



# Clinical Forum

## HAVE YOU HEARD OF *CANDIDA AURIS*?

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*Candida auris* is an emerging fungal pathogen that causes serious infection and is often resistant to multiple classes of antifungal therapies. During 2012–2015, the mortality rate among patients with *C. auris* infection was 30%–60%.<sup>1</sup> Certain *C. auris* isolates have demonstrated resistance to all three classes of antifungals, including polyenes (e.g., amphotericin B), triazoles (e.g., fluconazole), and echinocandins (e.g., micafungin).

*C. auris* has been linked to healthcare facility outbreaks, and the Centers for Disease Control and Prevention (CDC) infection prevention recommendations require that patients with *C. auris* be placed on Standard and Contact Precautions.

*C. auris* can persist on surfaces in healthcare settings, and routinely-used quaternary ammonia disinfection products may not be effective against *C. auris*. When *C. auris* is identified in a facility, CDC recommends daily and terminal cleaning with an Environmental Protection Agency-registered, hospital-grade disinfectant that is effective against *Clostridium difficile*.<sup>2</sup>

First identified in 2009 from the external ear canal discharge of a hospitalized patient in Japan, *C. auris* has been identified in patients from 20 countries and five continents.<sup>3</sup> The first known U.S.

(Continued on page 2)



<b><i>Candida auris</i> Clinical Snapshot</b>	
<b>What is it?</b>	Multidrug resistant yeast
<b>Mortality rate</b>	30%–60%
<b>Drug resistance</b>	Resistance testing has shown that ~90% of isolates were resistant to fluconazole, ~40% were resistant to amphotericin B, and ~5% were resistant to echinocandins.  Certain isolates have demonstrated resistance to all three classes.
<b>Commonly isolated from</b>	Blood (~54% of cases) and other sites, including urine, wounds, sputum, and bile

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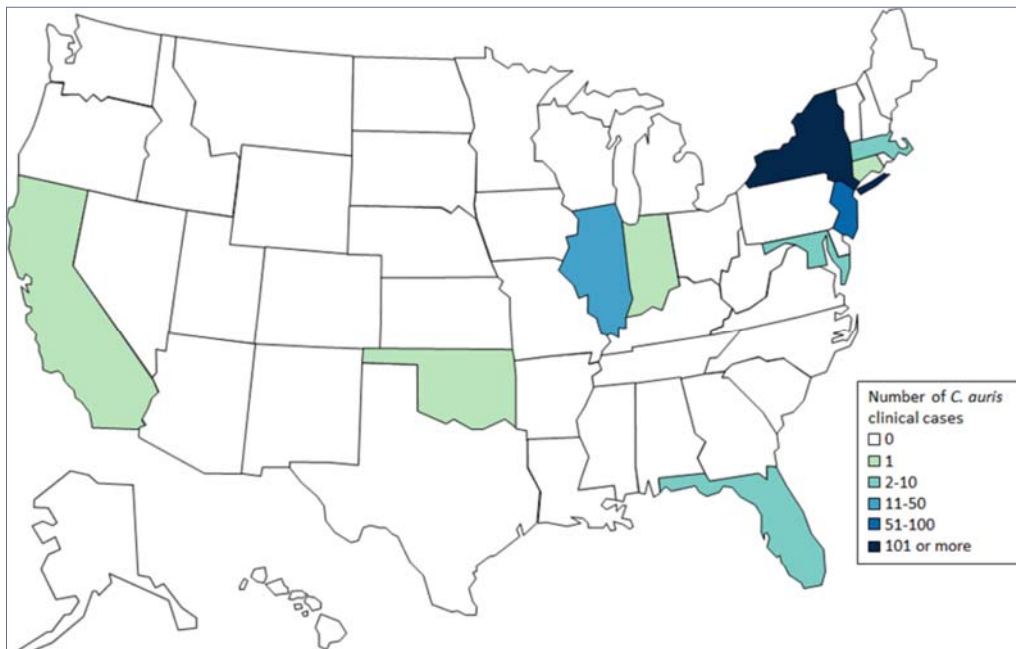


Figure 1. Clinical cases of *Candida auris* reported by state, United States, as of December 31, 2017

Source: CDC <https://www.cdc.gov/fungal/diseases/candidiasis/tracking-c-auris.html#caseconfirm>

## ADDITIONAL *C. AURIS* RESOURCES

Algorithm to identify *Candida auris* based on biochemical laboratory method and initial species identification: <https://www.cdc.gov/fungal/diseases/candidiasis/pdf/Testing-algorithm-by-Method-temp.pdf>

