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# Idaho Bureau of Laboratories Clinical Forum

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## Changes to the Idaho Laboratory Registration Program

Amanda J. Bruesch, MS

The State of Idaho Clinical Laboratory Registration program housed in the Idaho Department of Health and Welfare, Bureau of Laboratories would like to make you aware of upcoming changes to our program.

Previously, laboratories in Idaho have been required to submit not only a federal CMS-116 form but also a State of Idaho Clinical Laboratory Registration form to become certified under the Clinical Laboratory Improvement Amendments (CLIA) program and be a registered laboratory in the state. Labs were issued a federal CLIA certificate as well as an Idaho Notice of Laboratory Regis-

tration certificate. During the past several years, laboratories have expressed confusion over the difference between the federal CLIA certificate and the Idaho Notice of Laboratory Registration certificate, as well as confusion over the requirement to complete multiple forms in order to obtain certification and registration in Idaho.

It is with the laboratories in mind that we are announcing changes in the State of Idaho Clinical Laboratory Registration program. Starting July 1, 2017, the federal CMS-116

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## Lab Safety Risk Management Program

Michael Stevenson, PhD

The Ebola outbreak of 2014 highlighted a lack of comprehensive biosafety programs in most U.S. clinical laboratories. As a result, the Centers for Disease Control and Prevention awarded public health laboratories funding to enhance lab safety capacity within their jurisdictions. During 2017, Idaho Bureau of Laboratories (IBL) staff have used this funding to visit hospital labs and conduct lab safety outreach workshops. One module from the workshop focuses on risk management programs.

In relation to lab safety, risk can be defined as the probability of a hazard exposure occurring and resulting in an adverse effect.

An effective risk management program continually identifies, assesses, controls, and evaluates these risks. There are three basic components for risk management: identify the hazard, perform a risk assessment to determine if the risks working with that hazard are acceptable, and perform risk mitigation to reduce risks to acceptable levels (see Figure 1).

**Identify the hazard:** This process involves identifying the hazardous agent, host (staff

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Clinical Forum  
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Amanda Bruesch  
Matthew Burns  
Vonnita Barton  
Erin Peterson

# Changes to CLIA Program

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form will become the Department-approved form to register a lab with the federal CLIA program and the State of Idaho program. We will no longer be issuing Notice of Laboratory Registration certificates to Idaho labs. When your cur-

It is of continued importance that any changes to your CLIA certificate and laboratory operations are communicated to our office within 30 days of the changes. You can let us know of any changes by submitting the Idaho Clinical Laboratory Change of Information form found on our website at <http://statelab.idaho.gov>;

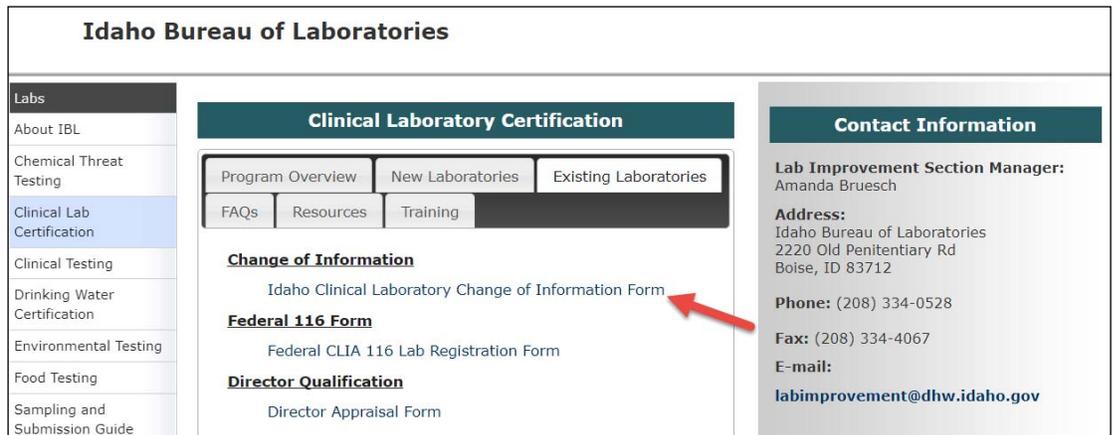


Figure 1. The Idaho Clinical Laboratory Change of Information Form can be found on the State Lab website, Clinical Lab Certification page, Existing Laboratories tab.

rent Idaho Notice of Laboratory Registration certificate expires, we will not issue a new one.

