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# Idaho Bureau of Laboratories Clinical Forum

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## Influenza Surveillance

Vonnita Barton and Matthew Burns

Idaho Bureau of Laboratories (IBL) would like to thank all participating labs for submitting samples for the Idaho Influenza Surveillance Project this year. Your participation is vital to ensuring that we can see the full picture of influenza infection in Idaho.

There are four primary objectives of influenza surveillance:

- Establish when and where influenza is

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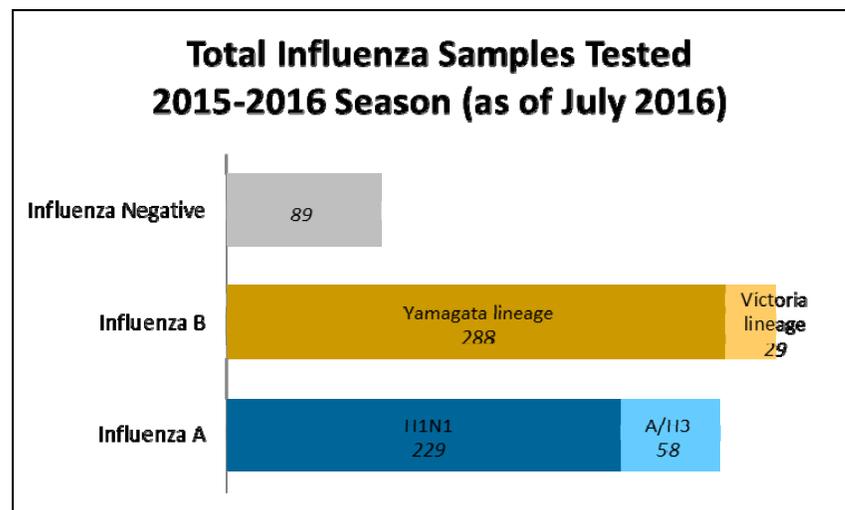


Figure 1. As of July 2016, IBL has tested 693 samples for influenza. The predominant strain for Influenza B has been Yamagata lineage and H1N1pdm09 for Influenza A.

## Helpful Web Portal Inbox Features

Kara Deobald

The Idaho Bureau of Laboratories' (IBL) web portal is a tool that allows IBL clients to access sample test result reports electronically. In addition to providing reports quickly to the client, the web portal stores these reports should the customer need to retrieve them at a later date.

Useful inbox functions include merge file(s), toggle preview mode, and search. To take advantage of these features, login to your web portal account and look in the top right corner of the page. You will see several toolbar buttons as shown in Figure 1.

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Whether you are a new web portal user, or an experienced one, you may not be aware of all the features available in your inbox.

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# Influenza Surveillance

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present in Idaho, providing situational awareness;

- Detect novel or reassortant viruses by genetically characterizing samples to look for emergent strains;
- Determine the strains of influenza in Idaho and match it to the vaccine; and
- Detect and monitor antiviral resistance.

During the summer months, when seasonal influenza prevalence is low, IBL continues to monitor for emerging novel strains with pandemic potential and for other pathogens that impact community health. We request **all** clinical laboratories performing influenza diagnostic testing to please continue to forward influenza samples to IBL, especially from patients with the following exposure conditions:

- International travel histories
- Unusual presentations/results
- Contact with swine or sick/dead poultry
- Antiviral treatment failure

Figures 1 and 2 show the distribution of influenza in Idaho for the 2015-2016 flu season.

Please visit the Idaho Department of Health and Welfare's Influenza webpage at <http://flu.idaho.gov> for general influenza information, weekly Idaho updates, and IBL submission guidelines.

