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Public Health Laboratory Newsletter

Lisa Piercey, MD, MBA, FAAP
Commissioner of Health

Richard Steece, PhD, DABMM)
Director, Laboratory Services

Inside This Issue:

TDH Laboratory Services Certified to Perform Lead Analysis in Drinking Water Samples

Lead is a toxic metal that is harmful to human health. Lead can be toxic at lower exposure levels and tends to bioaccumulate in the body over time. Children, especially young children and infants, are susceptible to even low levels of lead. Exposure in children has been linked to damage in the central nervous system and learning disabilities.

In May of 2018, the Tennessee General Assembly passed a law to address lead in the drinking water of Tennessee schools. The law, which took effect on January 1, 2019, requires local school boards to develop a plan to implement lead testing of drinking water in schools built before January 1, 1998. If the lead result is greater than 15 ppb but less than 20 ppb, the school is mandated to test on an annual basis until retesting confirms that the lead level is less than 15 ppb. If the lead result is equal to or greater than 20 ppb, the school is mandated to remove that drinking water source from service. The source is to remain out of service until retesting confirms that the lead result is less than 20 ppb. Within 24 hours of receiving that elevated lead result the school is required to notify the Commissioners of Environment and Conservation and of Health, the State Department of Education, the local governing body and the county health department. Parents and guardians of the students of the school are to be notified within five business days of receiving the lead result. If results are equal to or greater than 20 ppb, retesting of the drinking water source must occur within 90 days of any corrective action.
The Environmental Protection Agency has been authorized through the Safe Drinking Water Act to award a grant to states for assistance in voluntary testing for lead in drinking water at schools and child care facilities. EPA's goal is to reduce exposure of children to lead in drinking water. EPA announced the grant in September 2018. By the February 2019 deadline all 50 states declared their intent to participate in the grant program. EPA will award approximately $43.7 million to states that declare intent to participate. The states will have to develop work plans and budget narratives and these documents will be

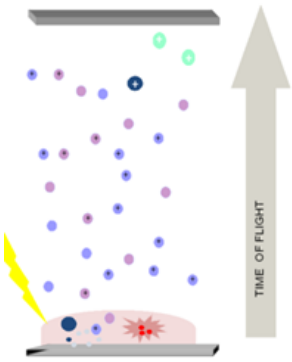
(Continued on page 5)

VDRL TESTING DISCONTINUED

Effective June 30, 2019, Tennessee Department of Health, Division of Laboratory Services will no longer perform VDRL testing for Syphilis. The discontinuation of this testing is a result of efforts to comply with the Governor's priority for fiscal strength and efficient government. By eliminating costs associated with maintaining low volume tests, we can focus our priorities on laboratory testing that is more beneficial to the people of Tennessee. Serum and whole blood specimens for Syphilis testing via Rapid Plasma Reagin, or RPR, will still be performed. If you have any questions, please contact Lindsay Jolly, Immunoserology Supervisor at 615-262-6375 or lindsay.jolly@tn.gov.

Spotlight on Safety

MALDI-TOF Instrument Considerations



Does your lab have a Matrix Assisted Laser Desorption Ionization —Time of Flight, or MALDI-TOF, instrument? If you have one in use or plan to purchase one in the future, it is important to perform a **biological risk assessment** prior to testing. With increasing workload and staffing concerns in the microbiology laboratories MALDI is a very useful piece of equipment; however with any new technology there are safety concerns to be considered and mitigated. Some areas to be considered include:

- Transfer "spotting" of isolate on target plate
- Chemical hazards of formic acid and trifluoroacetic acid
- Effective disinfection of reusable target plates
- Risk of dispersal of viable bacteria via exhaust due to incomplete inactivation

During 2019 to date, 24 microbiologists have been exposed to either *Brucella melitensis* or *Francisella tularensis* during test procedures involving MALDI-TOF technology. Sentinel laboratory costs for post exposure surveillance and prophylaxis can add up quickly with multiple exposures. These exposures may have been avoided had American Society for Microbiology protocols for handling bio-threat agents been followed. These guidelines include examination for trigger points by examination of growth characteristics, gram stain, biochemical reactions and patient history. Despite biosafety education, improved lab safety protocols, better engineering controls and biocontainment equipment laboratory acquired infections, or LAIs, continue to pose a risk.