The program will continue to operate under IDAPA 16.02.06 – Quality Assurance for Clinical Laboratories and will uphold all our statutory requirements. We will continue to maintain a list of labs that are certified to perform diagnostic testing in the state, and all clinical laboratory paperwork for the federal CLIA program and State of Idaho program will continue to come to our office. Our office will continue to serve as the state agency for the federal CLIA program and process all laboratory changes, registrations, and certifications for labs operating in the State of Idaho.

please go to the Clinical Lab Certification link and the Existing Laboratories tab for this form (Figure 1). You also can provide any updates on the federal fee coupon you receive at the time of your biennial CLIA renewal. This will help ensure that appropriate changes are made to your certificate as soon as possible.

We hope that the change in the clinical laboratory program will simplify the work involved to become CLIA-certified in Idaho and result in a better experience for all our laboratories. If you have questions regarding the changes in the program, please contact us at [LabImprovement@dhw.idaho.gov](mailto:LabImprovement@dhw.idaho.gov) or (208) 334-0528.

# 2016-2017 Influenza Season Overview

Vonnita Barton, Matthew Burns, and Leslie Tengelsen, PhD, DVM

Thank you to all participating laboratories for your clinical influenza sample submissions and weekly data reports captured by the Idaho Influenza Surveillance Project. Figure 1 shows the distribution of influenza sample contributions submitted to Idaho Bureau of Laboratories (IBL) throughout the state of Idaho during the 2016-2017 influenza season.

Two of the clinical labs in Idaho also participated in the weekly reporting of clinical laboratory data to CDC via the U.S. Outpatient Influenza-like Illness Surveillance Network-Laboratory Surveillance Data Section (ILINet). Although the number of participants in this process was low, their reported data was vital to ensure the full burden of influenza infection in Idaho is met. For additional information on how you can contribute to virologic surveillance in Idaho by voluntarily submitting clinical information please visit [www.flu.idaho.gov](http://www.flu.idaho.gov).

Influenza A/H3N2 was the most prevalent influenza virus subtype detected this season; however, Influenza A(H1N1)pdm09, Influenza B-Victoria lineage, and Influenza B-Yamagata lineage were also found circulating in low levels in Idaho and across the country. Per the Idaho Department of Health and Welfare, Bureau of Vital Records and Health Statistics, 72 Influenza-related deaths were reported during the 2016-2017 influenza this season; all but one in those ≥50 years of age. This number is considered high, when compared with the average number of Influenza-related deaths reported during each of the previous

7 influenza seasons (mean=23, range 5-35). Nationally, 100 deaths in children under the age of 18 were reported as of June 26, 2017; no pediatric deaths were reported in Idaho during the 2016-2017 season. Influenza vaccinations were available as trivalent (Influenza A(H3N2), Influenza A (H1N1) pdm09, Influenza B-Victoria lineage) and quadrivalent (trivalent plus Influenza B-Yamagata lineage) formulations. Each season CDC estimates vaccine effectiveness (VE) to prevent Influenza-associated, medically attended, acute respiratory illness. For the 2016-2017 Influenza season, the interim estimates published mid-season (February 17, 2017, <https://www.cdc.gov/mmwr/volumes/66/wr/mm6606a3.htm?s>) showed an average VE against influenza A and B viruses of 48%, reducing the need for medical visits by nearly half. Vaccine effectiveness did vary by component, estimated at

43% against A(H3N2) and 73% against Influenza B viruses.

IBL will continue to accept samples from patients with influenza-like illness, including those that were influenza rapid tested positive or negative. Novel strains (variants) of influenza can occur during the summer months due to various reasons including human flu viruses mixing with pig viruses in cases of close contact such as county fairs, so it's important to continue monitoring this virus.

Next-generation sequencing (NGS) is the latest Influenza surveillance testing/tracking tool used by CDC to generate increased genetic data. A representative group of the virus surveillance specimens submitted by clinical laboratories in Idaho are forwarded to national Influenza reference centers for antigenic, genetic and antiviral characterization and collective analysis of the data is used to identify optimal vaccine candidates in the upcoming influenza season. More data improves analysis capacity and diagnostic test development, which eventually leads to improved vaccine strain selection.

To learn more about influenza in Idaho, including surveillance trends and weekly updates, please visit <http://flu.idaho.gov>. This site is maintained throughout the active influenza season. Data updates for the upcoming 2017-2018 season will begin with the MMWR week 2017-40 (week ending October 7, 2017).

