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Public Health Laboratory Newsletter

Lisa Piercey, MD, MBA, FAAP
Commissioner of Health

Richard Steece, PhD, DABMM)
Director, Laboratory Services

In This Issue:

2020 Newborn Screening Fee Increase

Spinal Muscular Atrophy is a disease that causes deterioration of motor neurons resulting in progressive muscle weakness and wasting. More severe forms of SMA affect the muscles for feeding, swallowing and breathing, thereby making SMA the number one genetic cause of death for infants. Early detection of SMA provides the opportunity for treatment and disease management with new drugs and gene therapy.

In 2018, our genetic advisory committee recommended the addition of SMA to the Tennessee NBS panel, harmonizing with the national Recommended Uniform Screening Panel. The RUSP is a listing of disorders for which all infants born in the United States should be screened and is published by the Advisory Committee on Heritable Disorders in Newborns and Children in conjunction with the Department of Health and Human Services. Very shortly, the Tennessee newborn screening laboratory will begin a validation study for SMA with hopes to begin routine screening of all Tennessee newborns on or before January 1, 2020. However, remaining current with the RUSP and offering Tennessee babies the best service possible comes with a cost.

To fund the SMA screen and any additional confirmatory testing for SMA, and to provide appropriate follow-up services, the current fee of $145 will increase to $165. This increase has been approved by TDH Commissioner Lisa Piercy, MD, MBA, FAAP and will go into effect for all newborn screening samples received beginning January 1, 2020. The fee will cover the addition of SMA, the second tier survival of motor neuron, or SMN, copy number testing and our current panel of 70 disorders. It will also include the following: sustained weekend work to cover seven day a week testing to improve timeliness of reporting, sustained courier system, purchase of a specimen tracking and electronic demographic transfer and reporting system, and the expansion of the newborn screening laboratory space to accommodate the addition of the new disorders. The fee for unsatisfactory samples will also change from $290 to $330. This fee covers the first unsatisfactory submission and any additional repeat specimen submissions.

We appreciate your cooperation in providing these services for all Tennessee infants.

The Fungus Among Us

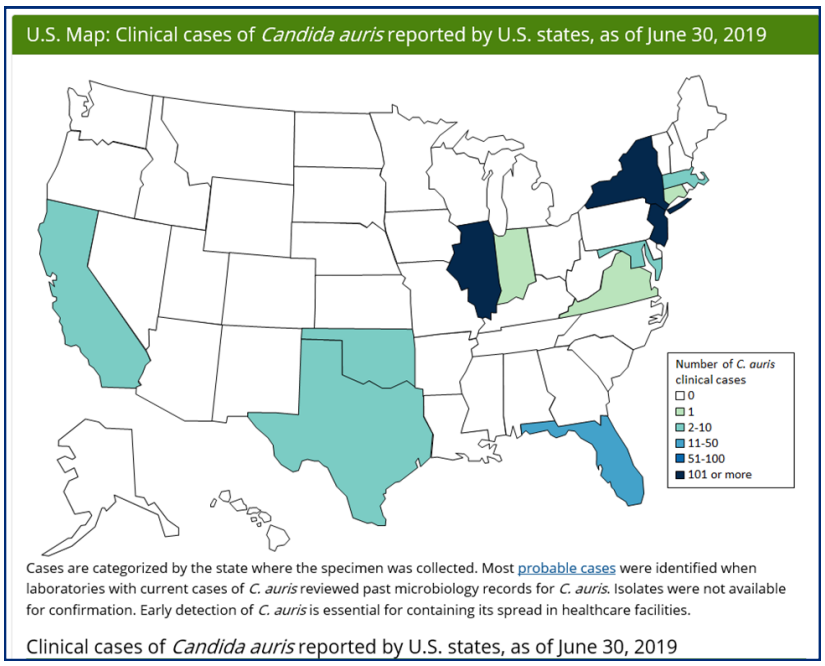
In recognition of Fungal Disease awareness week September 23-27, 2019, we are focusing on three fungal diseases that present with flu or pneumonia like illness symptoms and their prevention: histoplasmosis, blastomycosis and Valley Fever (Coccidioidomycosis). These three fungal diseases are often misdiagnosed and can cause life altering infirmity. All three of these fungal diseases are community-acquired infections. These fungi are particularly responsive to both humidity and temperature. The impact of long term climate change on the growth and distribution is not known.

