Idaho Bureau
of Laboratories

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Clinical Forum

Idaho Influenza Surveillance and Solicitation of Clinical Specimens

Vonnita Barton

IBL continues to serve as a World Health Organization Influenza Collaborating Laboratory to provide influenza surveillance on behalf of the Centers for Disease Control and Prevention (CDC) for the State of Idaho. Surveillance is performed for the following reasons: to detect the frequent genetic and antigenic shifts in these viruses; to rapidly identify the appearance of novel strains; to detect the emergence of antiviral resistance; and to provide the information needed to formulate vaccine components each year. This information is made available to Idahoans weekly on the Division of Public Health website at flu.idaho.gov along with other influenza surveillance data, and helps providers and citizens know more about how influenza is impacting Idaho.

IBL is once again asking our partners in the medical community to participate in surveillance by submitting a subset of respiratory specimens to us throughout the flu season. IBL accepts samples that have been previously tested for influenza (including positive and negative samples) or diagnostic samples that have not been tested. IBL performs RT-PCR for rapid identification of Influenza A and B, identification of Influenza A subtypes including seasonal and novel varieties, and Influenza B lineage genotyping. Our testing algorithm also includes antiviral resistance studies, and viral culture efforts for non-influenza respiratory viruses. IBL will provide patient results to submitters on RT-PCR and culture tests this season by mail or portal, but will not fax results on surveillance samples.

Nasopharyngeal and/or nasal swabs submitted in viral transport media are the specimens of choice; however, a complete list of acceptable specimens is found on the IBL Influenza Submittal Form. The form can also be downloaded from the IBL website (under Clinical Testing > Submission Forms).

Respiratory surveillance testing is free of charge, and a FedEx account number for free shipping of influenza samples to IBL can be provided upon request. Influenza collection kits consisting of swabs, transport media and submittal forms can be ordered at no charge on the IBL website (under the Bureau Guide menu on the right side of the home page) or by visiting this link. If you would like more information about participating in the Idaho influenza surveillance program, please contact the IBL Influenza testing group at (208) 334-0594. To learn more about influenza activity in the state, visit flu.idaho.gov.

Thank you for your participation!

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Lab Safety: Personal Protective Equipment

Michael Stevenson, PhD

The Occupational Safety and Health Administration (OSHA) defines personal protective equipment (PPE) as equipment worn to minimize exposure to hazards that cause serious workplace injuries and illnesses. Employers must provide appropriate PPE for employees and ensure that PPE is disposed or, if reusable, is cleaned, laundered, repaired, and stored after use. The CDC categorizes PPE as the last step in a hierarchy of controlling exposure to occupational hazards (visit this link for more information about the hierarchy of controls).

Use of PPE also involves monitoring behaviors, such as being careful to remove gloves before using a cell phone or handling ear buds. Staff may not know they have a "bad habit" (e.g., touching their glasses, rubbing their nose). It can be beneficial to ask a co-worker to observe you for a period of time to identifyany bad habits you may be unaware of.

Finally, all PPE policies should include lab staff washing hands after removing PPE and before leaving the lab. Consider having a dedicated sink for hand washing only, and place a sign at the lab door reminding staff to wash hands before leaving.

PPE Best Practices

Gloves

Materials

- nitrile, latex, vinyl
- sterile or non-sterile
- powder-free only

Recommendations

- Don't touch your face or adjust PPE with contaminated gloves.
- Change gloves whenever necessary; consider washing hands between glove changes.
- Discard used gloves in an appropriate receptacle; never wash or reuse.

Eye Protection

Types

- safety glasses
- face shields

Recommendations

- Find eye protection that is comfortable to wear.

Lab Coats

Materials

- synthetic, natural
- resistance to fluid penetration
- reusable or disposable
- lab coat vs. closed-front gown

Recommendations

- Choose a style that has snaps instead of buttons, and that has elastic cuffs.
- Change a lab coat whenever necessary.
- Do not take a lab coat home to launder; work facility should provide laundering services.

Respiratory Protection

Types

- Disposable N95, P95, N100, P100
- Powered air purifying respirator (PAPR)
- Half- or full-face mask respirator

N = not resistant to oil vapor
P = oil vapor resistant

Recommendations

- User must have initial medical evaluation, annual training, and fit-testing (qualitative or quantitative).

Hand Hygiene Tips

- Always wash hands after removing PPE.
- Use soap and water or an alcohol-based hand rub.
- Recite the alphabet for proper duration, and get solution under the fingernails.
- Post signage at sinks designated for hand washing only, and have a sign at the lab exit door reminding staff to wash hands.