*C. auris* factsheet: *Candida auris*: A drug-resistant germ that spreads in healthcare facilities: [https://www.cdc.gov/fungal/diseases/candidiasis/pdf/Candida\\_auris\\_508.pdf](https://www.cdc.gov/fungal/diseases/candidiasis/pdf/Candida_auris_508.pdf)

CDC's Clinician Outreach and Communication Activity (COCA) Webinar Recording on *Candida auris* (August 15, 2017): [https://emergency.cdc.gov/coca/calls/2017/callinfo\\_081517.asp](https://emergency.cdc.gov/coca/calls/2017/callinfo_081517.asp)

CDC recommendations on when to conduct species-level identification from non-sterile sites: <https://www.cdc.gov/fungal/diseases/candidiasis/c-auris-alert-09-17.html>

CDC recommendations for infection prevention and control for *Candida auris*: <https://www.cdc.gov/fungal/diseases/candidiasis/c-auris-infection-control.html>

Morbidity and Mortality Weekly Report (MMWR) Notes from the Field: Ongoing Transmission of *Candida auris* in Health Care Facilities — United States, June 2016–May 2017: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6619a7.htm>

## *C. AURIS* REFERENCES

<sup>1</sup>Tsay, S., et al. (2018). Approach to the Investigation and Management of Patients With *Candida auris*, an Emerging Multidrug-Resistant Yeast. *Clin Infect Dis* **66**(2): 306-311. <https://academic.oup.com/cid/article-abstract/66/2/306/4083688?redirectedFrom=fulltext>.

<sup>2</sup>CDC (2017). "Fungal Diseases - Healthcare Professionals - Recommendations for Infection Prevention and Control for *Candida auris*." from <https://www.cdc.gov/fungal/diseases/candidiasis/c-auris-infection-control.html>.

<sup>3</sup>Lockhart, S. R., et al. (2017). Simultaneous Emergence of Multidrug-Resistant *Candida auris* on 3 Continents Confirmed by Whole-Genome Sequencing and Epidemiological Analyses. *Clin Infect Dis* **64**(2): 134-140. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5215215/>.

<sup>4</sup>CDC (2017). "Fungal Diseases - Healthcare Professionals - Recommendations for Identification of *Candida auris*." from <https://www.cdc.gov/fungal/diseases/candidiasis/recommendations.html>.

<sup>5</sup>CDC (2017). "Algorithm to identify *Candida auris* based on biochemical laboratory method and initial species identification." from <https://www.cdc.gov/fungal/diseases/candidiasis/pdf/Testing-algorithm-by-Method-temp.pdf>.

## HAVE YOU HEARD OF *CANDIDA AURIS*?

(Continued from page 1)

*C. auris* case was reported in a New York resident in May 2013; the majority of reported U.S. *C. auris* cases have been concentrated in the northeast (Figure 1). However, cases are increasingly being reported elsewhere in the United States. For example, as of May 2017, transmission of *C. auris* in an Illinois long-term care facility was documented in a cluster of four cases. By February 2018, 19 clinical cases had been reported from multiple facilities in Illinois. California also reported its first clinical case of *C. auris* in 2017.

CDC recommends species-level identification of all *Candida* isolates obtained from a normally sterile site. Because colonization with *C. auris* might pose a transmission risk and require infection control precautions, species-level identification of isolates from nonsterile sites is also encouraged under certain circumstances.<sup>4</sup> However, *C. auris* identifica-

tion can be challenging. Common identification systems have misidentified *C. auris* as other yeast species, most commonly, *Candida haemulonii* (Table 1). No cases of *C. auris* have been reported in Idaho; however, given the 2017 case in California and dynamic population movement in Idaho, knowledge of *C. auris* and the ability of commonly used laboratory identification systems to identify the fungal pathogen are key to our ability to generate prompt and correct clinical and public health responses.<sup>5</sup>

Laboratories are encouraged to send clinical samples or isolates of confirmed or suspected *C. auris* to the Idaho Bureau of Laboratories (IBL) for additional testing. For support in interpreting results, particularly when laboratory misidentification is suspected, please consult Matthew Burns at IBL at 208-334-0567 or [matthew.burns@dhw.idaho.gov](mailto:matthew.burns@dhw.idaho.gov).