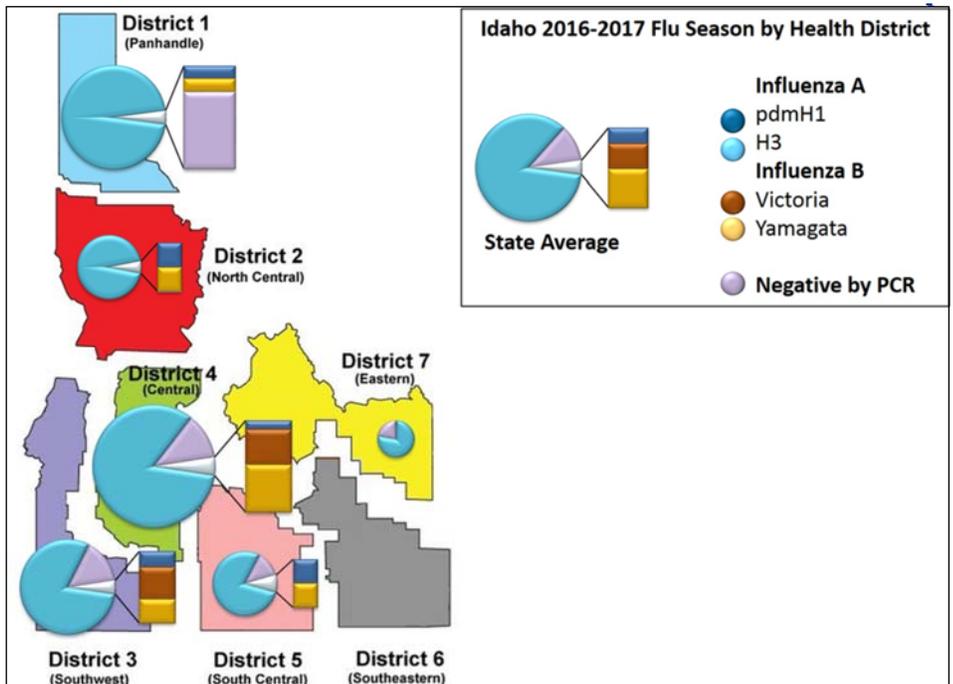


Figure 1. The area of each pie chart represents the number of samples sent to IBL adjusted by district population. There were insufficient sample numbers received from District 6 to accurately assess the distribution of types.

# Lab Safety Risk Management Program

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working with the agent), and procedure involved with the hazard. Hazard identification may include determining the Risk Group (1 = not causing human disease, 4 = causing serious or lethal disease).<sup>2</sup> Staff who work with the hazardous agent may have a health condition which could compromise their health status if exposed to the agent (e.g., pregnant, immunocompromised, diabetic). Finally, the procedure used to work with the hazard may require more details or have gaps in crucial steps that could expose the individual.

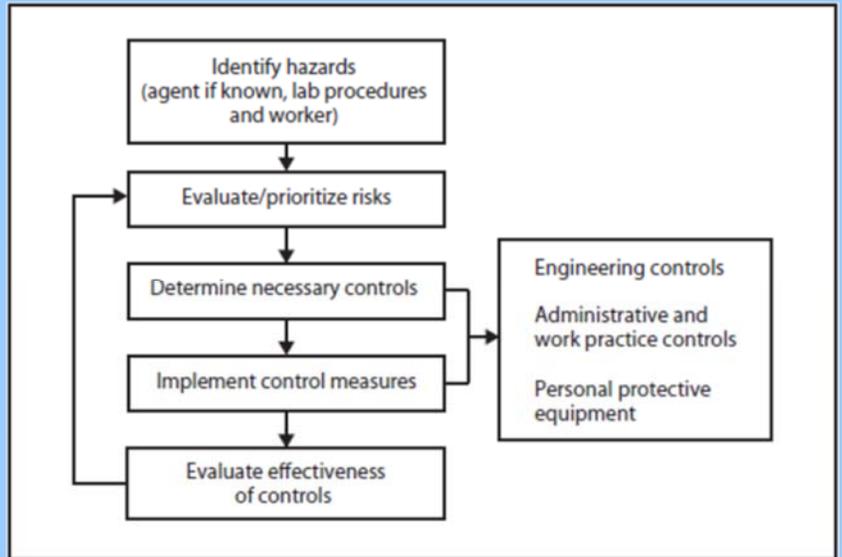


Figure 1. Components of a risk management program<sup>1</sup>

**Perform a risk assessment:** A risk assessment is a systematic process of evaluating the likelihood and consequence of exposure to a hazard. Risk assessments center around the hazard, the host, and the lab procedure. A risk assessment should be performed when working with a new hazardous agent in the lab and should be reviewed at least annually or when significant standard operating procedure (SOP) changes have occurred. Note that this risk assessment type is different from a risk assessment involved with an Individualized Quality Control Plan (IQCP). In an IQCP, a risk assessment identifies potential problems that may occur in the testing process to prohibit accurate test results.

