TN Department of Health

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PUBLIC HEALTH LABORATORY NEWSLETTER

Mycobacterium tuberculosis Samples Requested

The State Public Health Lab would like to perform a validation study of the GeneXpert MTB/RIF assay on non-sputum specimen types. Currently, Cepheid (the manufacturer of GeneXpert) only has Food and Drug Administration approval for testing on sputum. The SPHL has previously performed this validation study but due to a change in instrumentation now must repeat the verification process. This validation is important in the treatment and control of tuberculosis because *Mycobacteria* can disseminate to various body fluids and may often be present at detectable levels in those fluids prior to developing respiratory symptoms, and often times a non-sputum source may be the only specimen received.

To perform this study, we are asking our clinical partners to submit any suspicious *Mycobacterium tuberculosis* non-sputum specimen types to the SPHL for analysis. Specimen types could include bronchial washing or lavage, lymph node, urine, stool, blood, CSF, bone marrow and endotracheal aspirates. Non-sputum specimen types will be initially processed, if necessary, upon receipt using N-acetyl-L-cysteine and sodium hydroxide method. Additionally, an AFB smear and culture will be performed. AFB smear positive specimens will reflex for GeneXpert testing. Smear negative specimens will be frozen and stored at -70°C until culture identification is determined. If *Mycobacterium tuberculosis* is identified by growth on culture, the frozen specimen will be thawed and a GeneXpert test will be performed. Smear negative, culture negative and cultures other than tuberculosis specimens will not be tested by GeneXpert.

CDC/Alissa Eckert; James Archer

Mycobacteria smear and culture results will be made available to the

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National SARS-CoV-2 Strain Surveillance

Since the emergence of SARS-CoV-2, changes in the SARS-CoV-2 genetic code has resulted in the continued transmission and evolution in humans. To identify these changes, national and global efforts have focused on sequencing methods. Due to these changes, the response can impact diagnostics, antivirals and vaccines. The Centers for Disease Control and Prevention has organized a national strain surveillance program, NS3, that routinely sequences and characterizes clinical specimens that are positive for the SARS-CoV-2 as part of the public health response to the COVID-19 pandemic. Their objectives are population-level molecular epidemiology/virus monitoring, outbreak investigations and virus characterization. To help fulfill this goal, the Tennessee State Public Health Laboratory has been sending positive COVID specimens to the CDC for sequencing. In addition, the TN sequencing section began the validation and implementation of COVID sequencing for the detection of SARS-CoV-2 variants.

There are several variants of concern because they can spread easier, cause more severe disease, reduce the ability for the body to fight the infection or reduce effective treatments including vaccines. These variants of concern are as follows: B.1.1.7 (UK variant), P.1, B1.351 (South Africa), B.1.427, and B.1.429. There are two more variant classifications: variant of interest and variant of high consequence. Variant of interest are those specific genetic markers that are predicted to affect treatments, infections, vaccinations and immune response. To date, there have been no variants of high consequence identified in the United States.

Spotlight on Safety: Safety Data Sheets

The Hazard Communication Standard (CFR 1910.1200) was revised in 2012 to align with the Globally Harmonized System of Classification and Labeling of Chemicals. The GHS was updated in 2016 and now includes universal , specific hazard classifications and requirements for pictograms. The information in the Safety Data Sheet is similar to the previous Material Safety Data Sheet, which now requires the user-friendly 16-section format. Sections 1 through 8 of the SDS have general information about the chemical, identification, hazards, composition, safe handling practices and emergency control measures. Sections 9 through 11 and 16 contain technical and scientific information, such as physical and chemical properties, and stability. Section 12 through 15 contain other information such as ecological information and disposal considerations.

One of the key provisions in the OSHA HAZCOM Standard is the use of Material Safety Data Sheets . Now called an SDS, it requires any manufacturer, distributor or importer to provide an SDS for every hazardous chemical they use.