**Table 1: Summary of Instruments and Common Misidentifications of *Candida auris***

Identification System	Organism <i>C. auris</i> can be misidentified as the following
Vitek®† 2 YST	<i>Candida haemulonii</i> <i>Candida duobushaemulonii</i>
API®§ 20C	<i>Rhodotorula glutinis</i> (characteristic red color not present) <i>Candida sake</i>
BD Phoenix®¶ yeast identification system	<i>Candida haemulonii</i> <i>Candida catenulata</i>
Microscan®**	<i>Candida famata</i> <i>Candida guilliermondii</i> * <i>Candida lusitanae</i> * <i>Candida parapsilosis</i> *

Source: Centers for Disease Control and Prevention

Note: This list is based on knowledge about *C. auris* misidentification. This information might change as more is learned about misidentification of *C. auris*. Recommendations are continuously updated and can be found at <https://www.cdc.gov/fungal/diseases/candidiasis/recommendations.html>.

† Vitek® 2 YST (bioMérieux, Marcy l'Etoile, France).

§ API® 20C (IHS Markit, Englewood, California).

¶ BD Phoenix™ (Becton, Dickinson and Company, Franklin Lakes, New Jersey).

\*\* Microscan® (Beckman Coulter, Incorporated, Indianapolis, Indiana).

## PACKAGING AND SHIPPING: MOT EXCEPTION

MICHAEL STEVENSON, PHD

To be certified to ship Division 6.2 infectious materials, a shipper must complete training on the hazardous materials (HazMat) regulations as specified in the Department of Transportation (DOT) Title 49, Code of Federal Regulations (49 CFR), Parts 171-180. Facility-specific training is also required, and ultimately it is the employer who gives authorization for staff to package and ship infectious materials.

Division 6.2 Category A and Category B packages must be appropriately marked and labeled before given to the shipping company (e.g., FedEx). This includes triple packaging the sample, placing a biohazard symbol inside the outer package, and including the appropriate labels and markings on the outer box (e.g., UN3373 Biological Substance, Category B or UN2814 Infectious Substance, Affecting Humans).

There is a Materials of Trade (MOT) Exception (49 CFR 173.6) that allows a shipper to transport infectious material by motor vehicle without having to comply with all Division 6.2 HazMat regulations. The following requirements must be met:

- Category B samples only (not Category A)
- Patient specimens (not cultures)
- Transported by motor vehicle only
- Couriers whose service is only to transport samples (not industry carriers like taxis)

With the MOT Exemption, triple packaging is not required. Instead the sample can be packaged as follows:

- The sample must be in a primary receptacle (leak-proof and sealed with tape or parafilm).
- It is recommended to place the primary receptacle and test submission form in a plastic bag or stat bag (not paper bag).
- The primary receptacle is put in an exterior package of adequate size and strength (e.g., cooler), which is secured against movement in the vehicle.
- A proper description must be on the exterior package (e.g., "blood samples" or "clinical specimen").
- A biohazard label must be on the primary receptacle or outer package.

For more information, contact Michael Stevenson at IBL at [michael.stevenson@dhw.idaho.gov](mailto:michael.stevenson@dhw.idaho.gov) or 208-334-0569.

# IDAHO CLIA PROGRAM—2017 YEAR IN REVIEW

JENNIFER STREET

A review of top-cited Idaho deficiencies identified by Idaho Bureau of Laboratories (IBL) staff in 2017 was conducted, and it revealed common challenges experienced by laboratories. This is a good time to review a couple of the top-cited regulations and provide you with resources.

Of the citations written in 2017, 109 citations were written in the Analytic Systems, and 41 citations were written in the Proficiency Testing (PT) section of the CLIA regulations (Figure 1). One of the most commonly cited deficiencies (known as D-tags) occurred when a lab had poor PT performance. A lab will be cited for failing two PT events in a row, or two out of three PT events for the same analyte. For example, if a lab scores a 60% on sodium for the first PT event of the year, and then on the next event, the lab forgets to submit the scores for all the chemistry analytes and receives '0' scores for all Chemistry analytes then the lab has failed two events in a row for the analyte sodium. At this point the lab would receive a CMS-2567, Statement of Deficiencies, that lists the D-tags, or regulations that the lab is out of compliance with. The lab must respond to the deficiencies and undertake actions to correct the problem that lead to the failures and prevent the problem from recurring. If the lab fails another event within the next two PT events, the lab may be subject to sanctions by the CMS Regional office, which can include not being able to perform testing on patient specimens in the specialty area of the failures, civil money penalties, or even revocation of the lab's CLIA certificate.