Risk Assessment template and instructions may be found at:

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

Questions or requests for more information on MALDI-TOF safety may be directed to Rolinda.eddings@tn.gov

Submitted by:
Rolinda Eddings MT(ASCP), Safety Officer

Building a Custom Database for MALDI-TOF Identification

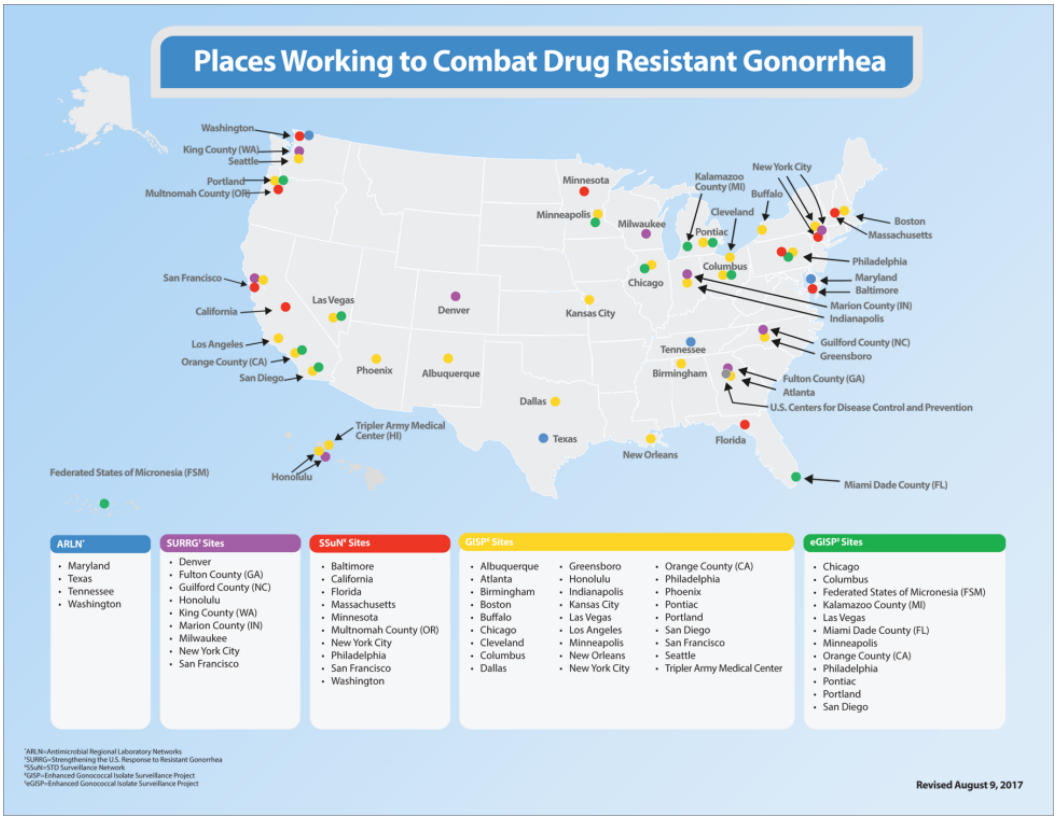
Matrix-assisted laser desorption/ionization time-of-flight mass spectrometry, or MALDI-TOF MS, is a relatively simple and cost-effective tool for the identification of bacteria using protein mass spectrum profiles. This has increased the accuracy and speed of routine ID testing in labs, and in many instances it can replace the need for conventional biochemical tests. The Tennessee Department of Health Public Health Laboratory currently uses the Bruker Biotyper database which contains around 8,000 MSPs, representing a wide range of unicellular organisms. However, issues can arise with organisms that are not commonly encountered in a standard clinical lab as they are not thoroughly represented within the manufacturer's database. This can delay genus and/or species level identification, requiring additional testing such as 16S rRNA sequencing, conventional biochemical tests or characterization by the CDC. The General Bacteriology department at the TDH Public Health Laboratory will address this matter by creating a custom in-house reference library. Over 200 isolates that previously could not be reliably identified, but verified through 16S sequencing or alternative testing methods will be collected and a separate MSP database will be built for future referencing in tandem with the Bruker database. Adding the custom database to our testing workflow will allow the lab to increase efficiency for the reliable identification of a more diverse set of organisms and reduce the need for additional testing of isolates that do not meet the screening criteria with the standard library.