(Continued on page 6)

Tennessee's Efforts in Tracking *Candida auris*

Why is *Candida auris* a concern?

Candida auris has been receiving an increasing amount of attention as it becomes more of a global public health concern. *Candida auris* was first identified in 2009 and a decade later, there is still a lot that is unknown about this yeast. What is known so far is that it can cause bloodstream infections and even death for more than 30% of patients with invasive *C. auris*. Hospitalized and immunocompromised patients are the most susceptible to infections associated with *C. auris*. Due to its lack of response to commonly used antifungal drugs, *C. auris* is a difficult pathogen to treat.



What is TN doing?

The Tennessee Department of Health, Division of Laboratory Services, as an Antimicrobial Resistance Lab Network regional laboratory, serves the southeast region of the United States. As a *Candida* AR Lab Network laboratory, Tennessee confirms *Candida auris* using PCR, culture with MALDI-TOF identification and performs antifungal susceptibility testing using a microdilution panel. In the last quarter, the Tennessee *Candida* AR Lab Network team has experienced a large influx of specimens from across the region, primarily in long-term care facilities located in Florida. The Tennessee team has been working collaboratively with the CDC and the HAI/AR team in Florida to track cases of *Candida auris.*

What should clinical labs be doing?

C. auris cannot be detected by conventional identification methods such as API 20 AUX C or most automated ID/AST platforms and therefore, can be misidentified. Most laboratories rely on MALDI-TOF for identification of *C. auris*. In Tennessee, confirmed cases of *C. auris* must be reported to Tennessee Department of Health by the next business day and isolate submission is required.

Submitted by
Tabatha East, MBA, MLS(ASCP)^{CM}
Assistant Director, Clinical Microbiology

References:

https://www.cdc.gov/fungal/candida-auris/candida-auris-qanda.html
https://www.cdc.gov/fungal/candida-auris/c-auris-drug-resistant.html

MacConkey Broth Study for CRE

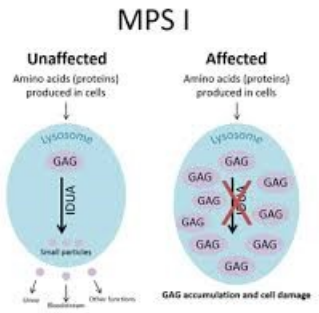
In July, TDH Laboratory Services worked with UT-Memphis intern Christopher Justus to improve recovery of carbapenem-resistant Enterobacteriaceae from cultures. Justus was able to prove a hypothesis which stated that broth incubation would facilitate the growth of organisms that are difficult to isolate. Based on these findings, recovery of these very important organisms will increase, improving the efficiency and effectiveness of determining resistance mechanism status of CRE in the lab.

Submitted by
Tracy McLemore, MBA, MT (ASCP)
Manager, Molecular Enteric Microbiology and Antibiotic Resistance Program

What is Mucopolysaccharidosis Type 1?

What is Mucopolysaccharidosis Type 1?

Mucopolysaccharidosis Type 1, also known as Hurler syndrome, is a progressively debilitating disorder belonging to a group of disorders known as Lysosomal Storage Disorders. LSD's are a group of inherited diseases that involve the malfunction of lysosomes that aid in the digestion and transportation of large molecules for cellular waste. MPS1 is characterized by the reduction or lack of alpha-L-Iduronidase, commonly called IDUA. The IDUA gene provides instructions for the breakdown of glycosaminoglycans, or GAGs, which are large sugar molecules that are useful to the body as a lubricant or as a shock absorber[1]. Mutations in the IDUA gene lead to an accumulation of GAGs in tissues and organs, enlarging them, which results in various medical problems such as hepatomegaly and splenomegaly[2].