Another area similar to proficiency testing that is often misunderstood is biannual verification. A lab is required to subscribe to a proficiency test program for regulated analytes that it tests. You can find the list of regulated analytes on page 7 of the CMS-116 Application found at <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>. For all non-regulated analytes that a lab tests, they are required to document twice each year that they can accurately perform the test. For example, a physician office lab performs only two microscopic tests, KOH and urine sediment examination. Both tests are not regulated analytes and therefore require biannual verification. Biannual verification can be performed in a number of different ways such as subscribing to a commercial proficiency test program, performing testing on a blinded panel, or splitting samples with another lab and comparing the results each lab obtained. It is important to document the testing for biannual verification and rotate among staff that perform patient testing to demonstrate accuracy. The *CLIA Regulations on Proficiency Testing* training on the IBL website clarifies differences between PT and biannual verification and discusses a lab's responsibilities in this area.

By far the most deficiencies cited in 2017 were in the Analytic System section of the CLIA regulations, 42 CFR Part 493.1250, which covers the requirements for the entire testing process. One important area that is often overlooked is the laboratory director's responsibility for verifying that all tests offered in the lab have approved procedures which are signed and dated by the lab director. In a situation where a lab uses the manufacturer's instructions as the procedure manual, the director's review and approval is still required for those instructions. This director responsibility cannot be delegated to another person in the lab. Another misconception is the director must review these procedures on a yearly basis, but this is not required by CLIA; approval is only required in cases of changes to a procedure or when new procedures are added.

Quality control, which is part of the Analytic Systems regulations, was also a common problem throughout Idaho. The CLIA regulations for quality control (QC) state that QC must be performed according to the manufacturer's recommendation for a test system or as established in the laboratory when they meet or exceed at least two levels of control once each day patient specimens are examined. In layman's terms, this means that QC must include at least two levels (positive/negative or low/high values) and be performed each day that patient specimens are tested. The manufacturer may recommend, or the laboratory may have established, QC that includes more than just two levels. If so, the lab must follow these more stringent QC procedures. Labs have asked if this applies to KOH/wet preps and urine sediment exams. The quality control for these procedures will be considered as met if the lab has available reference material such as photomicrographs, charts, or books. Many of the cases where QC was cited were due to the lab not having an Individualized Quality Control Plan (IQCP) for a test system where the lab was not performing two levels of QC each day. This was seen in a number of microbiology labs, particularly for culture media used in the lab. The education period for writing IQCPs has come and gone, so this is time to review the quality control requirements and ensure all procedures in your lab have QC that meets the CLIA default or have an IQCP written.

## FIND IT ONLINE

Visit the IBL website ([www.statelab.idaho.gov](http://www.statelab.idaho.gov)) => **Clinical Laboratory Certification** => **Resources and Training** tabs for more information.

*Resources listed on the website:*

- **Self-Evaluation of Proficiency Testing** form: for use when results are returned 'Ungraded'
- **Proficiency Test Assessment and Corrective Actions** form: for use when identifying problems in proficiency testing and documenting corrective actions taken

*Trainings listed on the website:*

- **CLIA Regulations on Proficiency Testing:** this training will provide answers to common questions regarding proficiency testing requirements under CLIA

**Upcoming in April 2018:**

- A new interactive CLIA checklist

## REFERENCES:

142 CFR Part 493, Subpart I – Proficiency Testing Programs for Nonwaived Testing: <https://www.law.cornell.edu/cfr/text/42/part-493/subpart-I>