Anti-Fungal Resistant *Candida*

Matthew Burns

Across the US, drug-resistant *Candida* bloodstream infections have become a growing concern. In previous Clinical Forum articles, we have highlighted the highest profile species, *Candida auris*, and discussed its common misidentification as other more common *Candida* species. As understanding of this issue has grown, concern about anti-fungal resistance has spread from *Candida auris* to all *Candida* species (except *C. albicans*) isolated from normally sterile sites.The Antibiotic Resistance Laboratory Network (ARLN) is supporting efforts to contain drug-resistant *Candida* at three levels:

Idaho Bureau of Laboratories (IBL)

IBL currently performs ribosomal large subunit gene sequencing on fungal isolates that are difficult to identify using conventional testing methods. Depending on the particular sequence this can provide definitive species identification, or narrow the ID down to closely related species. In cases of suspected outbreaks, IBL can also help to facilitate direct shipping of target *Candida* isolates to our regional ARLN lab.

Regional ARLN Laboratory

The Texas Department of State Health Services Laboratory, Idaho's ARLN regional laboratory, currently provides molecular confirmation of *Candida* species identification and colonization and environmental sampling in the case of an outbreak anywhere in the mountain region. Anti-fungal susceptibility testing is currently being validated and will be available soon.

The Centers for Disease Control and Prevention (CDC)

The CDC curates a national isolate bank of multi-drug resistant *Candida* and offers a variety of resources for laboratories and providers on dealing with *Candida* in their facilities. These resources can be accessed at CDC.gov. Additionally, regional laboratory results can be confirmed, and more in-depth characterization can be performed to inform national public health action.

Illustration (right): CDC

ASM Updated Protocols for Suspected Biothreat Agents

Michael Stevenson, PhD

In coordination with the CDC and the Association of Public Health Laboratories (APHL), the American Society for Microbiology (ASM) has updated protocols designed to offer Laboratory Response Network (LRN) sentinel level clinical laboratories standardized, practical methods and techniques to rule out microorganisms suspected as agents of bioterrorism, or to refer specimens to public health laboratories for confirmation. Please visit ASM.org for further information, which includes the following topics:

- LRN Information
- Definition of LRN Sentinel Laboratories
- Introduction, General Recommendations and Biochemical Test Procedures
- Biological Safety
- Biothreat Agent Guidelines: *Bacillus anthracis*, *Brucella* species, *Burkholderia* species, *Yersinia pestis*, *Francisella tularensis*, and more

AMERICAN SOCIETY FOR MICROBIOLOGY

Logo courtesy ASM

training

teaching (a person) a particular skill or type of behavior through practice and instruction over a period of time.

competency

the ability to use knowledge and skills, acquired through training, to perform laboratory duties.

Got a question?

Drop us a line! Email labimprovement@dhw.idaho.gov for your CLIA-related questions.

Ask the Auditor

Jennifer Street

Question:

On our laboratory's recent CLIA survey, the lab was cited for not having documented training for the testing staff, although we perform competency assessments. Does the lab need to have additional training documented?

Answer:

The short response to this question is "Yes." The definitions of *training* and *competency* are not the same.

It is the Laboratory Director's responsibility to ensure that prior to testing patient specimens, all testing personnel have the appropriate education, experience, and training for the type of testing being performed, whether the testing is of moderate or high complexity.

The laboratory's training program should be performed according to the lab's policies and procedures and/or the manufacturer's instructions for the test system. Personnel must have their training completed and documented prior to performing tests on patient specimens. It is also the Laboratory Director's responsibility to ensure testing personnel are competent to perform approved laboratory procedures; however, it is the Technical Consultant or Technical Supervisor's[1] responsibility to evaluate the competency of the testing personnel.

The following six procedures are the regulatory requirements for competency assessment of all laboratory testing personnel, consultants, and supervisors who perform laboratory testing:

1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing
2. Monitoring the recording and reporting of test results
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. Direct observations of performance of instrument maintenance and function checks
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples
6. Assessment of problem solving skills

Training employees should be an active learning process that is documented and followed through with knowledge retention transferred to the bench. Competency assessment is a fluid process that occurs throughout the year so as to not have a big impact on the workload of staff. When you are inspected, how can you demonstrate to your inspector that personnel competency assessment was not just a checked box?

See the CLIA brochure, "What Do I Need To Do To Assess Personnel Competency?" for more specific information and a list of frequently asked questions.

For more information, please refer to the CLIA Regulations and Interpretative Guidelines for Laboratories.

[1]Or a person that meets the requirements to fulfill the role of Technical Consultant or Technical Supervisor.