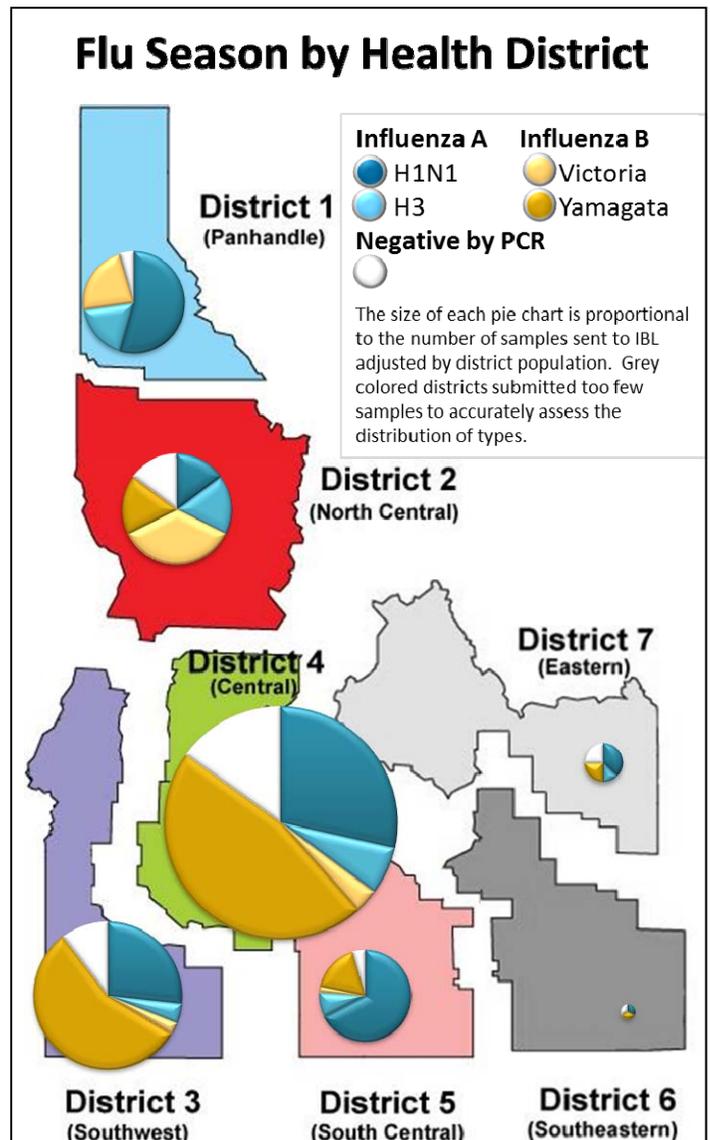


Figure 2. The distribution of influenza strains by district health department for Idaho's 2015-2016 influenza season.

To be added or removed  
from the Clinical Forum  
email list, contact  
[statelab@dhw.idaho.gov](mailto:statelab@dhw.idaho.gov).

# Web Portal Inbox

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Figure 1. Example of web portal inbox displaying toolbar options.

Name	Date	Page(s)	Size (KB)	Subject
clinical report C151100001 001_145	03/14/16 10:09 AM	1	50	Sam ple: C151100001-001; 1
clinical report C151100002 001_1128	03/14/16 10:09 AM	1	50	Sam ple: C151100002-001; 2
clinical report C151100003 001_1128	03/14/16 10:09 AM	1	50	Sam ple: C151100003-001; 3
clinical report C151100004 001_1128	03/14/16 10:10 AM	1	50	Sam ple: C151100004-001; 4



The **Merge File(s) function** allows users to merge individual reports into a single PDF document, providing a more efficient way to print reports or forward reports as an email attachment. The PDF document will show each report on consecutive pages, and users are provided with the option to either open or save the PDF.



To narrow the list of reports visible in the Inbox, users may use the **Search function** to enter criteria and filter their results (see Figure 2). It also lets them define what they'd like to search for (e.g., a specific file name or subject). To define a search parameter, the \* symbol can be used as a wildcard, both leading and trailing the search entered. For example, to search for a specific report among multiple reports under the workorder heading C110300023, the user can enter \*C110300023\*. The search function also allows users to select the web portal location they want to search reports from (such as inbox, file cabinet, etc.). In addition, the search function allows users to search a specific date range by entering a start and end date. When using this feature, the start and end dates refer to when the reports were completed and not when the sample was collected or submitted.

Figure 2. The web portal search function narrows the list of reports visible in the Inbox.



The **Toggle Preview Mode** gives the user the opportunity to view a copy of the report while also seeing the Inbox contents or simply see the Inbox contents alone. If the preview pane is hidden, it will allow more reports to be visible without having to scroll down. Please note that reports cannot be printed

from the preview window; you must use the print option  to print the report.

Give these functions a try! If you have a web portal account and have questions or need assistance, or if you would like to set up a new web portal account, please contact Kara Deobald at (208) 334-0585 or email at [deobaldk@dhw.idaho.gov](mailto:deobaldk@dhw.idaho.gov).

