Idaho Bureau of Laboratories

Clinical Forum

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State of Idaho

Bureau of Laboratories

2220 Old Penitentiary Rd

Boise, ID 83712-8249

Phone: 208-334-2235

Fax: 208-334-4765

E-mail: statelab@dhw.idaho.gov

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2016 Needs Assessment: Prioritizing for 2017

Wendy Loumeau

This fall, Idaho Bureau of Laboratories (IBL) conducted its annual partner needs assessment. The assessment solicits information from IBL's partners to direct training and outreach efforts for the following year. This year, 41 individuals responded from 30 clinical laboratories and 5 public health agencies.

Part A of the assessment collected information to update the laboratory contact list database. The database is used to send blast emails to partners on topics including new and emerging diseases, training announcements, and IBL updates. For example, IBL has sent one lab advisory and two lab updates about Zika virus testing and sample submission in 2016. IBL recently notified lab partners of the addition of *Bacillus cereus* Biovar *anthracis* to the national select agent list. The contact list database plays a critical role in state laboratory preparedness and outreach.

Part B inquired about testing processes, resources, and capabilities for Idaho Sentinel Laboratory Network (ISLN) laboratories. Seventeen respondents identified IBL as one of their reference labs, to which the assessment asked about barriers encountered when submitting samples to IBL. Twenty respondents indicated that they don't encounter any barriers. Figure 1 shows that barriers selected include number of certified shippers available and not enough information about IBL's services.

IBL is addressing these barriers in a number of ways. First, Packaging and Shipping Division 6.2 Materials training will be offered in the spring of 2017. Second, IBL is simplifying submission forms to ease the paperwork burden when submitting samples to IBL for testing. Updated forms are available on the

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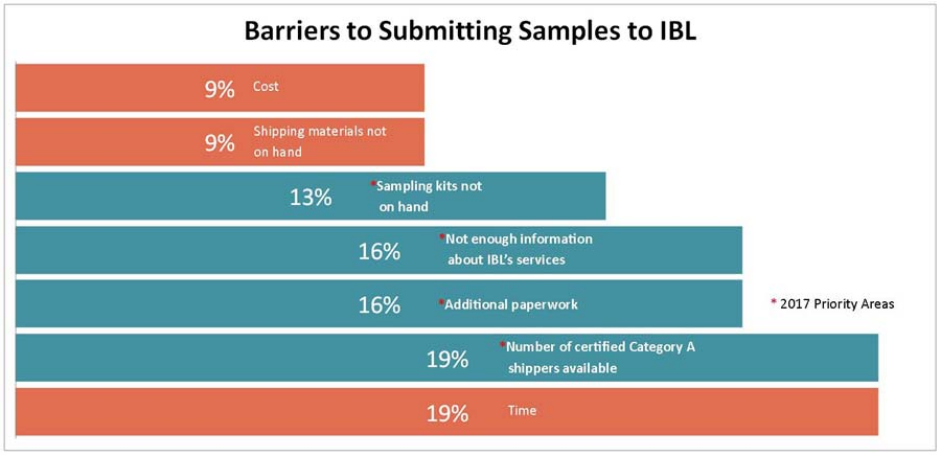

Figure 1. 2017 priorities were developed from barriers selected by needs assessment respondents.

IDAHO DEPARTMENT OF HEALTH & WELFARE
DIVISION OF PUBLIC HEALTH

Clinical Forum
Editorial Staff

Dr. Christopher Ball
Robert Voermans
Wendy Loumeau
Amanda Bruesch
Matthew Burns
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Liz Parent

Ask the CLIA Auditor: Record Retention

Amanda J. Bruesch, MS

Q: I have a record retention question. While reviewing our policy recently we noticed that the state statute and the federal regulations give different time frames for keeping test results. The state says 5 years, feds say 2 years. We want to make sure we are following the correct one. Which one is it?

1) Idaho Code/Statues – Title 39 (Health and Safety), Chapter 13 (Hospital Licenses and Inspection), 39-1394 b and c: *Clinical laboratory test records and reports may be destroyed five (5) years after the date of the test recorded or reported therein, pursuant to paragraph (d) of this subsection.*

2) §493.1105 Standard: Retention requirements: *(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting.*

A: Thank you for the question. Record retention is very important and we appreciate you asking for guidance in this area. After reviewing the statute you sent, we have determined that Title 39 Chapter 13 pertains to patient test results in the patient's electronic medical record (EMR) or chart; these results should be retained for five years. The federal regulation to retain records for two years extends to all laboratory records, not just patient test results. This includes quality control (QC), calibration, reports, and patient data.

