

# Lab-Oratory

NC Department of Health and Human Services | State Laboratory of Public Health



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## INSIDE

*this issue*

### PAGE 2

Quality Happenings

### PAGE 3

High School Interns Explore the State Lab

### PAGE 4

Biosafety Inspection Checklist for Facility and General Procedures

### PAGE 5

A Bulletin Board Says a Thousand Words: Newborn Screening's Wall of Saved Babies

What's Wrong with this Picture?

### PAGE 6

Molecular Unit Begins Real-time PCR Testing for Shiga-toxin 1 and 2

Jump Starting a Career in Public Health Laboratory Practice Through Fellowship

### PAGE 9

A Partnership for Timely Transport of Newborn Screening Specimens

### PAGE 10

Regulations and Guidance Affecting the North Carolina State Laboratory of Public Health

### PAGE 12

Laboratory Improvement Workshop Schedule

### PAGE 13

New Additions and Kudos!

## Public Health Scientist Brings Expertise in Vector-Borne Disease

Increased travel, urbanization, and climate change have contributed to outbreaks of vector-borne disease, of both emerging and re-emerging pathogens. Recent outbreaks of Zika virus in South America, Typhus and plague cases in the southwestern United States, and reports of deadly Powassan and Bourbon viruses underscore the need for taking a proactive approach toward diagnosing vector-borne disease.

In March 2017, I joined the North Carolina State Laboratory of Public Health (NCSLPH) as the Public Health Scientist in the Virology/Serology Unit. I came to NCSLPH from the National Institutes of Health (NIH) in Bethesda, Maryland where I worked in the laboratory of Ted Pierson studying the humoral response to Flavivirus infections. While there, I was part of the team developing the NIH vaccine for Zika virus, currently in Phase 2 clinical trials. I completed my Ph.D. at the University of Maryland, Baltimore, where my studies focused on the antimicrobial responses of ticks to tick-borne pathogens (*Rickettsia* and *Francisella*). While my training has primarily focused on vector-borne disease, I am interested in all aspects of host: pathogen interactions. I come from a basic research background, and this is my first experience in a clinical setting. I am eager to learn.

Since joining NCSLPH, I have worked closely with the Special Serology group, learning the different tests, with a focus on the Zika program. I hope to leverage my strong background in vector-borne disease to implement new assays and technologies to improve diagnostics in the state of North Carolina. ■

*Submitted by: Rebecca Pelc, Public Health Scientist (Virology/Serology Unit)*



*Rebecca Pelc, Public Health Scientist*

## MISSION STATEMENT

*The State Laboratory of Public Health provides certain medical and environmental laboratory services (testing, consultation and training) to public and private health provider organizations responsible for the promotion, protection and assurance of the health of North Carolina citizens.*

# Quality Happenings

## QUALTRAX

The State Lab has a new software program called Qualtrax. This software was purchased in June, and we are busy training employees and implementing it throughout the laboratory. Qualtrax will primarily be used for document control, but it can also be used for training and other compliance activities. We are sharing the software with the Office of the Chief Medical Examiner (OCME) since they are in our building, but our procedures and documents will be kept entirely separate. This purchase took us two years to complete, but we are grateful that it was finally completed successfully.

The main reason for purchasing Qualtrax is to implement an electronic and automated system for managing our many policies, procedures and forms. We can upload our existing documents to the software, and it provides routes for reviews, electronic signatures for approvals and email reminders when the documents are due for annual review. Published documents can

either be read on the computer or printed out in PDF form.

A neat feature of Qualtrax is that it lets the document owner develop a test with multiple choice questions that can be sent to designated staff members. This test can be used as an attestation for reading the assigned procedure or combined into a training session. The document owner can then pull reports to see who has taken the test, the test scores and how many times a person has taken the test. No more paper records to show employees have read procedures!

In addition to document management and trainings, we can build workflows that work like process flow charts. These workflows can be used to create an on-line document that can be sent to designated recipients. We are currently developing a workflow to document our non-conforming events.

Setting up Qualtrax takes a lot of planning and attention. Security and permissions

must be set, and folders set up for holding personnel are arranged in groups so they have the correct permissions and can be designated to see only certain types of documents. We also had to create multiple folders for each unit and laboratory to hold the documents.