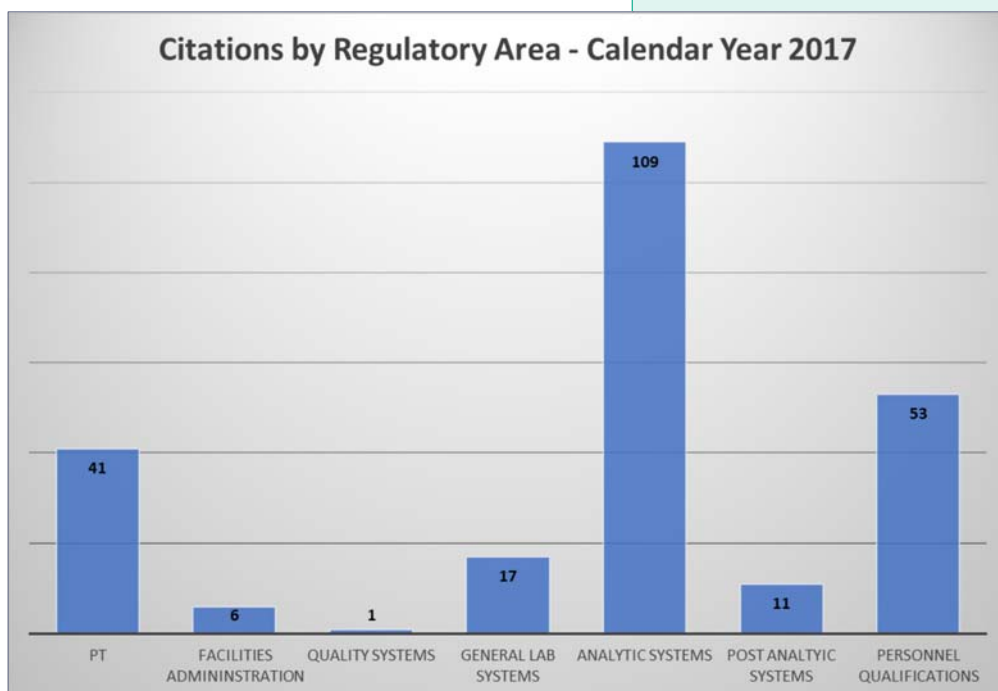


Figure 1. The number of citations by regulatory area of the CLIA regulations 42 CFR part 493 in Idaho for the calendar year 2017.

# NONTUBERCULOUS MYCOBACTERIUM (NTM)

STEVE GREGOIRE

Idaho Bureau of Laboratories (IBL) uses two methods for identifying mycobacterium recovered in the laboratory: DNA-RNA hybridization probes and partial 16S rDNA sequencing. Since there are approximately 200 NTM species currently characterized, it is important to understand their significance to patient disease.

While the public health consequence of *Mycobacterium tuberculosis* is unparalleled compared to NTM, some NTM can have substantial clinical implications. The majority of NTM are identified as *M. avium complex* (MAC), *M. gordonae* or *M. abscessus/chelonae*. The three combined represent 85% of NTM identifications made at IBL. All are ubiquitous and can cause human disease, with the elderly and immunocompromised being the most susceptible. Middle-aged and elderly women of low body mass and individuals with advanced HIV disease are at higher risk of lung disease caused by MAC. Whereas, cystic fibrosis patients and persons with chronic lung conditions are at greater risk of *M. abscessus/chelonae* infection. *M. gordonae* is the least pathogenic and is generally considered a contaminant however, there are rare cases of *M. gordonae* infections in patients with serious health issues. The long-term treatment and medical cost of chronic NTM disease is a significant healthcare concern that will only worsen with the projected increase of the elderly population.

Both MAC and *M. gordonae* are considered slow growing mycobacteria, typically taking 3-4 weeks before growth is visible on solid media such as Middlebrook 7H11. *M. gordonae* has yellow-orange pigmentation with colony morphology that is round, smooth, convex and glistening. MAC is a non-photochromogenic organism with buff to yellow pigment production with heterogeneous colony morphology that is thin, transparent, glistening or matte. MAC can be smooth and/or rounded with some older colonies appearing rough and wrinkled. *M. abscessus/chelonae* is a rapidly growing mycobacterium with growth on 7H11 media in less than 7 days with buff colonies that are smooth or matte with some scalloping and no branching filaments.

Figures A and B show NTM species identified at IBL from 2015 to 2017. These reveal that while MAC is most frequently identified, we have seen close to 20 different NTM species. This speciation can assist in treatment decisions and improve outcomes for patients. See the *Mycobacterium* spp. Identification Sampling and Submission Guide, accessed from the State Lab website ([www.statelab.idaho.gov](http://www.statelab.idaho.gov)), for more information on submitting samples for NTM identification.