Submitted by:
Victoria N. Stone, PhD, PH Laboratory Consultant 2
Andrew S. Lux , PH Laboratory Scientist 2

ARLN Regional Labs Help Combat Antibiotic Resistant Gonorrhoeae

Neisseria gonorrhoeae is a common human pathogen and one of the most frequently reported infectious diseases in the United States. *N. gonorrhoeae* is the etiologic agent of the STD known as gonorrhea and according to CDC estimates, infects up to 820,000 Americans every year. *N. gonorrhoeae* infections have become a threat to public health in recent years because of the organism's propensity to develop drug resistance—30% of new gonorrhea infections each year are resistant to at least one drug. This burgeoning resistance has resulted in a drastic reduction in treatment options available in the US since 2006.

In 2015, an executive order from the President created the National Action Plan for Combating Antibiotic Resistant Bacteria, a 5-year strategy to control, prevent and detect antibiotic resistance in bacteria. CARB funds the Antibiotic Resistance Laboratory Network, a network of public health labs funded to have enhanced capacity for culture susceptibility testing and genomic sequencing capabilities. Tennessee is one of the seven ARLN regional labs in the country, four of which are GC ARLN regional labs.



The isolates are sourced specifically from three projects, the Gonococcal Isolate Surveillance Project (GISP), the enhanced Gonococcal Isolate Surveillance Project (eGISP) and the Strengthening the United States' Response to Resistant Gonorrhea (SURRG). These programs have gradually increased in scope and specificity over the years, as well as provide valuable epidemiological data.

As of May 2019, the TDH Public Health Laboratory has performed culture-based antimicrobial susceptibility testing and genomic sequencing from over 1000 *N. gonorrhoeae* strains.

ARLABnetwork

Submitted by:
Zach Perry, M(ASCP), PH Laboratory Scientist 2

TENNESSEE IS ON THE VANGAURD WITH SCREENING FOR LYSOSOMAL STORAGE DISORDERS IN NEW BORN BABIES

Tennessee began screening newborn babies for diseases starting with Phenylketonuria in 1968. Since then, over 70 diseases have been added to the Newborn Screening profile for newborn babies in Tennessee, as well as for newborn babies from several clinics and hospitals across four Latin American Countries.

In 2017, the Lysosomal Storage Disorders, or LSD, panel was added to the list by the Secretary of Health and Human Services, bringing light to several genetic diseases presented at birth. Some LSDs can be treated, therefore screening is important in providing early detection and treatment of otherwise permanent developmental disabilities.

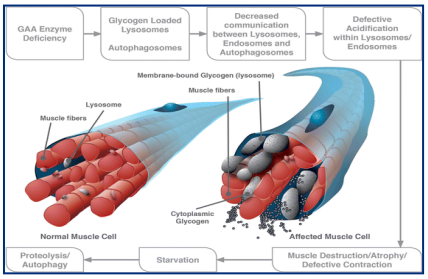


Figure 1. A normal muscle cell is presented on the left and an LSD-affected muscle cell on the right.

Lysosomes are subcellular organelles containing enzymes which breakdown cell waste, food particles, and bacteria and viruses. Missing enzymes in lysosomes result in toxic buildup of waste within the cell resulting in cellular dysfunction and disease. *Figure 1*. There are more than forty known LSDs, but due to the availability of therapy and treatments the TN Public Health Laboratory tests for five: Pompe, Krabbe, Gaucher, Fabry and Mucopolysaccharidosis Type I.