## Welcome Sandy!

Sandy Bruton joined the State Lab QA Office on July 1, 2017 in a new position, QA Consultant. Sandy was previously in the Newborn Screening MSMS Laboratory. Her major focus at present is to help implement Qualtrax and train staff to use it. Among other duties, she will be taking over posting items on our website and keeping Scope up-to-date. I'm sure you will be hearing from her in the future, and she will become a valuable resource for you.

## Adieu!

This is my last Laboratory column as I plan to retire at the end of December. I've been in the laboratory field for over 41 years and have seen many changes. I learned to mouth pipet in Med Tech school and did not have to wear gloves until I had been working almost 10 years (HIV was unknown until then). When I started at UNC (Memorial Hospital), we did not have a laboratory computer system and I remember being asked by a post-doctoral fellow in 1985, what did I know about DNA and electrophoresing it. Now we take computers for granted, and more and more assays are moving to molecular. I have enjoyed my time in the lab, but it is now time to spend more time with my husband, fix up the house, and do some traveling. I have enjoyed meeting many of you through the years, first when I was with CLIA and now through public health. I wish you well and keep up the good work! ■

*Submitted by: Karen Sanderson,  
QA Manager*



# High School Interns Explore the State Lab

This past summer, the staff at the North Carolina State Laboratory of Public Health opened its doors a third time to offer experiential learning experiences and internships to two Wake County Magnet High Schools. Athens Drive Magnet High School and Enloe Magnet High School provided dynamic interns for a truly memorable experience. Athens Drive Magnet High School offers a Career Academy for students interested in science and healthcare fields, and Enloe Magnet High School offers a Bio-Science Academy to provide students with sound academic foundations and technical skills that will enable them to obtain employment in health care fields. Both students proved to be energetic, ambitious, and enthusiastic to learn about the Laboratory. At the end of their experience, both ladies agreed to submit the following articles for the newsletter.

## **Laurel Thomas (Athens Drive Magnet High School)**

I first began interning at the North Carolina State Lab of Public Health on June 19, and after learning more about the lab, I started my internship project the following week. Originally, I was assigned to create a new inventory template matching the new safety hazard pictograms, update all the past inventories, and then match all the chemicals to their corresponding safety data sheet (SDS) within a binder in each lab section. As the internship continued, I progressed in updating all the inventories. My assignment then shifted to printing any safety data sheets that were not found in the SDS binders. Along with this main internship assignment, I also completed the safety inspections for the building that covered fire extinguishers, AED's, emergency showers/eyewash stations, and first aid kits.

I found the project to be a challenging and enjoyable experience. I believe that I now have a better understanding of what occurs inside of a clinical laboratory as well as how



*Juhi Modi and Laurel Thomas model PPE for their laboratory experiences!*

all the different units function together to test patients within North Carolina. I have also gained knowledge of the structure within a professional workplace in terms of employee relationships and physical layout of a building in order to follow safety standards. My most significant benefit from the internship was the experience of working at a job focused on a merge of science, computing, and public health. By learning more about the types of careers within the NCSLPH, I am better able to make choices regarding education for my future degree.

Currently, I plan to major within either biochemistry or chemistry and minor in statistics. I am still in the process of applying to college, and my top picks are UNC Chapel Hill, NC State University, and UNC Charlotte. My career plans are now focused on the research side of science and laboratory work, but I am also exploring the possibility of going into drug engineering. Because of the internship, I have also been presented with the decision between state and private laboratories. To be educated about this decision, I also plan to intern within a private company during

my time in college so that I may be able to determine which form is better suited for me. Whichever I choose, I am still thankful for being given this opportunity to intern with the state lab and for all the people within the lab that have helped me during my journey there. It was truly a memorable experience that will help equip me to choose the best paths as I go forward in life.

## **Juhi Modi (Enloe Magnet High School)**

My internship project at the North Carolina State Laboratory of Public Health included visiting all the units of the Laboratory and creating condensed "Specimen Requirements" pages for health professionals submitting samples.

Each page included:

- Analytes Tested
- CPT Code
- Methodology
- Authorized Submitters
- Specimen Types
- Specimen Collection and Submission Guidelines
- Rejection Criteria
- Shipment
- Turnaround Time
- Laboratory Contact Number(s)

Normally, individuals requesting this information would seek out SCOPE: A Guide to Laboratory Services, which is a 149-page document on the SLPH website that provides descriptions of testing services, special instructions for specific tests, and explanation of reports.