To be in compliance with both regulations, we suggest you maintain patient test results for five years and all other laboratory records for at least two years for your CLIA inspections. There is one exception, however, with validation studies which must be maintained for the life of the instrument or test system but no less than two years (§493.1105(a)(3)(i).

Introducing the IBL Biorepository

Matthew Burns

A Biorepository is a curated collection of living things preserved for their historic, conservation, scientific, or medical significance. Idaho Bureau of Laboratories (IBL) has begun building its own biorepository populated from bacterial specimens received from across the state. Under this program, when IBL is sent a specimen for identification it is preserved, catalogued, and stored in the biorepository. The specimens in the biorepository are primarily reportable illnesses but also include environmental samples and bacteria with interesting phenotypes such as drug resistance or unusual infectivity.

This bacterial library is intended to be a resource for clinical, academic, and public health activities statewide. Specimens can be revived for test verification, proficiency testing, case comparison, whole genome sequencing, and even antimicrobial research. You can also help populate the biorepository by answering our "call for samples" in the Clinical Forum and other communications from IBL. If you have any questions regarding the biorepository or want to request samples, please contact Matthew Burns at 208-334-0567 or Matthew.Burns@dhw.idaho.gov, or submit a request through the Isolate or Specimen Request Application at www.statelab.idaho.gov. IBL intends for the biorepository to become a valuable resource for the clinical and research community in Idaho and looks forward to your partnership on this exciting project!

2016 Needs Assessment

(Continued from page 1)

Clinical Testing page of the website at www.statelab.idaho.gov. Lastly, IBL is updating the website and will continue improvements to clearly convey information about services offered and improve access to resources.

Training needs were identified in Part C of the needs assessment. IBL will prioritize training topics that have generated the most interest (Figure 2). For example, IBL received funding to conduct on-site training in 2017 and plans to train laboratorians on biological risk assessments, biological safety, and packaging and shipping requirements. In addition, sentinel laboratory biological threat workshops and packaging and shipping training will be scheduled in 2017 in multiple locations.

To address the growing demand for online training modules (Figure 3), IBL launched an online training in 2016 titled "CLIA Regulations on Proficiency Testing: Online Training Course," available on the Training page of the website at www.statelab.idaho.gov. Online radiation safety training, a course for employees who use X-ray producing devices, is in development and will be launched in 2017. In addition, the Centers for Disease Control and Prevention Laboratory Training Branch (http://www.cdc.gov/labtraining/) offers online modules that are free of charge. Topics include basic microbiology, packaging and shipping, and biological terrorism.

Lastly, IBL will continue to meet the needs of our partners by addressing identified barriers to attending training (Figure 4). This can be done through on-site trainings with site visits and offering regional training sessions, in addition to further developing the online training menu.

The information collected from this year's needs assessment will guide activities in 2017. IBL thanks respondents for their participation and encourages additional feedback to be sent to wendy.loumeau@dhw.idaho.gov.

Figure 2. Word cloud representing interest in training topics where the larger the text indicates greater interest in the topic.

Figure 3. A summary of responses pertaining to training formats and time available for participants.

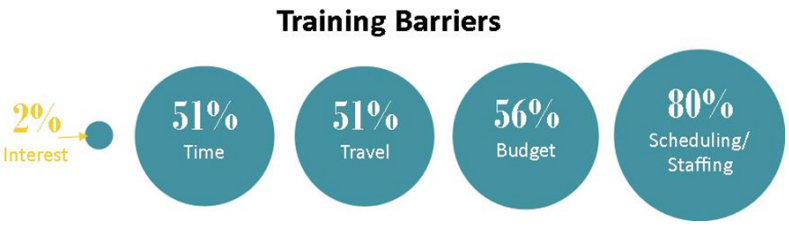

Figure 4. Respondents identified barriers encountered in attending training at IBL.

2016 Preparedness Survey Review

Wendy Loumeau

Idaho Bureau of Laboratories (IBL) has been sending preparedness surveys to Idaho's sentinel labs since 2005. The purpose of the surveys is to assess the ability of sentinel laboratories to recognize select agents of biological threat and emerging microbial pathogens and to assess each laboratory's available resources to perform testing related to potential biological threat (BT) agents.