MPS1 can be categorized into two types, the attenuated and the severe form[3]. Aspects associated with the severe form include decline in intellectual function, a shorter lifespan and an earlier onset of symptoms. There is currently no cure for MPS1; however, there are several treatment options available: enzyme replacement therapy, bone marrow transplantation and stem cell transplant.

Submitted by:
Azsa Morgan B.S., PH Lab Scientist 2

References:

1:. https://ghr.nlm.nih.gov/condition/mucopolysaccharidosis-type-i
2. https://rarediseases.info.nih.gov/diseases/12559/hurler-syndrome
3. Mucopolysaccharidosis 1: Management and Treatment Guidelines, Joseph Muenzer, James E. Wraith and Lorne A. Clarke Pediatrics 2009; 123; 19.
4. Image: https://newbornscreening.info/Parents/otherdisorders/MPSI.html

NTM INFEcT Registry

TN Laboratory Services is pleased to announce a CDC collaboration with the University of Iowa for non-tuberculosis mycobacterial infections, or NTM, associated with contaminated heater cooler devices during the following surgical procedures: heart transplant, coronary artery bypass, or placements of prosthetic valves, aortic grafts and left-ventricular-assist devices.

The Centers for Disease Control has provided funding for the NTM INFEcT Registry based at the University of Iowa to help identify infections caused by *Mycobacterium chimaera* and other NTM after heater cooler device exposure. This registry will also assist in identifying the patients who have this infection and will allow a better definition of the clinical manifestations, laboratory and pathology findings, treatments that have been tried and the outcomes of these treatments. The UI team aims to provide clinicians, facilities and health departments with information critical to identifying patients at risk, diagnosing infected patients rapidly and treating them effectively with minimal adverse effects. Patients must fall into one of the inclusion criteria that can be found at this link: https://www.ntminfect.org/Inclusions.html

If you suspect a patient has a *M. chimaera* associated illness caused by heater cooler device exposure, please submit all pertinent information to the NTM INFEcT Registry. You can contact the registry by email at contact@NTMINFEcT.org and one of the University of Iowa investigators will set up a time to discuss the patient with the clinician. The case definition, contact information and other resources are available at www.NTMInfect.org.

As a reminder, all NTM infections of extra-pulmonary origin are required for submission to TDH Laboratory Services for confirmation testing.

Submitted by:
Dorothy Baynham, MT (ASCP), Manager, Special Microbiology

Gonorrhea treatment failure? Ask about susceptibility testing!

Neisseria gonorrhoeae has developed resistance to nearly all of the antibiotics used for treatment. Culture methods to confirm treatment failure are available through the Tennessee Department of Health, Division of Laboratory Services when there are CDC defined gonorrhea treatment failures. Nucleic acid amplification test, or NAAT, has advantages over culture methods for the diagnosis of *Neisseria gonorrhoeae* due to enhanced sensitivity, automation and quick turnaround time for reporting. However, culture is the gold standard to determine antimicrobial susceptibility.

Antibiotic resistance trends have been monitored in the United States routinely since 1986. The data obtained helps ensure that gonorrhea is treated with effective antibiotics. TDH Laboratory Services is one of four regional reference laboratories that test isolates for resistance to drugs used for treatment of gonorrhea (Azithromycin, Ceftriaxone and Cefixime) in addition to other antimicrobials.

If a person's symptoms continue for more than a few days after treatment, a reevaluation of the patient could suggest the need to test for antibiotic resistance. TDH Laboratory Services provides transport media for specimen collection and culture. The culture media is provided to the county health departments so that they may readily request culture, and if isolated, antimicrobial susceptibility testing will automatically be performed.

Current guidelines for treatment and testing are available from the Centers for Disease Control and Prevention: 2015 STD Treatment Guidelines – Gonococcal Infections (June 4, 2015)

Culture methods are available when there are suspected treatment failures, when testing is requested on adolescents less than 14 years of age or unique sources of infection other than those acceptable for designated NAAT. The courier service made available through TDH Laboratory Services for the county health department will deliver collected specimens after overnight incubation. For additional information on culture and antibiotic susceptibility testing, feel free to call the TDH Laboratory at 615-262-6300.