Shipping Suspected Rabies or High Consequence Pathogens to IBL

Vonnita Barton

IBL frequently receives animal heads, brains, or intact bats for rabies testing. IBL also sees animal samples related to testing for high consequence pathogens (e.g., rule-out for *Yersinia pestis* (plague) or *Franciscella tularensis* (tularemia)). These samples must be packaged and shipped per the Department of Transportation's strict regulations. Not following these regulations can result in significant fines and penalties for the shipper if an accident occurs during transport that causes release of the sample.

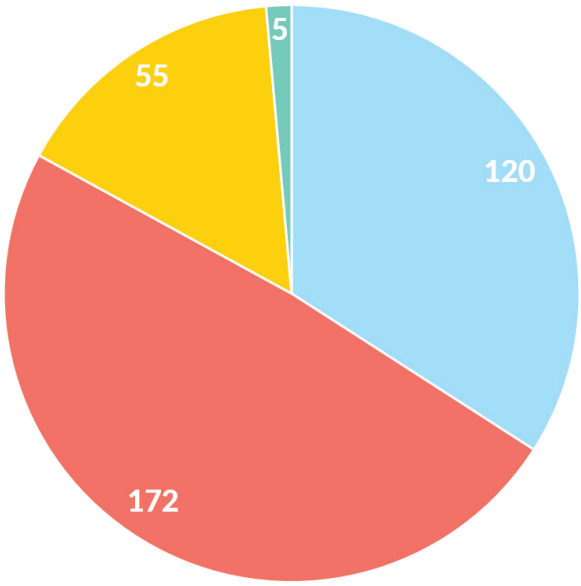
Suspect rabies and high consequence pathogen samples are considered "Category B" shipments because they contain potentially infectious materials. IBL has received several questions relating to proper packaging of these types of samples. To address these common questions, we have produced a laminated poster that outlines the required packaging and shipping steps. This poster has been mailed to our clients, including veterinary clinics and humane societies who are responsible for properly transporting animal remains to IBL for testing. The poster may also be found on the IBL website (under Clinical Testing > Packaging and Shipping) or by visiting this link.

One side of the poster addresses shipment of a suspect rabies sample, and the other side has information on shipping high consequence pathogens. If you did not receive a poster, but would like one, please contact the IBL Rabies Lab at (208) 334-0593.

IBL Biorepository

Angelo Sanfilippo

Since 2015, IBL has maintained a curated collection of preserved microorganisms collected from samples encountered in regular testing activities. This biorepository is available to clinical and research laboratories for use in test validation, as control material, or for specific research projects. The IBL biorepository offers over 9000 isolates ranging from aerobes to anaerobes, and *Abiotrophia* to *Xenophilus*. It continues to grow with nearly 700 new isolates acquired yearly. The specimen request application can be found on the homepage of the IBL website (under Bureau Guide > Data, Isolate, or Specimen Request Application).



Number of requested specimens by requester category

September 2017 through August 2018

- Hospital Laboratories
- State Programs
- Federal Programs
- Independent Laboratories

Total = 352

Syphilis Traditional vs. Reverse Testing Algorithm

Vonnita Barton

Syphilis has been documented as a disease as early as the 1500s, but the causative agent, *Treponema pallidum*, was not identified until 1905. Direct detection methods of the spirochete in conjunction with indirect detection by serologic assays are used for syphilis diagnosis, and a positive diagnosis relies on results for both nontreponemal and treponemal antibodies.

Serologic nontreponemal tests measure anti-lipid antibodies, or reagin antibodies, that bind to a cardiolipin-lecithin-cholesterol mixture. This mixture is formed by the host in response to lipids released from damaged host cells early in the infection with *T. pallidum*. In contrast, serologic treponemal tests detect antibodies to specific antigenic components of *T. pallidum* itself.

The traditional serologic syphilis testing algorithm begins with a nontreponemal assay (e.g., rapid plasma reagin (RPR) test or Venereal Disease Research Laboratory (VDRL) test) that is used for screening. If a positive result occurs, a follow-up treponemal test (e.g., *T. pallidum* particle agglutination (TP-PA) test or enzyme immunoassay (EIA) test) is performed to confirm a positive test result. Nontreponemal tests historically have the advantage of being widely available, inexpensive, convenient to perform with large numbers of specimens, and are useful for determining the efficacy of treatment. Limitations of the nontreponemal tests include their lack of sensitivity in primary and late syphilis, the possibility of a prozone phenomenon (high antibody titers that can interfere with the assay), and false-positive results.

The reverse serologic syphilis testing algorithm uses a treponemal assay for screening of populations with low prevalence of the disease and is then followed by a non-treponemal test (such as RPR) if positive. This algorithm has been formalized since serologic treponemal immunoassays have been developed and allows for higher throughput with objective (unbiased) results that detect IgG and/or IgM antibodies against *T. pallidum*. The reverse algorithm may identify past infections previously undetected with the traditional algorithm and has the potential to detect early infections, but cannot distinguish between early or late infections. This approach might be more attractive to laboratories that have high testing volumes and where the manual labor involved with non-treponemal tests is no longer appropriate for laboratory workflow and staffing needs.