# Ask the CLIA Auditor

Liz Parent

**Q:** What types of deficiencies have been identified during recent Idaho surveys?

**A:** A number of deficiencies have involved proficiency testing (PT) and PT failures identified at the time of the survey and throughout the year. During a CLIA inspection, PT requirements are reviewed; these CLIA requirements can be found in 42 CFR 493.801. Proficiency testing questions during a survey include the following:

- Can the lab produce the raw data for the PT samples, such as worksheets and printouts from instruments used in the testing process?
- Are the attestation statements signed by testing personnel?
- Are the PT samples being rotated among all testing personnel?
- Is the PT being run as if it was any other patient sample?
- Are the results returned from the PT Provider being reviewed when they become available, are failures being addressed, are any plans of correction being written?
- Has the director or designee reviewed and signed off on all results?

**Q:** How does the State CLIA program respond to my lab's PT failures?

**A:** In response to PT failures, the State CLIA program previously sent out letters each time a laboratory failed a single PT. Now, however, we will only send a letter along with a citation when a lab fails 2 out of 3 PT events for a test or specialty. A 2 out of 3 failure is unsuccessful participation and places the laboratory out of compliance at the Condition level, a serious matter. The citation will be received on a CMS-2567 Statement of Deficiencies. The laboratory will also receive a letter requesting an Allegation of Compliance (AOC). An AOC is documentation stating

what issues were found in the laboratory that lead to the PT failures, if any patients were affected, and the changes the laboratory has made to resolve the problem along with documentation indicating that the deficient practice has been identified and corrected. Basically, the AOC is the laboratory's statement detailing what they found that went wrong and proof that the problem has been fixed.

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.

**Q:** How should my lab respond to PT failures?

**A:** The AOC by the laboratory must be made within ten days of receiving the letter from the State CLIA program. There is a very specific set of questions that need answered on the CMS-2567, and the AOC cannot be accepted unless the appropriate information is provided along with evidence of correction. Requirements for an AOC can be found on the state lab website at [www.statelab.idaho.gov](http://www.statelab.idaho.gov) on the Clinical Lab Certification page under Resources.

**Q:** How should my lab document corrective actions and troubleshooting for PT failures? Why is this important?

**A:** Is your laboratory staff documenting corrective actions and troubleshooting? Does your laboratory have a policy on documenting corrective actions and troubleshooting? While it may not be convenient at the time that issues are occurring or when an instrument is giving the laboratory trouble, having corrective actions documented is paramount in troubleshooting PT failures and other issues with patient results when questions arise. Documentation of corrective actions is required by 42 CFR 493.1282.

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# Category A Packaging and Shipping Drill

Cassie Dayan



Figure 1. Example of materials needed to ship Category A infectious substances.

The first cases of Ebola virus disease within the United States were confirmed in 2014. These confirmations illuminated issues associated with transporting Category A infectious substances from healthcare facilities and agencies to the Centers for Disease Control and Prevention (CDC) for testing. Idaho Bureau of Laboratories (IBL) received funding through CDC’s Public Health Emergency Preparedness (PHEP) Ebola supplemental cooperative agreement, which aims to assist public health departments in strengthening their abilities to respond to emerging infectious diseases and build more resilient communities. Through this grant, IBL has been offering Category A packaging and shipping drills to Idaho sentinel laboratories. There is a need for these drills, as shipping Category A infectious substances is a lengthy process that requires correct packaging and shipping materials (Figure 1) and an individual within the laboratory who is trained and certified in packaging and shipping infectious substances.

shipping materials (Figure 1) and an individual within the laboratory who is trained and certified in packaging and shipping infectious substances.

The Category A drill provides Idaho sentinel laboratories an opportunity to package and ship a suspected Category A specimen via FedEx. If participating in the drill, each laboratory will be sent two empty InfeKta Category A boxes (one for use in the drill the other for use as needed) and a separate Category A box containing a Shiga toxin producing *Escherichia coli* (STEC) culture. Upon receipt of materials, the laboratory will repackage the STEC slant and ship it to the drill evaluator as a Suspected Category A infectious substance. The evaluator will then assess the packaging and labeling and send the evaluation via e-mail to the participating laboratory.