Historically, the surveys were sent as lyophilized swabs purchased commercially that were then rehydrated in the recipient's lab. With the addition of a developmental science program, IBL is now able to lyophilize samples in-house, resulting in significant cost savings to the preparedness program. The specimens are now stabilized viable microorganisms lyophilized directly into a sterile vial instead of a swab. Participating labs are provided with rehydration fluid and directions for hydrating the samples.

IBL sent vials for all three of the 2016 surveys and has compared a few factors to determine the impact of this change. Figure 1 shows the rates of completion for 2015 and 2016 surveys. These rates were obtained by comparing the number of surveys sent to the number of results received. The difference of 4% was slight and could be attributed to other factors including laboratory workload and reagents available. The preparedness surveys are not a regulatory requirement, so completion rates vary between years.

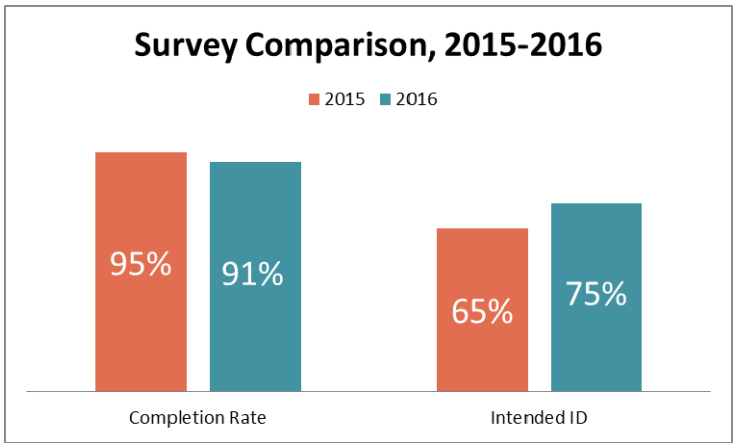

Figure 1. The Completion Rate compared the number of surveys sent to the number of results submitted and was similar in 2015 and 2016. The Intended ID indicates whether or not the identification of the specimen sent was correct. There was an increase in correct identifications from 2015 to 2016.

Figure 1 also shows the percentage of responses that were intended for each sample sent. For example, if *Bacillus anthracis*, Sterne strain was sent, the intended response would be "Gram positive bacillus, refer to rule out *Bacillus anthracis*." Sixty five percent of responses submitted in 2015 were correct, whereas 75% were correct in 2016. This indicates that the new sample type may be a slight improvement in the quality of specimens.

Feedback from a few laboratories reveals concern pertaining to removal of the vial cap. IBL recommends using forceps to open the vials in a biosafety cabinet to reduce contamination of specimens (Figure 2).

Figure 2. Unwrap the foil cap with gloved hands and then use forceps to carefully pry the lip of the plug away from the vial. Break the seal slowly as the vial is sealed under vacuum. Trying to grasp the entire plug is not recommended.

IBL thanks participants for their feedback and flexibility during this change. Contact Wendy Loumeau at wendy.loumeau@dhw.idaho.gov to provide additional feedback pertaining to the preparedness surveys.

Category A Packaging and Shipping Drill

Cassandra Dayan, MPH and Michael Stevenson, PhD

Idaho Bureau of Laboratories (IBL) facilitated a 2016 Category A Infectious Substances packaging and shipping drill for sixteen participating sentinel laboratories across the state. The drill was supported by the Epidemiology and Laboratory Capacity (ELC) Ebola supplemental grant. Certified staff packaged a Shiga toxin *E. coli* (STEC) culture, which was sent to them because it is illegal to ship a Category A labeled package without a suspected Category A sample inside the box. The package then was shipped via FedEx to either IBL or the Montana State Public Health Laboratory for evaluation.

Overall, participating labs did well in this drill. Issues encountered included the following:

- Supplying IBL with documentation of participants certified to package and ship Division 6.2 Infectious Substances
- Repackaging the STEC sample provided by IBL
- Labeling the outside of the shipping box
- Filling out the Shipper's Declaration of Dangerous Goods (DG) form
- Setting up the FedEx account to ship a Category A package

See Figure 1 for tips to get your Category A package to its destination.