The selection of the testing algorithm used in a facility should take into consideration factors such as prevalence, which indirectly affects positive and negative predictive values, as well as testing volume and throughput, labor needs, sensitivity, specificity, turnaround time, and cost.

IBL serves as a confirmation laboratory for clinical labs in Idaho by performing the traditional testing algorithm using the nontreponemal VDRL for screening and the quantitative nontreponemal assay (VDRL-Q) to determine end-point antibody titers for disease and treatment progression. This is followed by the TP-PA test for treponemal antibody detection.

Photomicrograph (left): CDC

About Idaho Bureau of Laboratories

The role of IBL is to provide laboratory services that support the programs in the Department of Health and Welfare, the seven public health districts, other state agencies, and Idaho residents. IBL offers services in four areas: testing, inspection, training, and outreach. IBL is certified by the Environmental Protection Agency for drinking water analysis and by the Centers for Medicare and Medicaid Services as a high-complexity clinical laboratory. IBL is also a registered entity with the Centers for Disease Control and Prevention's Division of Select Agents and Toxins, and is the only Laboratory Response Network reference laboratory for the confirmation testing of biological and chemical threat agents in Idaho.

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IDAHO DEPARTMENT OF HEALTH & WELFARE
DIVISION OF PUBLIC HEALTH

Updates

IBL Website Resources

Amanda Bruesch, MS

CLIA Checklist

The Idaho CLIA program has created a checklist of the federal CLIA regulations that laboratories can use to review the CLIA requirements and perform internal audits. It is our hope that this resource will help make the regulations more accessible for laboratories and help your lab identify areas that need additional attention and effort to be prepared for your next inspection. Visit the Checklist tab of the Clinical Laboratory Certification page to access this resource.

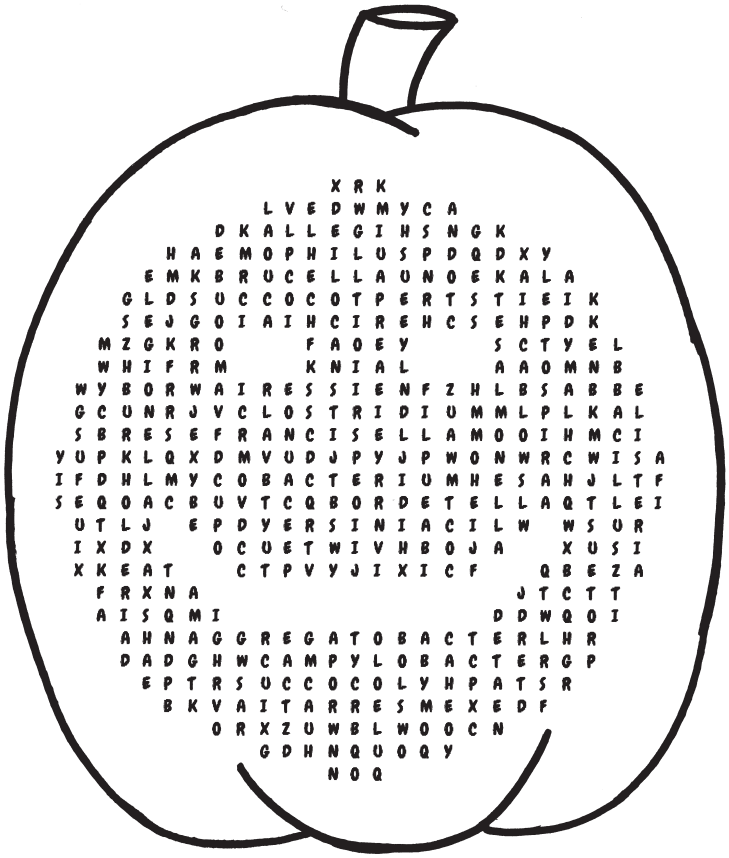
FDA Recall Information

The Idaho CLIA Program now has a link to the current FDA recall of medical devices, including all types of medical devices such as laboratory test systems and reagent kits. Visit the Recalls tab of the Clinical Laboratory Certification page to access this link, and then select the year you want to view or search the device recall database.

National Ebola Training and Education Center (NETEC) Free Online Courses

NETEC offers free online courses for continuing education credit. One relevant course is on special pathogens of concern and will discuss infectious, communicable, and hazardous issues related to these pathogens. Visit NETEC.org/training for more information, and for announcements on upcoming hands-on workshops throughout the year.

Bloodcurdling Bacteria Halloween Word Search



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SHIGELLA
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