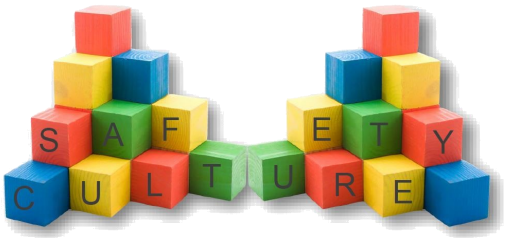
Submitted by:
Henrietta D. Hardin, M.P.A., MT-Microbiology Manager , General Bacteriology and GC ARLN

Spotlight on Safety

TDH Laboratory Services Safety Webpage

The TDH Laboratory Services Safety Webpage has recently been updated. The webpage includes many resources related to the following topics:

- **Biological Risk Management and Assessment**
- **Decontamination**
- **MALDI-TOF Technology**
- **Biological Safety Cabinets**
- **Personal Electronic Devices**
- **ASM Sentinel Laboratory Guidance**
- **Online Training Links**



ABSA INTERNATIONAL

OCTOBER 2019

Biosafety and Biosecurity Month

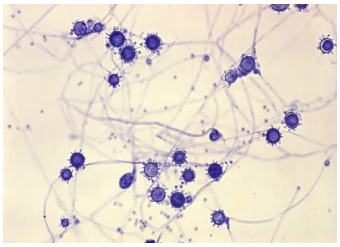
Beyond the Lab:
Increasing the Visibility of Biosafety and Biosecurity

ABSA INTERNATIONAL
The Association for Biosafety and Biosecurity

The Fungus Among Us

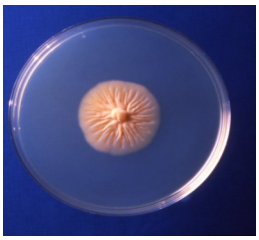
(Continued from page 1)

Histoplasmosis is caused by a soil dwelling fungus called *Histoplasma capsulatum*. The fungus can be carried on the wings, feet and beaks of birds and infect soil under the roosting sites. The fungus is prolific in nitrogen rich soils where large quantities of bird droppings or bat guano are found. Active and inactive roosts of blackbirds (e.g. starlings, grackles, red-winged blackbirds and cowbirds) have exhibited heavy fungal concentrations of *H. capsulatum*. In the United States, it can be found mainly in the central and eastern states, especially around the Ohio and Mississippi river valleys. People can get histoplasmosis by breathing in the fungus in these areas. It is not transmittable person to person.



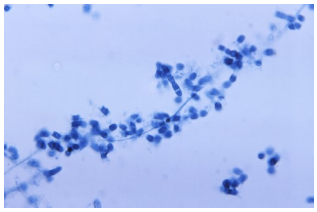
H. capsulatum—CDC/ Dr. Libero Ajello

Symptoms of infection usually appear between three to seventeen days after breathing in the fungus. Symptoms include: fever, cough, extreme fatigue, chills, headache, chest pain, body aches. Since the symptoms are similar to other diseases such as tuberculosis, correct diagnosis and treatment is often delayed. Severe chronic illness can occur in individuals with weakened immune symptoms and people who are exposed to a large amount of the fungus. However, the majority of people who breathe in the fungus that causes histoplasmosis are asymptomatic or have mild symptoms.



Blastomyces dermatitidis
CDC/ Dr. Arvind A. Padhye

Blastomycosis is caused by the fungus *Blastomyces dermatitidis*. This environmental fungus is found in soil where wood and leaves are decomposing throughout the Ohio and Mississippi River valleys and the Great Lake regions. Much like histoplasmosis, individuals contract the illness by breathing fungal spores from the air. Flu –like symptoms typically appear three weeks to three months after exposure. Symptoms can become severe in individuals with weakened immune systems spreading from the lungs to other parts of the body, such as skin, bones, joints and central nervous system. People who participate in outdoor activities that are exposed to wooded areas such as forestry, hunting and camping are at a higher risk for contracting the illness.



