness

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shipping, remote locales, weather issues, and courier schedules.

What can you, the submitter, do to decrease turnaround time and maintain quality of TB samples? **UPAR!** See Figure 2 for an explanation. In addition, submitting labs are welcome to notify IBL when

samples are on the way or with any questions.

**References**

<sup>1</sup>Healthy People 2020 Immunization and Infectious Diseases Objectives. Retrieved from <http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives>

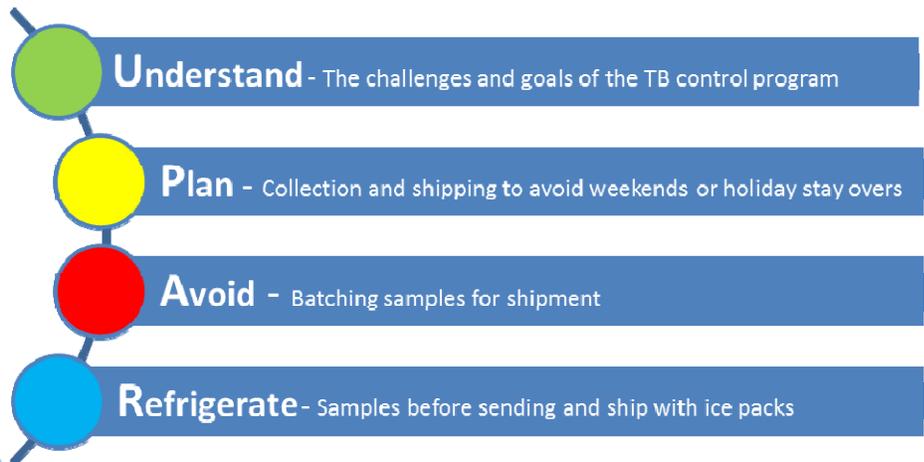


Figure 2. Submitting laboratories can remember UPAR (Understand, Plan, Avoid, Refrigerate) to decrease turnaround time and ensure quality of TB samples is maintained.

## Training Calendar: May 2016

Mon	Tue	Wed	Thu	Fri
2	3 <b>Boise</b>	4 <b>Boise</b>	5	6 <b>Hayden</b>
Sentinel Laboratory Biothreat Preparedness Workshop 9:00 am to 4:00 pm Register online at <a href="http://keysurvey.com/f/1021921/7e2b/">http://keysurvey.com/f/1021921/7e2b/</a>				
9	10	11	12	13
16	17 <b>Idaho Falls</b>	18	19 <b>Boise</b>	20
Packaging and Shipping Division 6.2 Materials 8:00 am to 5:00 pm Register online at <a href="http://www.aphl.org/courses/Pages/021-16.aspx">www.aphl.org/courses/Pages/021-16.aspx</a>				

# Ask the CLIA Auditor

Liz Parent



CLIA program staff (left to right): Cina Brown, Amanda Bruesch, Liz Parent

**Q:** Who are the new Idaho CLIA program personnel at the Idaho Bureau of Laboratories?

**A:** Amanda Bruesch, MS is the Lab Improvement Section Manager, a position previously held by Katey Anderson and David Eisentrager at IBL. Amanda has Bachelor's and Master's degrees in Microbiology and Biology, respectively, and has been with IBL for over 8 years. She brings extensive experience in research and public health biology as well as a broad foundation in classical microbiology and molecular diagnostic test development.

Cina Brown, who has been at IBL for 7 years, is our new Technical Records Specialist. Cina is available to answer your CLIA questions or route you to the correct resource. Cina maintains our databases and paper records and provides excellent customer service.

Liz Parent is our new CLIA Clinical Laboratory Inspector. She has 15 years of laboratory experience in research, genetics, and clinical laboratory testing. Liz holds both an ASCP Medical Laboratory Science certification as well as an ASCP Specialist in Cytogenetics certification.