Every hazardous chemical used in the lab that has a mixture of >1.0% of a hazardous chemical, or >0.1% of a carcinogen MUST have a Safety Data Sheet, according to the Hazard Communication Standard (CFR 1910.1200). The SDS must be able to be accessed either physically or electronically. Before using any chemical in the laboratory, ensure that you are aware of the hazards and first aid measures, as well as the proper handling and disposal.

It is important to know how to access a SDS and to locate the information needed prior to an emergency.

Summary of Discontinued Tests

- **Viral Culture (11/2/2020)**
- **Bordetella PCR (10/22/2020)**
- **Biofire FilmArrray Meningitis Panel (1/29/2021)**
- **Biofire FilmArray Respiratory Panel (1/29/2021)**
- **Zika/Dengue/Chikungunya PCR (1/29/2021)**
- **MRSA PCR (May 2021)**
- **Rubella IgM (May 2021)**

For additional information, please visit: https://www.tn.gov/content/dam/tn/health/program-areas/lab/directory-of-services/announcements/SPHL_Test_menu_changes.pdf

Mycobacterium tuberculosis Samples Requested

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provider. GeneXpert results are for validation purposes only; results will not be issued or made available to providers. Upon completion of the validation study, if findings are favorable for the inclusion of non-sputum specimen types in the GeneXpert testing algorithm, results will be issued for any specimen received thereafter.

Specimens for the validation study can be sent to :

Dorothy Baynham, MT (ASCP)
Manager, Special Microbiology
Tennessee Division of Laboratory Services
630 Hart Lane
Nashville, TN 37243

Thank you in advance for your assistance in completing this important validation study for our mutual patients. For questions regarding this request, please contact Dorothy Baynham by email at Dorothy.Baynham@tn.gov or at 615-262-6366.

Newborn Screening Accomplishments

While much of Public Health Lab was wrestling with COVID-19 in 2020, the Newborn Screening staff was also hard at work. Throughout 2020 there have been many accomplishments despite the interruptions and hardships encountered by the pandemic, tornadoes and a Christmas Day bombing of downtown Nashville that directly impacted laboratory operations. The Public Health Lab is proud of the NBS staff for its fortitude and perseverance in 2020. A smattering of the highlights is below. Thank you to everyone involved in making our NBS program successful and consistently one of the best in the nation.

1. Over 84,810 TN infants screened (does not include repeat screens or South American infants tested) with approximately 100,000 total specimens, and 175 infants identified with disease.
2. Decreased turnaround time (met goal of 100% reported by day of life 5 and 99.7% by day of life 7 for first time in Quarter 4 of 2020).
3. Conducted an Artificial Intelligence Study for Isoelectric focusing for Hemoglobinopathies with Perkin Elmer.
4. Concluded an HPLC study for Hemoglobinopathies with Trinity Biotech.
5. Awarded $15,000 (APHL) in funding for the addition of C3/HCY/MMA testing.
6. Awarded over $25,500 (APHL) in funding for purchase of battery back-up for SMA/SCID analysis.
7. Received Year 2 funding for the OZ remote data entry project.
8. Implemented Lunch and Learns (peer lectures for employee development).
9. Facilitated continuity of operations plan, or COOP exercises with South Carolina and Florida in April 2020.
10. Participated in the X-Linked Adrenoleukodystrophy harmonization project with New York NBS (manuscript awaiting publication).
11. Contributing to the Clinical Laboratory Standard Institute Document Development Committee for blood spot collection.
12. Provided a presentation for Newborn Screening Rare Disease Day Activity February 2020.
13. Implemented Spinal Muscular Atrophy screening for production in February 2020.
14. Valerie Ragland was selected for Newborn Screening and Genetics in Public Health committee with the Association of Public Health Laboratories.
15. Valerie Ragland presented a poster presentation on the QI initiative at the 2020 NBS Symposium.
16. Enacted COOP with Florida to facilitate continued NBS during the Christmas Day bombing.