Coccidioides immitis
CDC/ Lucille Georg

Coccidioidomycosis, also known as Valley Fever, is caused by the fungus *Coccidioides*. The fungus can be found in the soil in the southwestern United States, as well as parts of Mexico and South America. The illness is contracted by breathing in microscopic fungal spores from the air. Most often people exposed to the fungus never have symptoms, while others may have self-limiting flu-like symptoms that appear between one to three weeks of exposure. Severe Valley Fever can occur in approximately 5-10% of people who contract the illness as chronic lung issues develop and the infection spreads to other parts of the body.

Exposure prevention is the best way to prevent infection from all three of these fungal organisms. Avoiding situations where contaminated material might become aerosolized and inhaled is particularly important for individuals with weakened immune systems. Avoid disrupting soils in potentially contaminated areas where *Blastomyces* is suspected and avoid dust in regions where *Coccidioides* is endemic. Respiratory protection in the form of properly selected NIOSH approved respirators and other personal protective equipment in conjunction with training may be needed when the activities cannot be avoided. Awareness of potential infection is paramount in correctly diagnosing and initiating treatment of these illness.

Natasha Lindahl, MT(ASCP)
Supervisor, Special Microbiology

References

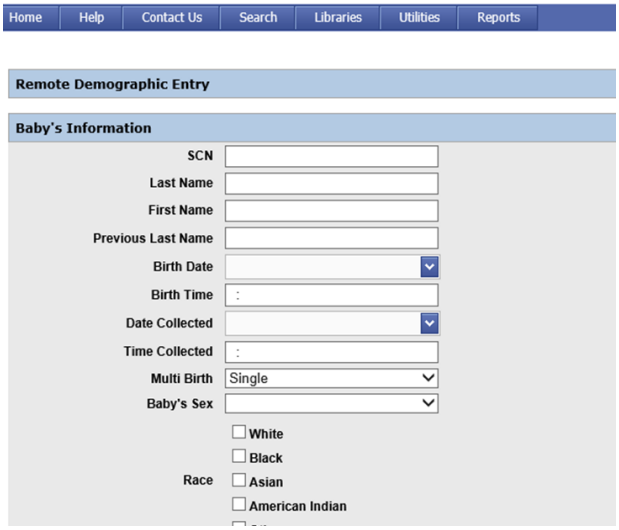
Centers for Disease Control and Prevention. Fungal Diseases page. (2013) Retrieved from https://www.cdc.gov/fungal/index.html 09/09/2019.

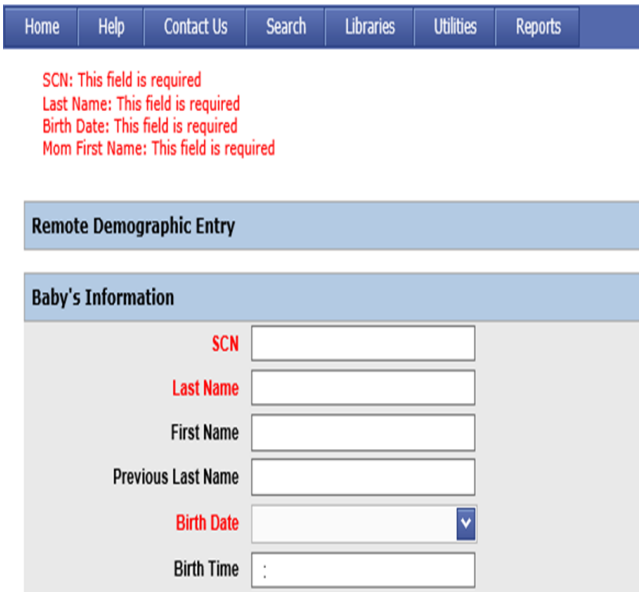
Centers for Disease Control and Prevention. Histoplasmosis: Be Safe Around Bird or Bat Poop! (July 1, 2019). Retrieved from https://www/cdc/gov/fungal/features/histoplasmosis.html 09-09-2019.

Centers for Disease Control and Prevention. Histoplasmosis: Protecting Workers at Risk (2004) Retrieved from https://www.cdc.gov/niosh/docs/2005-109/pdfs/2005-109.pdf 09-09-2019.