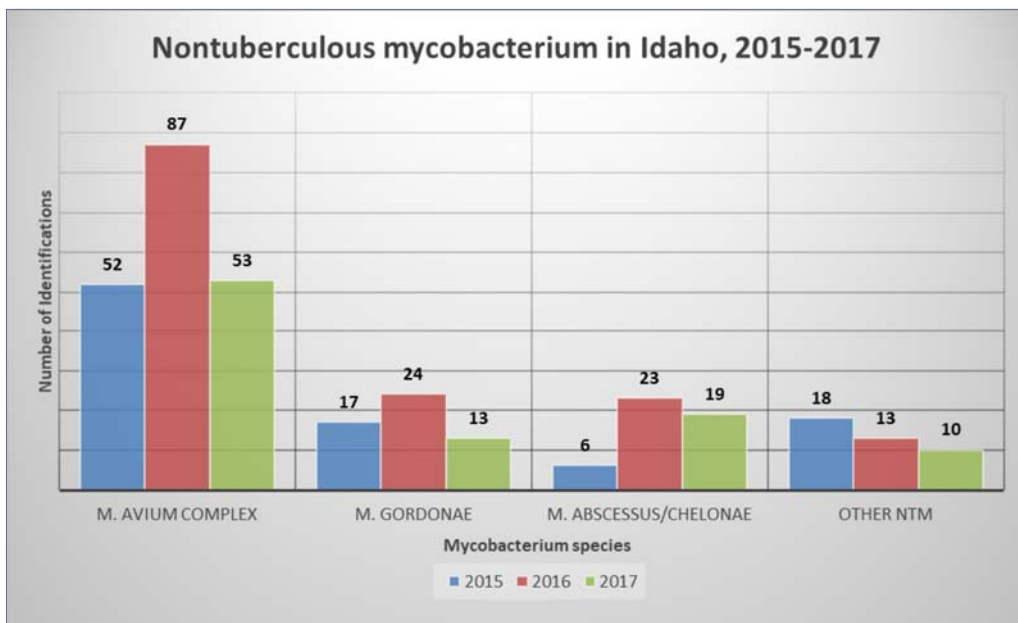


Figure A. *M. avium complex* has been the most predominant NTM strain in Idaho from 2015-2017.

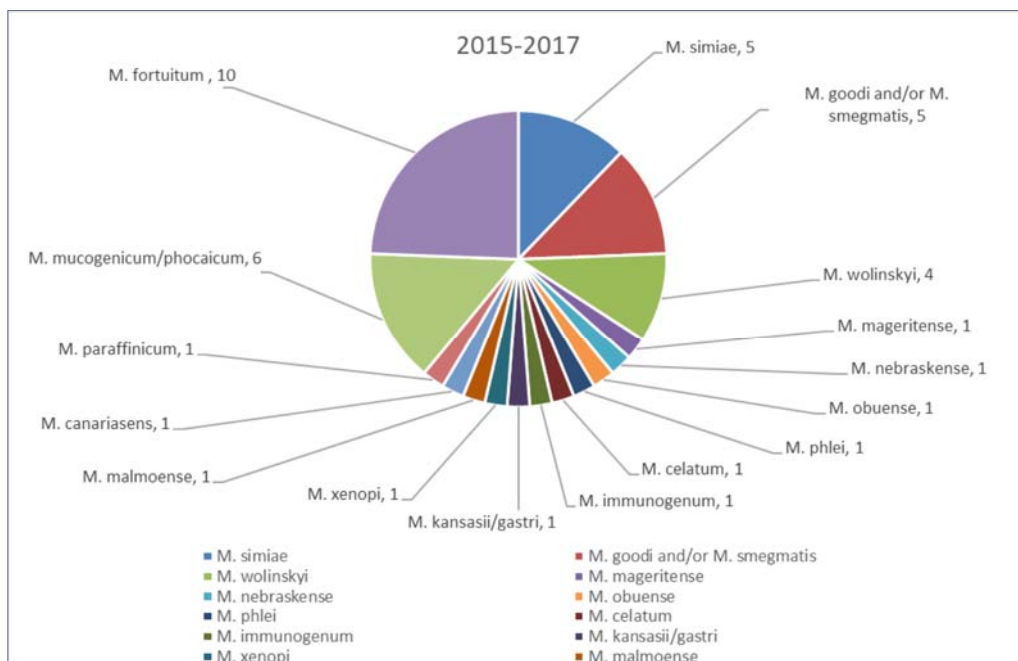


Figure B. Chart of "Other NTM" by IBL from 2015 to 2017.

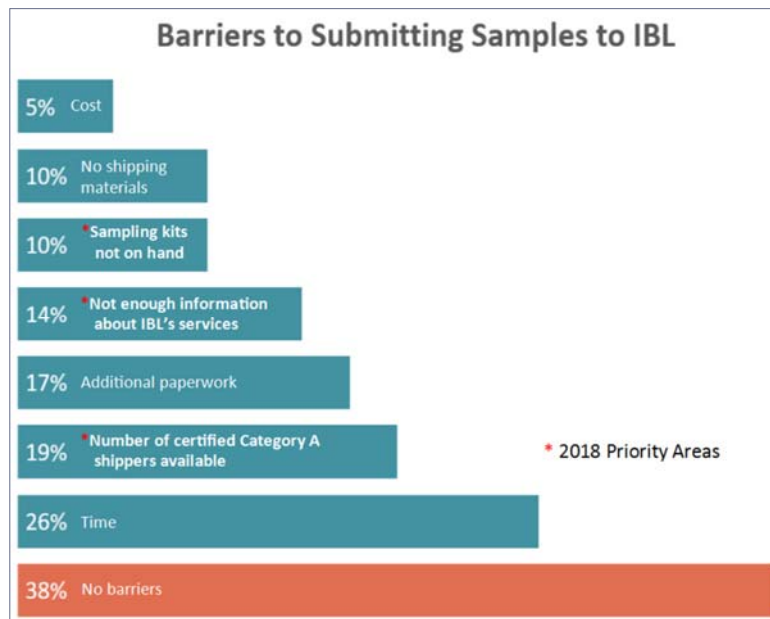


Figure 1. 2018 priorities for IBL were developed from barriers identified by needs assessment respondents.