It is important to detect these diseases as early as possible, a task made difficult due to the lengthy procedure, which takes two days from sample receiving to reporting. Once a punched dried blood sample is eluted, it is incubated for eighteen hours, and then processed further in order to separate into identifiable enzymes using a tandem mass spectrometry instrument. Each sample plate, which can contain up to 88 patient samples, takes approximately 3.5 hours to complete on the mass spectrometer. Furthermore, a preliminary positive result is processed a second time to confirm, which then takes a total of four to five days of processing time. To improve turnaround times, the TDH Public Health Laboratory recently has added weekends and holidays to the work schedule.

Newborn screening programs across the United States, including Tennessee, are increasing screening for LSD utilizing tandem mass spectrometry, or MS-MS. At present, there are six state programs using MS-MS for LSD screening: New York, Illinois, Tennessee, Kentucky, Massachusetts, Minnesota and Ohio. Mass Spectrometry measures specific masses within a given sample by giving each specific mass an electrical charge (ion) and sorts each ion to a mass to charge ratio. With MS-MS, compounds are separated by molecular weight by one mass spectrometer, fragmented as they exit and are identified on the basis of their fragments by a second mass spectrometer. In the last decade, technology has expanded and methods are evolving for MS-MS. This might allow for additional LSDs to be added to the Newborn Screening panel in the future. The table to the right shows the number of LSD-confirmed babies in Tennessee during the time period of July 2017 through December 2018.

Submitted by:

Emily C. Mackie, MLS (ASCP), PH Laboratory Scientist 1

Lawrence Pastor, M.D., PH Laboratory Scientist 1

1.5 Years of Tennessee LSD Screening Totals

Krabbe, Pompe, Gaucher, Fabry and MPS-I Screening - July 1, 2017 to December 31, 2018 (~131,618 Births)

Disorder	Screen Positives	Confirmed Disorders	Pseudo-deficiencies	Carriers (1-Pathogenic or 1-VOUS)	Normal based on Sequencing
Pompe	22	16 2-IOPD 14 LOPD	4	2	0
Gaucher	12	1	0	6	4
Fabry	31	11	0	0	11
MPS-1	41	3	27	10	0
Krabbe	26	2 - LOKD	12	10	0
Aggregate	132	15	43	28	15

False Positive Rates: Pompe = 0.004%, Gaucher = 0.007%, Krabbe =0.018%, Fabry = 0.008%, MPS I = 0.028%,

Positive Predictive Values: Pompe = 72.7%, Gaucher = 8.33%, Krabbe = 15.38%, Fabry = 64.5%, MPS I = 7.32%,

References:

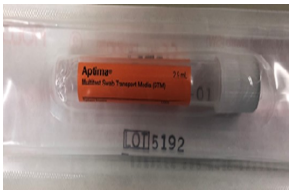
- https://www.tn.gov/health/health-program-areas/newborn-screening.htm
- https://rarediseases.org/rare-diseases/lysosomal-storage-disorders/
- https://bmcneurol.biomedcentral.com/articles/10.1186/s12883-015-0412-3
- International Journal of Neonatal Screening: Current State of the Art of Newborn Screening for Lysosomal Storage Disorders. Millington and Bali

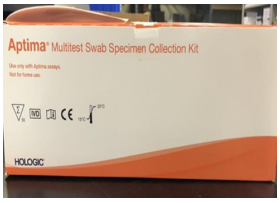
Change In Specimen Collection Device for CT/GC Testing

Aptima Multitest Swab Specimen Collection Kits should now be used to collect specimens from vaginal, throat, and rectal sources. The transition to Aptima Multitest Swab Specimen Collection Kits is the result of recent FDA approval of clinician-collected throat and rectal samples as specimen types for detection of *Chlamydia trachomatis* and *Neisseria gonorrhea*. The Aptima Multitest Swab Specimen Collection Kits will replace the Aptima Unisex Swab Specimen Collection Kits previously issued for collection of CT/GC testing of throat and rectal sources and you may begin using the Multitest Swab kits immediately. The Aptima Unisex Swab Specimen Collection Kits should be used for collection of endocervical and urethral specimens. Beginning August 1, 2019, only the source/collection kit combinations below will be accepted for CT/GC Testing.