Newborn Screening Remote Demographic Entry Update

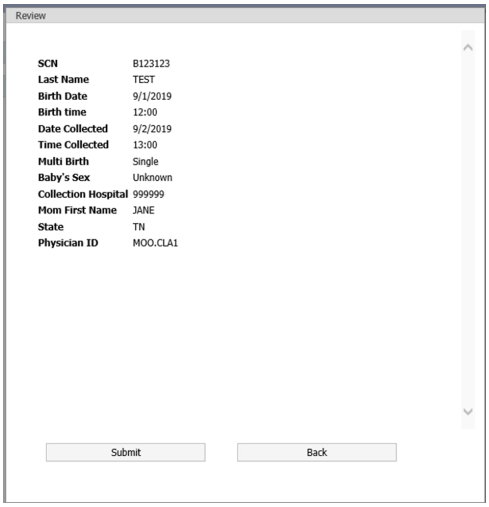
The TN Newborn Screening Program made the decision to move forward with HL7 two years ago. Because HL7 messaging is still under development, it will be some time before it is implemented. Instead of waiting for HL7 messaging to be ready, the decision has been made to split the HL7 and Remote Demographic Entry projects. This was done to provide a way to give users the ability to enter demographic data remotely. Because the Secure Remote Viewer is already in place, it will not require much to put RDE in place. Users will need a separate login from SRV to use Remote Demographic Entry. A request has been made with the vendor to combine the tasks.





The online form (above) requires the same information as included on the Blood Spot Card. The form gives three options: Save, Submit and Cancel. To save a record, the SCN, last name, birth date and mother's name must be completed on the form. In order to submit the form, all of the previously mentioned entries, plus the birth time, date of collection, time of collection, baby's sex, birth weight, gestation age, current weight, birth hospital and physician ID (infant's PCP) must be entered. Also, if yes is marked for transfused, the transfusion date and time, as well as the transfusion type, must be entered. In the event that the form does not contain the required information above, the user will receive a warning (left) that the required fields are not complete when submitting.

Once all of the required information has been entered, the user will click submit. A pop-up window (right) will display an overview of the data being sent. In order to send the data to the lab, submit will have to be clicked once more on the overview pop-up screen. If any information needs to be corrected before submission, the user can click the back button to make changes.



Once you click submit the data will go on hold until the lab receives the sample. You can verify that the lab has received the sample by using the search link.

(Continued on page 8)

TDH Laboratory Services participates in Harm Reduction Resource Team demonstration project

In August 2019, TN began the Harm Reduction Resource Team, or HRRT, demonstration project. By determining outbreaks and clusters of significance this project will effectively promote prevention, early detection, and rapid response to HIV/HCV infected people who inject drugs. The project will focus on clusters of significance in three highly vulnerable rural public health regions in eastern TN (Knox, East, and Northeast).

All HCV specimens will be shipped to the Knoxville Regional Public Health Laboratory for HCV antibody testing and nucleic acid amplification RNA testing. RNA positive specimen will be routed to the Nashville Public Health Laboratory for global hepatitis outbreak and surveillance technology, also known as GHOST, testing using next generation sequencing. This surveillance technology compares the positive HCV sequences to determine how closely the specimens are related to each other. This comparison of genetic fingerprints of the HCV specimens is presented both in the form of a phylogenetic tree and/or a GHOST diagram and will provide useful information for studying transmission links between patients. This is one component of epidemiology investigation.

The implementation of HRRT demonstration project will strengthen interventional surveillance and response capacity, which includes detection of existing and potential HIV and HCV transmission networks. In addition, it will improve understanding of drug use behaviors amongst persons who inject or snort drugs, and reduce transmission from people living with HIV therefore preventing new infections between at risk persons for HIV. This will help develop referral directories for prevention and treatment services for members of identified HIV and/or HCV transmission networks or clusters of significance. The goal of a referral directory is to reduce ongoing transmission and the prevention of future outbreaks.