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

## ASSESSING TRAINING NEEDS IN IDAHO

WENDY LOUMEAU, MPH

This fall, Idaho Bureau of Laboratories (IBL) conducted its annual partner needs assessment. The assessment solicits information from IBL's partners to assist training and outreach efforts for the following year. This year, 45 individuals responded from 34 clinical laboratories and 4 public health agencies.

Part A of the assessment collected information to update the laboratory contact list database. IBL created multiple distribution lists from this information to delineate notification needs among respondents. 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. The assessment asked about barriers encountered when submitting samples to IBL. Figure 1 on page 4 reveals that 38% of respondents (compared to 54% in 2016) have not encountered submission barriers and shows the barriers listed. These include packaging and shipping personnel available, knowledge about IBL's services, and sampling kits not on hand.

IBL is addressing these barriers in several ways. First, Packaging and Shipping Division 6.2 Materials training will be offered in the spring of 2018 in condensed four-hour sessions to account for time limitations. Second, information about IBL's services is included in the Lab Safety Workshop curriculum, which will be offered in 2018. This information is also available on the State Lab website at [www.statelab.idaho.gov](http://www.statelab.idaho.gov). Lastly, IBL provides sampling kits for select tests including influenza surveillance and tuberculosis identification; these kits can be ordered on the website in the IBL Supply Request section.

Training needs were identified in Part C of the needs assessment, and top selections are similar to those from the 2016 survey (Figure 2). IBL will prioritize training topics that have generated the most interest. For example, IBL's Laboratory Improvement section is continuing lab outreach on CLIA regulations and will consider developing additional online training modules and webinars. In addition, sentinel laboratory biological threat workshops, laboratory safety

workshops, and packaging and shipping training are scheduled in multiple locations in 2018.

58% of respondents to the partner needs assessment indicated they preferred online training. To address this growing demand for online training modules (Figure 3), IBL updated the State Lab website Training & Outreach page with relevant training for partners. The Online Courses tab provides access to IBL-developed training including *X-Ray Basics* and *CLIA Regulations on Proficiency Testing*. It also provides links to training developed by the Centers for Disease Control and Prevention Laboratory Training Branch (<http://www.cdc.gov/labtraining/>), including basic microbiology, packaging and shipping, and biological threat preparedness.

Responses pertaining to training interest and barriers in attending training (Figure 4) reveal that 98% of respondents were interested in receiving training from IBL but only 16% felt they had the time and staffing to follow up on this interest. IBL will continue to address these needs by scheduling regional or on-site training sessions with a variety of topics, in addition to further developing the online training menu and pursuing IBL-sponsored webinars on topics of interest to sentinel labs.

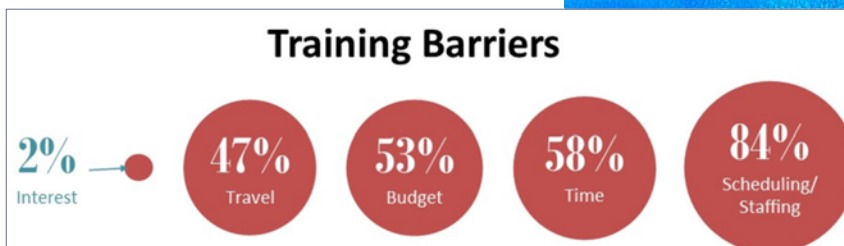


Figure 4. Respondents identified barriers encountered in attending training at IBL.

The information collected from this year's needs assessment will guide activities in 2018. IBL thanks respondents for their participation and encourages additional feedback to be sent to [wendy.loumeau@dhw.idaho.gov](mailto:wendy.loumeau@dhw.idaho.gov).

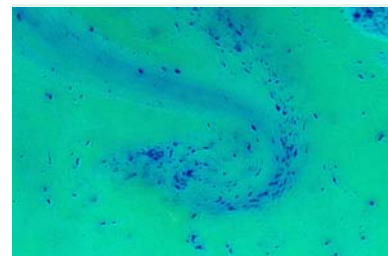


Figure 3. A summary of responses pertaining to training formats and time available for participants.