Since practice is the best form of preparedness, IBL will plan to offer this drill again in 2017. We look forward to your participation to help ensure Idaho meets the appropriate packaging and shipping requirements for infectious substances.

Figure 1. Tips for shipping Category A Infectious Substances.

Select Agent Update

On September 14, 2016, the Federal Select Agent Program sent a notice of the publication of an Interim Final Rule that added *Bacillus cereus* Biovar *anthracis* as a Tier 1 Select Agent.

B. cereus Biovar *anthracis* infections mimic anthrax infections and have the potential to pose a severe public health threat. This organism is a **non-hemolytic, motile** *Bacillus* and shares virulence plasmids with *B. anthracis*. These plasmids can only be detected with molecular methods by the Laboratory Response Network for Biological Threats (LRN-B); the LRN-B laboratory at Idaho Bureau of Laboratories (IBL) performs these methods.

If your laboratory identifies a non-hemolytic *Bacillus* spp. **regardless of motility**, please call IBL at 208-334-0515 to refer the isolate for testing. Further information and guidance will be sent as needed.

Antibiotic Resistant Microbes

Matthew Burns

Antibiotic Resistant Microbes (ARMs) are a major growing threat to public health across the world. Unfortunately, for many illnesses we don't have a complete understanding of how common these ARMs are. To help address this, the CDC is requesting that each state collect specific ARMs, assess their antibiotic resistance, and then forward them to the CDC. If you come across any of the organisms listed, please send them to IBL.

Organism	Resistant to…	MIC*
Escherichia coli	Imipenem Meropenem Doripenem	≥4µg/mL
Klebsiella oxytoca		≥4µg/mL
Klebsiella pneumoniae		≥4µg/mL
Any *Enterobacter* species		≥2µg/mL
Pseudomonas aeruginosa	Imipenem Meropenem Doripenem Ertapenem	≥8µg/mL
and any unusual resistance patterns observed		

*Minimum Inhibitory Concentration

Happy Holidays from IBL!

Back row: Matthew Burns, Sonu Mathews, Vonnita Barton, Corrine Dalzell, Keith Klein, Courtney Meek, Lisa Lam, Michael Stevenson, Amanda Bruesch; Middle row: Mohammed Al Charakh, Robert Voermans, Erin Peterson, Kari Getz, Dan Rousselle, Gabe Kimlinger, Steve Gregoire, Rachel Beukelman, Lavanya Vempati, Ashley Machado, Kimberly Dillon, Kara Deobald; Front row: Russell Eck, Wendy Loumeau, Misty Daniels, Christopher Ball, Jeffrey Johnson

New Micro Senior

Mohammed Al Charakh was recently promoted to Microbiologist, Senior at the Idaho Bureau of Laboratories (IBL). He previously worked at IBL as a Biorepository Technician through an Idaho Department of Labor internship program to assist in preparing highly skilled workers the needed United States work experience. Mohammed then moved into a part-time temporary position continuing his work in IBL's biorepository.

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 his new position, Mohammed will be working in the Clinical section performing testing in the mycobacteriology, virology, and serology labs.

Upcoming Webinars

December 14, 2016; 12:00 pm Mountain Time
MALDI-TOF: Additional Applications

December 21, 2016; 11:00 am Mountain Time
Introduction to Basic Molecular Biology and Techniques

January 3, 2017; 11:00 am Mountain Time
Implementation of Molecular in the Laboratory: Optimizing Space and Workflow

January 12, 2017; 11:00 am Mountain Time
Quality Control, Quality Assurance, and Regulatory Issues

January 18, 2017; 11:00 am Mountain Time
Verification of Quantitative Assays

January 24, 2017; 11:00 am Mountain Time
Quantitative Assays and Standards

February 2, 2017; 1:00 pm Mountain Time
CLSI 2017 AST Update

February 7, 2017; 11:00 am Mountain Time
Verification of FDA Approved Tests

February 14, 2017; 11:00 am Mountain Time
Is that Amplicon Real? Dealing With Contamination in the Microbiology Lab

February 21, 2017; 11:00 am Mountain Time
New Diagnostics for Antimicrobial Resistance: Recent Advances and Considerations for Implementation

February 28, 2017; 11:00 am Mountain Time
Weighing the Cost and Benefit of Molecular Diagnostics for Stool

March 7, 2017; 11:00 am Mountain Time
Verification of Non-FDA Approved Tests

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