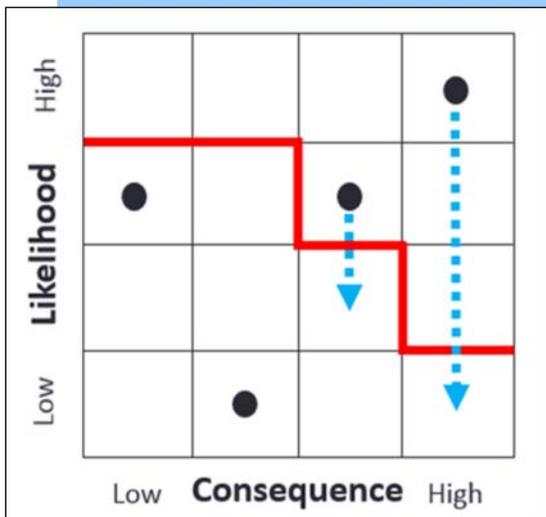


Figure 2. Risk assessment and risk mitigation on procedures that have a likelihood and consequence of hazard exposure

**Perform risk mitigation:** In risk mitigation, steps are taken to reduce the likelihood of a hazard exposure to a more acceptable risk level. These measures involve administrative controls (e.g., medical surveillance, staff training, detailed SOPs), engineering controls (e.g., use of autoclave or biosafety cabinet), and work practices (e.g., use of disinfectants and personal protective equipment). Figure 2 shows a risk assessment matrix of likelihood versus consequence of exposure to a hazard at several procedural steps (black dots), and how risks that are considered unacceptable (above the red line) can be reduced to an acceptable level (below the red line) through risk mitigation.

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## Upcoming Webinars

There are no upcoming webinars at this time. Visit [www.statelab.idaho.gov](http://www.statelab.idaho.gov) => Training & Outreach for an updated list.

# Malaria Speciation PCR at IBL

Erin Peterson

Malaria is a serious and sometimes life threatening disease transmitted by mosquitoes; approximately 1,500 malaria cases are diagnosed in the United States annually<sup>1</sup>. Most human cases are caused by four species in the genus *Plasmodium*: *Plasmodium falciparum*, *P. vivax*, *P. malariae*, and *P. ovale*. While direct observation of this parasite in blood samples can diagnose malaria, it is not generally possible to speciate it in this way. The Idaho Bureau of Laboratories (IBL) has developed a real-time PCR (rt-PCR) test for the speciation of *Plasmodium* in human patients. The rt-PCR test can reliably differentiate between these four species to provide a rapid and definitive answer. Speciation is clinically important, as it can impact treatment plans for the patient.

We are requesting that Idaho Sentinel Laboratories submit positive malaria samples to IBL

for speciation. Please note that this rt-PCR is not a diagnostic test for malaria; it is only intended to determine the species of *Plasmodium* in a patient that has been diagnosed with an active malaria infection.

The acceptable sample is 1-5 mL of whole blood in an EDTA vacutainer tube. Please fill out the [Clinical Test Request Form](#) and specify “Malaria Speciation” in the “**Other RT-PCR**” field in the Molecular Testing section. See Figure 1 for information on the process.

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

References:

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

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## Speciation Process for Malaria PCR Test