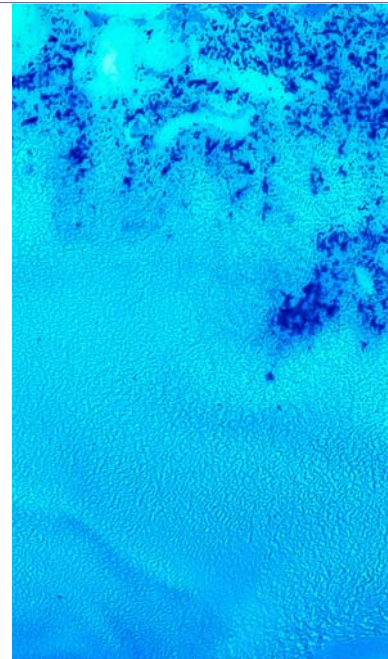
Respondents reported interest in brief online training modules, webinars, and onsite workshops.

**100%** time available to commit to training listed as **10 minutes to 1 hour**

**82%** training format of interest was **online training modules**

**78%** training format of interest was **IBL webinars**

**58%** training format of interest was **onsite workshops**



## IDAHO BUREAU OF LABORATORIES

The role of the Idaho Bureau of Laboratories (IBL) is to provide laboratory services that support the programs in Department of Health and Welfare, the 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. The laboratory is 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 of biological and chemical threat agents in Idaho.



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IDAHO DEPARTMENT OF HEALTH & WELFARE  
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# Upcoming Events

## ANTIMICROBIAL STEWARDSHIP TOWN HALL MEETINGS

Meridian, Idaho: April 24, 2018; 4:00 pm—7:00 pm

Moscow, Idaho: May 2, 2018; 4:00 pm—7:00 pm

Pocatello, Idaho: May 17, 2018; 4:00 pm—7:00 pm

Contact Susan Heppler at 208-334-5871 or [susan.heppler@dhw.idaho.gov](mailto:susan.heppler@dhw.idaho.gov) to register or for more information.

## BIOTHREAT PREPAREDNESS WORKSHOP

Pocatello, Idaho: May 9, 2018; 9:00 am—3:30 pm

Hayden, Idaho: June 7, 2018; 9:00 am—3:30 pm

The **Biothreat Preparedness Workshop** provides an overview of the sentinel laboratory's role in the presumptive identification of agents of biological threat. Participants will review the Laboratory Response Network (LRN) and sentinel laboratory protocols for ruling out suspect agents. Laboratory demonstrations will outline the microbiology of these agents to recognize the culture, staining, and biochemical characteristics.

Register online at <https://keysurvey.com/f/1195561/200c/>.

## LABORATORY SAFETY WORKSHOP

Pocatello, Idaho: May 10, 2018; 8:00 am—12:00 pm

Hayden, Idaho: June 8, 2018; 8:00 am—12:00 pm

The **Laboratory Safety Workshop** will cover topics on biological and chemical safety, hazard identification and risk assessment, personal protective equipment (PPE), and use of biosafety cabinets.

Register online at <https://keysurvey.com/f/1195561/200c/>.

## PACKAGING AND SHIPPING TRAINING

Pocatello, Idaho: May 10, 2018; 1:00 pm—5:00 pm

Lewiston, Idaho: June 6, 2018; 1:00 pm—5:00 pm

Hayden, Idaho: June 8, 2018; 1:00 pm—5:00 pm

The **Packaging and Shipping Training** will provide training to aid in certifying staff to properly package and ship Division 6.2 infectious substances. Topics covered will include identifying Category A or B infectious substances, triple-packaging requirements, marking and labeling packages, and appropriate documentation.

Register online at <https://keysurvey.com/f/1195561/200c/>.

# Updates

- New Association of Public Health Laboratories (APHL) resources for biothreat rule out identification assistance, Biothreat Agent Bench Cards for the Sentinel Laboratory and Biothreat Agent Poster: available at [www.statelab.idaho.gov](http://www.statelab.idaho.gov) => Sentinel Labs => Select Agents
- New APHL community, **Laboratory Biosafety CollABorate**: to engage both public health professionals and non-public health clinical laboratory representatives in biosafety and biosecurity to connect and facilitate the sharing of ideas, biosafety tools and other resources as well as assist with answering biosafety-related questions. Follow these steps to join:

1. 'Create an Account' at [aphl.org](http://aphl.org) —if you do not already have an account.
2. Contact APHL at [biosafety@aphl.org](mailto:biosafety@aphl.org) with your name, institution and position title.
3. If accepted, APHL will send an email acknowledging your acceptance into the Biosafety Community and share tools for use of the platform.