Source	Collection Kit	Label/Swab Color
Endocervical	Aptima Unisex Swab Specimen Collection Kit	Blue
Urethral	Aptima Unisex Swab Specimen Collection Kit	Blue
Urine	Aptima Urine Collection Kit	Yellow
Rectal	Aptima Multitest Swab Specimen Collection Kit	Orange
Throat	Aptima Multitest Swab Specimen Collection Kit	Orange
Vaginal	Aptima Multitest Swab Specimen Collection Kit	Orange

TN County Health Departments may request Aptima Multitest Swab Specimen Collection Kits from our shipping department using the current lab supply requisition by marking Chlamydia/Gonorrhea (Gen-Probe) Multitest Kit. If you have any questions, please contact Lindsay Jolly, Serology Supervisor, at 615-262-6375 or lindsay.jolly@tn.gov.





E. Coli O103 Outbreak affects Tennessee

For many weeks, multiple states, including Tennessee, have been investigating an outbreak of Shiga toxin-producing *Escherichia coli* O103 infections, presumably linked to ground beef. A total of 196 people have been reported from ten states as being affected, with ages ranging to from infants to 84 years. Thankfully, no patients have developed hemolytic disease or expired as a result of this outbreak event. Ill people associated with this outbreak are suspected of having eaten ground beef from two main suppliers. According to the CDC, much of the affective ground beef has been recalled, but more contaminated product may still be unidentified and on the market. The investigation continues.

Submitted by:
Tracy S. McLemore, MT (ASCP), MBA, Manager, Molecular Enteric Microbiology & Antibiotic Resistance Program

Lead Testing *(Continued from page 1)*

reviewed and approved before the grant is awarded. The state of Tennessee's allotment has been announced at $697,000.

The Tennessee Department of Health Laboratory is certified by the EPA to perform analysis for lead in drinking water samples. The analysis is performed on an inductively coupled plasma-mass spectrometer, or ICP-MS, which offers quick throughput and low detection limits. The laboratory performs this testing according to prescriptive guidelines set forth in EPA Method 200.8: Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma Mass Spectrometry. The Tennessee Department of Health Laboratory is available to assist in the testing of lead in school drinking water if called upon.

Submitted by:
Craig Edwards, Environmental Assistant Director

LRN Laboratory Response Network for BIOLOGICAL THREATS

20 years of Progress

2019 marks the 20th anniversary of the Laboratory Response Network (LRN). The Laboratory Response Network for Biological Threats (LRN-B) was created to strengthen the nation's ability to detect biological threat agents, like smallpox and anthrax. Its structure and unique capabilities enable it to respond not only to biothreats, but also emerging infectious diseases, like Ebola.

Data for Decisions

The LRN-B rapidly detects and accurately characterizes potential threats to guide critical decisions. CDC develops protocols, manufactures test kits, and ensures LRN-B laboratory staff have specialized training to consistently identify disease threats and emerging infections. Decision makers know they can trust results to inform response efforts, including the use of medical countermeasures.

Leading the Way

CDC remains committed to sustaining and strengthening the LRN-B's capacity to:

- Develop and improve diagnostics
- Harness new technologies
- Strengthen partnerships
- Ensure tests can be rapidly deployed in a response
- Sustain an elite group of trained professionals

Strength in Partnerships

The LRN-B leverages the skills and expertise of federal, state, and local public health and clinical laboratory partners, as well as national leadership organizations like the Association of Public Health Laboratories. The LRN-B includes a vast network of sentinel laboratories that provide a first line of defense to quickly recognize, rule out, and refer suspected threats to LRN-B reference laboratories for further testing.

By the Numbers

120+
LRN-B member laboratories in the US

84%
of US population lives within 100 miles of an LRN-B lab

45
distinct tests for biological threats, emerging infectious diseases, and other high-consequence pathogens—like Ebola, plague, and smallpox

67,000
specimens LRN-B member laboratories tested for Zika in 2017

3,000
specimens LRN-B member laboratories tested for potential threat agents in 2017

Distinguished Impact

First Line of Defense

From protecting Democratic and Republican National Conventions, Super Bowls, and the Olympics against potential biothreats, to serving as the experts any time a suspicious white powder needs to be tested, the LRN-B stands ready to protect Americans every day. Day in and day out, year after year, the LRN-B provides reliable results.