NBS Public Health Lab Staff to the Rescue

Over Memorial Day weekend, the South Carolina Newborn Screening Laboratory experienced a network outage that adversely affected laboratory operations. They quickly reached out to the TN NBS laboratory (because of the continuity of operation agreement that the two labs share) and the TN NBS lab staff were quick to mobilize into action. Unscheduled NBS staff came into the laboratory on Sunday, May 30 to process 190 South Carolina specimens.
We are grateful to the NBS lab staff, their work ethic and the compassion towards our neighbors from the East.

Testing Wastewater To Help Detect COVID-19

The COVID-19 pandemic has necessitated the rapid implementation of surveillance programs worldwide to track and control the spread of SARS-CoV-2. Initially, such programs relied on syndromic surveillance, community testing, contact tracing and the monitoring of morbidity and mortality rates. Consequentially, wastewater-based epidemiology , or WBE, has been explored as a tool to track the spread of SARS-CoV-2 by many countries. Wastewater-based epidemiology for SARS-CoV-2 can be a vital source of information for COVID-19 management during and beyond the pandemic. Environmental surveillance as a part of WBE of SARS-CoV-2 can provide an early, cost-effective, unbiased community-level indicator of circulating COVID-19 in a population. Wastewater testing can detect even small numbers of asymptomatic cases, something not previously documented with other surveillance methods.

Raw wastewater and primary sludge provide a well-mixed and concentrated sample that may be advantageous for monitoring SARS-CoV-2. As viral shedding can occur before cases are detected, there is evidence that the time course of SARS-CoV-2 RNA concentrations in primary sewage sludge is a leading indicator of outbreak dynamics within a community served by the sampling utility. Studies have alluded to the existence of a strong and measurable, statistically significant relationship between the SARS-CoV-2 daily wastewater treatment plant viral RNA load and the number of detected COVID-19 cases in the week(s) preceding wastewater sample collection. Additionally, surveillance methods may include monitoring the effectiveness of population vaccination and the identification of variant viral genetic material.

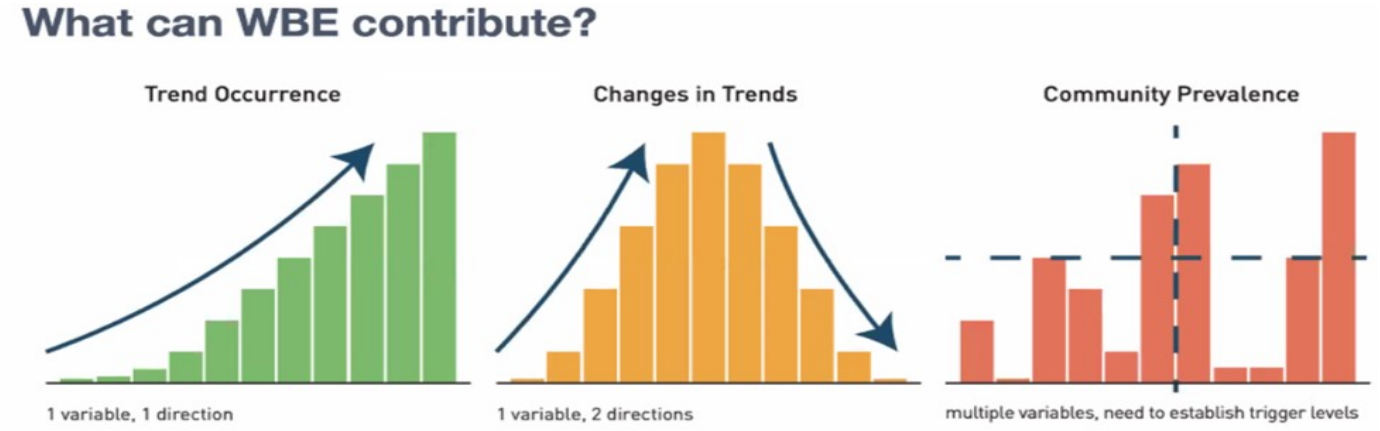

Image Water Research Foundation (www.waterrf.org)