**Q:** Who do we contact if we need to change our director or make changes to our CLIA certificate?

**A:** You can reach any of the new CLIA program staff at [LabImprovement@dhw.idaho.gov](mailto:LabImprovement@dhw.idaho.gov) or (208) 334-0528 with questions or to make changes to your certificate.

**Q:** What changes should we be aware of for our next CLIA inspection?

**A:** The Interpretive Guidelines (IGs) for laboratories have changed, effective January 4, 2016.

The new IGs for inspecting laboratories can be found online:

[https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive\\_Guidelines\\_for\\_Laboratories.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html).

As of January 1, 2016, CLIA has updated its acceptable quality control (QC) practices to include only the default CLIA QC or Individualized Quality Control Plans (IQCP). During a lab's CLIA inspection, Liz will be looking for IQCP for any test the lab is running less than the default CLIA QC.

We are also in the process of re-qualifying all laboratory personnel this year. At the time of inspection, we will require a copy of a high school diploma or equivalent, or a copy of the highest degree obtained for all personnel, including laboratory directors. CLIA does not recognize certificates or certifications to meet personnel requirements for education; diplomas, degrees, or transcripts are required.

**Q:** Do we need written orders for a health fair we plan on holding?

**A:** Each health fair must have an affiliation, in writing, with a provider licensed in the State of Idaho to practice medicine. This person will be responsible for all testing completed at the health fair, including critical results or results for reportable diseases.

**Q:** How do we look up the complexity of tests in our laboratory?

**A:** On the Food and Drug Administration (FDA) website: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>

Ask the Auditor will be an ongoing column for 2016 Clinical Forum issues. Email [LabImprovement@dhw.idaho.gov](mailto:LabImprovement@dhw.idaho.gov) to submit a question to the CLIA auditor. Responses may be made in a future issue of the Clinical Forum or directly to the submitter.

# CLIA Regulations on Proficiency Testing Online Training Course - 2016

Sponsored by the Association of Public Health Laboratories  
in collaboration with the Idaho Bureau of Laboratories

### Description

This intermediate-level, interactive online training module covers the regulations under CLIA for proficiency testing for registered laboratories.

### Target Audience

This course is intended for Idaho clinical laboratorians seeking additional information on CLIA proficiency testing regulations and requirements.

### Access Requirements

To view this module, you will need a computer with internet access and speakers or headphones to hear the audio.

### Special Needs

Course content is closed captioned where applicable.

### Continuing Education

The Idaho Bureau of Laboratories is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program.

This course is approved for 1.0 contact hours.

For questions, contact Amanda Bruesch at 208-334-0545 or [bruescha@dhw.idaho.gov](mailto:bruescha@dhw.idaho.gov).



## Objectives

At the conclusion of this training, the participant will be able to:

- 1) Classify proficiency test requirements for different CLIA certificate types
- 2) Identify differences in proficiency test requirements between regulated and non-regulated analytes
- 3) Describe examples of troubleshooting proficiency test failures
- 4) Identify guidelines for an acceptable plan of correction

## Registration

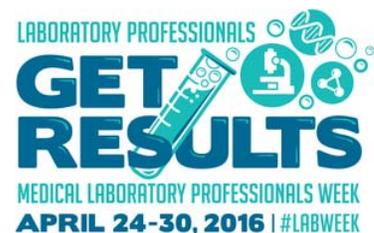
This course is offered on-demand at no cost. You can find the online training course at [www.statelab.idaho.gov](http://www.statelab.idaho.gov), then click on the Training link.



IDAHO DEPARTMENT OF HEALTH & WELFARE  
DIVISION OF PUBLIC HEALTH

Happy Lab Professionals Week 2016!

Thank you for all you do!



## Malaria PCR Development at IBL

Erin Peterson

Idaho Bureau of Laboratories (IBL) is in the process of developing a real time PCR for the detection of malaria in human patients. Malaria is a serious and sometimes life threatening disease transmitted by mosquitoes; approximately 1500 malaria cases are diagnosed in the United States annually<sup>1</sup>. The PCR test will aid in detection in Idaho by differentiating between four species of malaria: *Plasmodium falciparum*, *P. vivax*, *P. malariae*, and *P. ovale*. In order to verify this method, we are asking Idaho Sentinel Laboratories to submit suspected malaria samples to IBL.