IBL contacted 30 Idaho sentinel laboratories performing microbiology about participating in this drill (Figure 2). Of those, 22 agreed to participate and were divided into three regional groups: Panhandle/North Central, Southeastern, and Treasure Valley. These groupings determined the time for the drill to be completed and the evaluating public health lab. The Panhandle/North Central and Southeastern groups were assigned to send packages to IBL for evaluation, and the Treasure Valley group to the Montana State Public Health Laboratory. The Panhandle/North Central group began the drill in March and completed it by the end of April; the Southeastern group began in May (in progress), and the Treasure Valley group is currently underway. A future Clinical Forum article will share results from these drills.

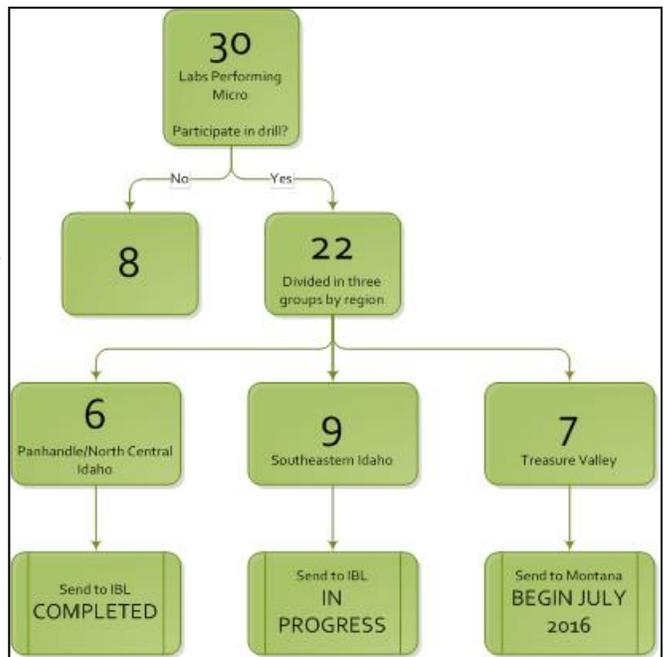


Figure 2. 2016 Category A packaging and shipping drill participants and status.

IBL has received positive feedback from drill participants. Lisa Cook from Pathologists’ Regional Lab said “It is nice to have a good network between the lab, local health department and state lab. The exercise was beneficial and helped us examine our processes. We look forward to participating in the next drill using a different certified shipper to help all our employees experience the exercise.” In fact, a number of labs requested to participate in additional drills, so more drills will be scheduled in 2017. IBL thanks participating labs for their time and feedback as we aim to improve laboratory preparedness throughout the state.

## Ask the CLIA Auditor

(Continued from page 4)

**Q:** I would like to learn more about CLIA Regulations. Where can I find more information?

**A:** You may brush up on CLIA Regulations by reviewing this website: <http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5>.

**Q:** I would like to familiarize myself with the Interpretive Guidelines. Where can I access them?

**A:** You may access the Interpretive Guidelines online at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap\\_c\\_lab.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf). The Interpretive Guidelines are used by the Surveyor during the inspection to make sure the laboratory is following the federal CLIA regulations. They take the regulatory language of the CLIA regulations and provide some clarification of the rules. They can be helpful in understanding the intent of the CLIA regulations in many instances.

The state is moving towards paperless record retention, and labs are no longer required to mail paper-based state CLIA forms if they have been received electronically.

Questions? Send them to [LabImprove-ment@dhw.idaho.gov](mailto:LabImprove-ment@dhw.idaho.gov).

## Upcoming Webinars

October 11, 2016; 11:00 am Mountain Time  
“Rapid Diagnostics: Live Streaming for Bloodstream Infections”

October 25, 2016; 11:00 am Mountain Time  
“2016 Influenza Update”

November 1, 2016; 11:00 am Mountain Time  
“New Drugs, New Tests, Practical Approaches in New Antimicrobials”

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

## Congratulations!



Vedaansh Gurajala was born in March to Lavanya Vempati, a Senior Microbiologist at Idaho Bureau of Laboratories, and her husband Murali Gurajala. Lavanya and Murali are very thankful and happy to welcome him. He joins big sister Pragnya who adores her baby brother. Congratulations to the Vempati and Gurajala families!