EPA Drinking Water Assessment Inspection

In May, the Environmental Division hosted EPA auditors for its EPA Drinking Water Assessment for certification renewal. The inspection was entirely virtual, and documents were supplied to auditors securely via the MediaLab platform. Although the Environmental Division is currently responding to minor findings and recommendations, it is expected that the EPA will renew certification for drinking water analysis. The successful inspection is due to the efforts of the Radiochemistry, Chemistry (inorganics and metals), Environmental Microbiology and Quality Management teams.

Vector Borne Diseases Host Tick University



The Vector-Borne Diseases Program hosted Tick University from June 2-4, 2021. This training made use of a hybrid model: to limit the amount of contact during the training. Synchronous Zoom sessions and camera-enabled trainings were used to support social distancing efforts. A total of 57 individuals attended from 8 states in the southeastern US including TN, KY, MO, NC, SC, VA, GA, AL, and FL. The course provided lecture, laboratory and field experiences in order to harmonize regional tick/pathogen survey activities being conducted this summer that are being supported through the CDC Southeastern Vector-Borne Disease Center of Excellence at the University of Florida.



Water Laboratory Alliance Workshop

In May, the TN Public Health Laboratory Environmental Division hosted a Water Laboratory Alliance Workshop with the U.S. EPA. The workshop included representatives from nearly thirty agencies across the state of Tennessee and was designed for the Water Sector and laboratories to enhance their preparedness to respond to an all-hazard water contamination incident. The workshop, which included a pre-workshop, took place over three days and included a full tabletop exercise and breakout sessions.

The objective of the workshop was for participating organizations to develop a roadmap that will guide the revision (or creation) of their emergency response plans that includes analytical support considerations.

Roadmap development was accomplished through the following:

a) Gathering and reviewing plans and documents in advance of the workshop (preworkshop meeting).
b) Learning about EPA water-security resources through participation in an interactive tabletop exercise with a water contamination incident scenario.
c) Networking and learning from fellow colleagues in the Water Sector through small group breakout sessions, individual brainstorming sessions and facilitated large-group discussions.

The Tennessee PHL was excited to have hosted this event that brought agencies from around the State of TN to coordinate emergency planning, share best practices, and harmonize response efforts. Continuing education credit was offered to all participants of the three day event.

EMPLOYEE NEWS

Welcome New Employees!

Sierra Bernard
Admin Services Assistant 2
Administration

Cody Karnes
Procurement Officer 1
Administration

Conner Nixon
Procurement Officer 1
Administration

Cherelle Jones
PH Laboratory Technician 2
Media Prep/Support Services

Trey Jones
PH Laboratory Technician 2
Media Prep/Support Services

Kala Priester
PH Laboratory Technician 2
Media Prep/Support Services

Liza Vega-Ross
PH Laboratory Scientist 1
Knoxville Regional Lab

Heather Edwards
PH Laboratory Scientist 1
Serology

Brad Montgomery
PH Laboratory Scientist 1
Serology

Taylor Maxwell
PH Laboratory Scientist 1
Enterics

Byron Lee
Admin Services Assistant 5
Procurement

Promotions

Taylor Neal
PH Laboratory Scientist 1
Special Microbiology

Olivia Welch
PH Laboratory Technician 3
Media Prep/Support Services

Cheyenne Gallina
PH Laboratory Technician 3
Media Prep/Support Services

Jamie Raby
PH Laboratory Scientist 3
Knoxville Regional Laboratory

Ariana Allgood
PH Laboratory Scientist 2
Enterics

Michelle Therrien
PH Laboratory Scientist 3
ARLN

The Mission of Laboratory Services is to provide quality testing services through innovation, collaboration, and education that protects and improves the health of all.

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TN Department of Health

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