The requested sample is 1-5 mL of whole blood in an EDTA vacutainer tube. Please fill out the Bacteriology Test Request Form and specify "Malaria PCR Verification Study" in the **Other (specify)** region at the top of the page. See Figure 1 for the validation process.

Contact Erin Peterson for any questions or concerns (208-334-0596 or [petersoe@dhw.idaho.gov](mailto:petersoe@dhw.idaho.gov)).

### References

<sup>1</sup>Centers for Disease Control and Prevention. (2016). Malaria. Retrieved from <http://www.cdc.gov/malaria/>

### Verification Process for Malaria PCR Test



## Russell Eck, Microbiologist Principal

In September 2015, Russell was hired as a Microbiologist Principal over the Environmental Microbiology laboratory. Here, he is the primary analyst for testing water samples for microbiological contaminants. Russell was born and raised in Reno, Nevada and earned a Bachelor's of Science degree from the University of Nevada, Reno. He comes to Idaho Bureau of Laboratories (IBL) with international experience setting up disease prevention programs for mosquitos, sand flies, and other vectors primarily in the Caribbean and South America.

In his spare time, Russell has a wide range of hobbies including playing musical instruments, music production and recording, photography, wood working, home renovation, traveling, hiking, camping, biking, snowboarding, and skateboarding.



## Mohammed Al Charakh, Bio-Repository Technician

Mohammed Al Charakh is the Bio-Repository Technician at the Idaho Bureau of Laboratories (IBL). The Division of Public Health is working with the Idaho Department of Labor (IDOL) to provide an intern position to assist in preparing highly skilled workers the needed United States work experience. The program through IDOL is funded through the Workforce Investment Act, a law passed by Congress. After nearly five years of interviews, security checks, medical examinations, and paperwork, Mohammed and his family were approved to seek refuge in the United States. He moved to Chicago and then to Idaho from Baghdad, Iraq in 2015 with his wife, daughter, and two sons. In Baghdad, he completed his education and worked for twelve years as a veterinarian. In addition to working at IBL, Mohammed volunteers at the Idaho Humane Society.



### Upcoming Webinars

April 12, 2016; 11:00 am Mountain Time  
*2016 CLIA Update: Top Ten CLIA Cited Deficiencies*

April 14, 2016; 11:00 am Mountain Time  
*Update on FDA's Role in Regulatory Oversight of Laboratory Developed Tests*

April 21, 2016; 11:00 am Mountain Time  
*Whole Genome Sequencing of Bacterial Pathogens*

April 28, 2016; 11:00 am Mountain Time  
*Diagnosis of Free-Living Ameba Infections*

Contact Wendy Loumeau at  
[loumeauw@dhw.idaho.gov](mailto:loumeauw@dhw.idaho.gov) to register.

## Matthew Burns, Developmental Scientist



Matthew Burns was hired as the Developmental Scientist for the Idaho Bureau of Laboratories in November. He graduated from the University of Idaho with degrees in Microbiology, Molecular Biology and Biochemistry before attending graduate school at the University of Colorado Health Sciences Center in Biomedical Science. He has recently returned to school part-time at Boise State where he is working on an interdisciplinary Master's degree in public policy and emerging biotechnology. Matthew has worked in research and development for over a decade: as a research fellow in NASA's Office of Planetary Protection, a scientist and safety officer for the Simplot Plant Sciences laboratory, and as lead molecular biologist for a small biotech start-up on the east coast.

At IBL, Matthew is working to refine existing methods, implement new technology, and foster connections with other public health, academic, and research labs in the region. He is grateful to be applying his skills and experience to support the public health of the people of Idaho. Matthew loves living in the Treasure Valley for summer drives through the desert, picnics by the river, the unique culture, and great craft beer.