Anthrax in New Hampshire

In 2009, the New Hampshire Public Health Laboratory diagnosed a young woman with gastrointestinal anthrax, an extremely rare illness. The laboratory worked with LRN-B partners to collect, test, and confirm 145 samples, tracing the infection to a drumming event–anthrax spores can be found in animal hides used on drums. Quick work by the laboratory and LRN-B partners ensured that the patient received an accurate diagnosis and life-saving treatment. It also meant that the community could take steps to prevent further infections.

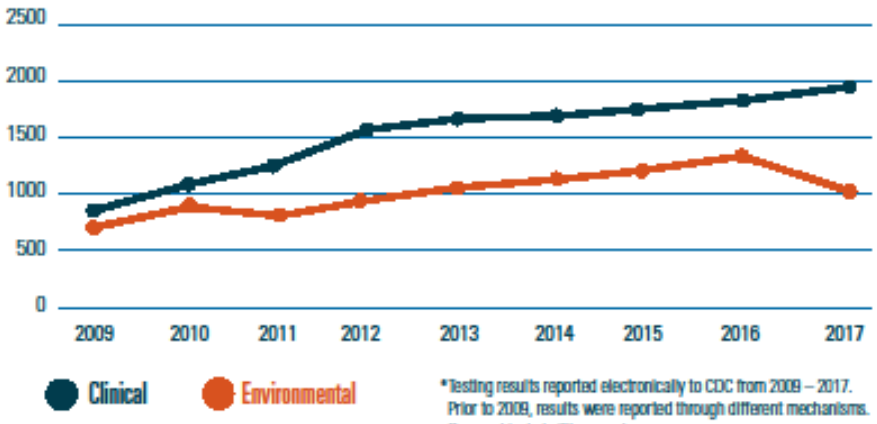
Ebola in West Africa

During the Ebola outbreak in West Africa, CDC worked with its own scientists and external partners to develop and deploy Ebola laboratory tests into the LRN-B, ensuring the US was prepared and able to test for this deadly pathogen.

Zika

During the recent Zika outbreak, CDC developed and deployed two Zika diagnostic assays to LRN-B reference laboratories across the US. From March 2016 through April 2017, LRN-B reference laboratories tested and reported over 90,000 distinct results to CDC–a staggering volume.

Total Samples Tested in LRN-B laboratories 2009 – 2017*



*Testing results reported electronically to CDC from 2009 – 2017. Prior to 2009, results were reported through different mechanisms. Does not include Zika samples.

LRN-B TIMELINE

1999
LRN-B established in 17 laboratories

2001
Anthrax attacks: LRN activates for first major response

2002
SARS: CDC develops and deploys new test to LRN-B

2004
RNC and DNC: LRN-B experts deploy for rapid response

2009
Anthrax in New Hampshire: quick diagnosis for prevention of additional cases

2012
MERS: CDC develops and deploys new test to LRN-B

2014
Ebola: CDC develops and deploys new tests to LRN-B

2016
Zika: CDC develops and deploys new test to LRN-B

2019
Over 120 member laboratories in all states

301716J

TDH Vector-Borne Diseases Hosts Mosquito University 3.0

On May 1-2, 2019, TDH hosted a mosquito control training session called Mosquito University 3.0. With support from the Southeastern Center for Excellence for Vector-Borne Diseases, the workshop focused on teaching attendees about pesticide resistance in mosquitoes. Much like with antibiotics used against bacteria, resistance can occur in the pesticides used to combat mosquitoes. Since pesticides are one of our most important tools in battling disease carrying mosquitoes, being able to identify and manage resistance is of great public health importance.

Participants included vector control groups, epidemiologists, entomologists and program directors from several programs and states (AL, AR, KY, MO, MS, SC), as well as partners in TN. On May 1, Dr. Janet McAlister from CDC presented on pesticide resistance testing mechanism of resistance, how to conduct the CDC bottle bioassay and strategies to manage resistance during an outbreak. Dr. Abelardo Moncayo, Director of TDH Vector-Borne Diseases Program, introduced field and lab experiences to demonstrate egg collection methods and how to raise mosquitoes from eggs to adults to obtain adults to conduct the CDC bioassay in their jurisdictions on both days of the training. He also trained attendees on larval identification techniques using specimens provided by the SE and NE Centers of Excellence in Vector-Borne Diseases. Participants appreciated the hands-on training and demonstrations that will facilitate implementation of training material.