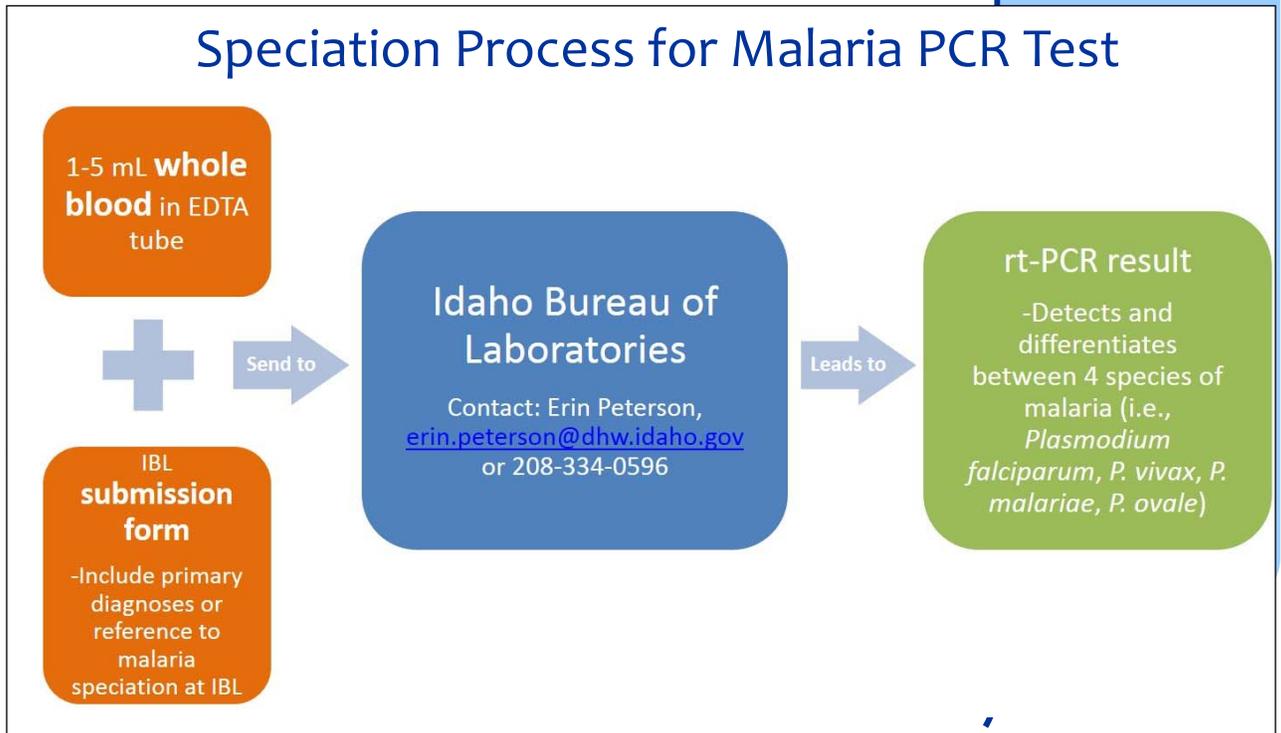


Figure 1. IBL is requesting that labs submit positive malaria samples to IBL for speciation.

## Jenny Street, Clinical Lab Inspector



Hello my name is Jennifer Street. I recently departed from the Idaho State Department of Agriculture, where I worked in the PCR lab testing animal and plant specimens. I am grateful for the opportunity to become an integral member of the Laboratory Improvement section at the Public Health Laboratory at DHW.

In my spare time, I help my husband, Jeff, take care of our 9-year-old son, Gabe, two dogs, three horses, 14 chickens, and one lizard. We spend as much time as we can outdoors enjoying Idaho. We like camping, hiking, bug hunting, and most importantly horseback riding. I also find myself knitting in the evenings if I have time.

I look forward to meeting you all and working with you in the future.

## Check it Out!

Idaho Bureau of Laboratories' (IBL) staff Erin Peterson, Robert Voermans, and Christopher Ball were co-authors on a Mortality and Morbidity Weekly Report (MMWR) article pertaining to a 2016 case where an automated system misidentified *Veillonella* spp. as *Francisella tularensis*. Get the full story at <https://www.cdc.gov/mmwr/volumes/66/wr/mm6621a4.htm#contribAff> or <https://goo.gl/Kfz6SZ>.

## Lab Safety Risk Management Program

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### Resources:

- APHL Clinical Laboratory Biosafety Risk Management Program Assessment Checklist: <https://goo.gl/MkdVlK>
  - ◊ Recommendation: Have the lab manager, safety officer, and other relevant staff (e.g., infection prevention) reserve two hours to go through this checklist together to determine if any safety gaps may exist.
- APHL Lab Biosafety and Biosecurity Resources: <https://goo.gl/hnEsve>
- APHL Risk Assessment Best Practices and Examples: <https://goo.gl/KFaVhR>
- Idaho Bureau of Laboratories risk assessment example (Excel file consisting of 23 questions identifying route(s) of infection, likelihood of exposure, and consequence of disease): available upon request

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

### References

<sup>1</sup>CDC. Guidelines for Safe Work Practices in Human and Animal Diagnostic Laboratories. MMWR 2012; 61(01). Retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/su6101a1.htm>

<sup>2</sup>CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5<sup>th</sup> edition (<https://goo.gl/HslU3a>)