Submitted by:
Xiaorong Qian, Ph.D, HCLD (ABB), Assistant Director, Molecular Biology
Linda Thomas, MAFM, BSMT(ASCP), Manager, Molecular Biology and Sequencing
Christina Moore, MLS(ASCP)^{cm}, Supervisor, Sequencing Section, Molecular Biology
Jeannette Dill, M(ASCP), Supervisor, Molecular Biology

Newborn Screening Remote Demographic Entry Update

(Continued from page 7)

The search screen shows the status of a sample through the process:

- *Saved*: Information has been saved but has not been submitted.
- *Submitted*: Data has been sent to NBS, but the sample has not been received.
- *Merged*: The sample has been received is being processed.

Select	123455	LNAME		Unknown	9/1/2019			999999		MFNAME		Merged
Select	E456848	TEST SARA		Unknown	9/1/2019			999999		SARA		Saved
Select	E698784	TEST SUBMIT		Female	9/2/2019	9/5/2019		999999		TEST SUB		Submitted

The date for implementation of Remote Demographic Entry will announced at a later date. If you have any questions about the RDE portal please contact hugh.peeples@tn.gov .

Submitted by :
Hugh Peeples, MLS(ASCP) Clinical App Coordinator

TRAINING NEWS

Biosafety Workshops Postponed

The Biosafety Workshops scheduled for October 2019 have been postponed. New dates and registration information will be posted on the TDH Laboratory Services Training and Workshops webpage.

TDH WORKSHOPS

TDH Laboratory Services workshops are provided at no charge and are funded by the Public Health Emergency Preparedness Grant. The purpose of these workshops is to provide training to laboratory staff working in sentinel microbiology laboratories in Tennessee. Sentinel hospital laboratories analyze or refer samples that may contain microbial agents, biological toxins, chemical agents, chemical agent metabolites or radiological agents of public health significance, and therefore, function as "sentinels" in the public health laboratory system.

Workshops planned for 2020 include:

- **Infectious Substance Packaging and Shipping Training for Laboratory Personnel**
  Offered at multiple locations across the state. Two sessions (morning and afternoon) are offered at each location.
- **2020 LRN Workshop**
  Laboratory Response Network Workshops are all day workshops held in Nashville, Knoxville and Memphis. Topics are chosen from recommendations from previous LRN Workshops.
- **Bio-Threat Preparedness: Rule Out or Refer**
  This workshop is designed for laboratorians working in sentinel microbiology laboratories in Tennessee. This all day wet workshop is held in Nashville and is offered 6 times per year. This workshop does have selective admission requirements.
- **Biosafety Workshops**
  This all day workshop focuses on biosafety in the clinical microbiology laboratory. The workshop is held in Nashville, Knoxville and Memphis.

Dates for the 2020 TDH workshops will be announced after the new year. Details and registration information will be posted on the TDH Laboratory Services Training and Workshops webpage: https://www.tn.gov/health/health-program-areas/lab/lab-education.html.

New HIV, Viral Hepatitis and TB Resources from APHL

APHL has recently published a number of new and updated resources and tools for public health laboratories. While directed to the public health laboratories, these resources may also be useful and of interest to clinicians, epidemiologists and TB Control program staff. In order to easily share these materials, APHL has created flyers for the HIV and Viral Hepatitis publications, as well as the Tuberculosis resources.

Welcome New Employees!

June 2019

Bethany Wheeler—PH Lab Scientist 1—NBS

July 2019

Christopher Turrill—PH Lab Tech 2—ARLN

Sara Belknap—APHL Fellow—ARLN

August 2019

David Bryant—PH Lab Tech 2—Media Prep

Shelby Lowrie—PH Lab Scientist 1—Serology

Daniel Wade—PH Lab Tech 2—Sample Coordination

Congratulations on your Retirement!

September 2019

Claudia Lowe—PH Lab Scientist 3—Newborn Screening

Congratulations on Your Promotions!

July 2019

Kevin Woods—ASA 5—Administration

June 2019

Ian Jasitt—PH Lab Tech 2—Warehouse

Nicole West—PH Lab Scientist 3—Virology

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TN Department of Health

The Mission of Laboratory Services is to provide high quality analytical services of medical and environmental testing and to achieve the Mission of the Department of Health.

https://www.tn.gov/health/health-program-areas/lab.html

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