Submitted by:
Abelardo Moncayo, PhD, Director, Vector-Borne Diseases Program

TDHDLS Hosts Bio-Threat Preparedness Rule Out or Refer Workshop

On June 14, 2019, TDHDLS hosted an all-day, intermediate level, hands-on workshop focusing on practical methods that clinical microbiology labs can use to remain alert for the agents of bioterrorism. Participants learned about surveillance and evaluation procedures that can be integrated into the routine work of the clinical microbiology lab. Procedures for the referral of suspect cases were also discussed. Following appropriate safety precautions, participants examined actual cultures and organisms in a laboratory setting.

Two more opportunities remain for Medical Laboratory Scientists and Medical Laboratory Technicians working in microbiology laboratories in Tennessee. To submit your application for the remaining 2019 workshops, click the date you wish to attend below or visit:

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

LOCATION: **Nashville, TN**

DATES: Thursday September 26 Friday September 27

TRAINING NEWS

2019 TDH WORKSHOPS

The following TDH workshops are brought to you at NO CHARGE by the Public Health Emergency Preparedness Grant. Click on the date/location to complete the online application or visit the Lab Services webpage https://www.tn.gov/health/health-program-areas/lab/lab-education.html to register or download the workshop flyers.

2019 INFECTIOUS SUBSTANCE PACKAGING AND SHIPPING TRAINING

DESCRIPTION:

Individuals who send or oversee the transportation of infectious or biological substances must know and understand regulations that apply to the mode of transportation they employ. This workshop will assist participants in maintaining compliance with regulations associated with transport of Division 6.2 infectious substances.

AUDIENCE:

Laboratory personnel involved with the classification and shipment of Category A and/or Category B biohazardous substances working in clinical laboratories in Tennessee. CE Credit will be provided for TN Lab Licensure renewal.

DATES/LOCATIONS: July 25: Nashville September 11: Memphis September 12: Jackson

TIME: 2 Sessions Offered at Each Location: AM (8:15 — 11:15) PM (1:15 — 4:15)

Each session is limited to 20 participants. Sessions and/or locations with low enrollment may be canceled.

2019 LRN WORKSHOP

DESCRIPTION:

The Laboratory Response Network (LRN) workshop is a full day course (9:00 AM—3:30 PM *local time*) that covers a variety of clinical microbiology laboratory topics. Topics have been selected from suggestions from laboratorians across the state and include: Bioterrorism, High Consequence Pathogens, Foodborne Illness, Influenza and Antibiotic Resistance. *Lunch will be provided. Lodging and travel expenses are not covered.*

AUDIENCE:

Clinical/Medical Laboratory Scientists and Medical Laboratory Technicians working in microbiology laboratories in Tennessee. CE Credit will be provided for TN Lab Licensure Renewal.

DATES/LOCATIONS: July 17 Memphis August 9 Knoxville

Welcome New Employees!

April 2019

Domonique Allen—PH Lab Technician 1—NBS

Kristy Hite—PH Lab Technician 1—NBS

May 2019

Elizabeth Kassens—PH Lab Scientist 1—Serology/Virology

Penny Coe—PH Lab Scientist 1—ARLN CRO

June 2019

Brittany DuVal—PH Lab Scientist 2—Inorganic Chemistry

Jason Mitchell—PH Lab Scientist 1—Enterics

Congratulations on your Retirement!

Bob Read—32 years of Service

PH Laboratory Division Director—Environmental Lab

Congratulations on Your Promotions!

April 2019

Ying Qi—PH Lab Scientist 2—NBS

June 2019

Chanice Wilkes—PH Lab Scientist 1—Sequencing

Rhett Milam—PH Lab Scientist 1—Radiochemistry

Holly Jones—PH Lab Scientist 1—Metals

Ron Trubilowicz—PH Lab Manager 1—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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