This internship was a great experience because I visited different labs to see the work that is done each day within each of them while compiling the condensed documents. It was a wonderful experience to be shown around the laboratory by various supervisors as they took the time to talk with me and help me understand more about their areas.

**Cont. on page 4**

High School Interns Explore the State Lab cont. from page 3

Two rotations that stand out for me include mycobacteriology and laboratory improvement. The rotation with Ms. Lavonda Benbow in mycobacteriology was great because I was “hands on” in the laboratory while she talked and explained procedures. I had the opportunity to dress in the necessary personal protective equipment (PPE) for her lab and conducted a small experiment, which was very engaging as well as enjoyable. During my lab improvement rotation, I had the opportunity to view different samples such as gonorrhea and *Staphylococcus Aureus* through a microscope and participate in the classroom portion of a workshop. It was quite fascinating to see how both a sexually transmitted disease (STD) and bacteria appear on a microscopic level.

Throughout my high school career and through the participation of this internship at SLPH, I have gained a significant interest in the field of public health, geared specifically towards global health. My initial thought for interning at the State Laboratory was that it would be an extremely beneficial experience, as it would help me gain a better understanding of what professionals do within the Public Health field. After completing my internship, I am positive that I want to make an impact on a global level within public health.

Being able to see firsthand the work that was done in the labs, learn about the settings and procedures of the lab, as well as meet with laboratory supervisors, managers, and technicians was the best opportunity to learn about this field. Not only did I learn about public health, but I learned about what working is like in a laboratory setting and how different tests are performed, which I found very interesting.

Additionally, this internship provided me an experience that mirrored life after college and gave me a glimpse of “work life” and how to perform duties in a laboratory setting along with other coworkers, exhibiting values of teamwork and cooperation. Overall, this internship presented many opportunities for me to learn about public health careers, and I appreciate my learning experience. ■

*Compiled by: Shaneeka Cannon, Lab Improvement Staff Development Specialist III*

# Biosafety Inspection Checklist for Facility and General Procedures

Please use the biosafety checklist below to do a quick inventory of your facility and general biosafety practices. These are some simple items that can help your lab be the safest it can be! Look in the next issue for a checklist so that you can review personal protective equipment and safety plans. As always, please do not hesitate to contact me if you have any questions or if I can assist with your biosafety needs in any way. ■ *Submitted by: Kristin Long, [kristin.long@dhhs.nc.gov](mailto:kristin.long@dhhs.nc.gov)*

Question	Yes	No	N/A
Is a biohazard sign posted at the lab entrance door, indicating the biosafety level, any required immunizations, emergency contact numbers, and any personal protective equipment that must be worn in the lab?			
Are biohazard signs or labels on storage and use areas?			
Are refrigerators/freezers labeled “Not for Storage of Food for Human Consumption”?			
Does the lab contain a sink for hand washing? Does staff wash hands after removing gloves and before leaving work area?			
Are operable windows fitted with screens?			
Are work surfaces decontaminated at least daily and immediately after spills?			
Are written procedures in place for large and small spills or leaks?			
Is a biohazard spill kit available and properly stocked?			
Is biohazardous waste placed into appropriately labeled or color-coded receptacles that are kept closed when not in use?			
If materials are decontaminated outside the laboratory, are they transported in durable, leakproof containers?			
If viable materials are centrifuged, are safety containment cups or sealed rotors with O-rings used?			
Are eating, drinking, smoking, applying lip balm or cosmetics, and handling contact lenses prohibited in the work area?			

# A Bulletin Board Says a Thousand Words: Newborn Screening's Wall of Saved Babies

The Centers for Disease Control considers newborn screening one of the top ten great public health achievements from 2001-2010 (<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6019a5.htm>). Every baby born in North Carolina is screened in the NC State Laboratory of Public Health's Newborn Screening Laboratory for over 50 genetic, endocrine and metabolic disorders. We recently established a "Wall of Saved Babies" to represent how many newborns have been saved and the families that have been positively impacted by the work done every day. As you can see by the flower pot on the right, hundreds of North Carolina citizens are impacted on an annual basis by the tireless work of the NBS program. The clothesline which is updated monthly shows how many babies have been saved in the current calendar year; each article of clothes represents five babies while each sock represents one. As of July 2017, 152 babies have the hope for a bright and productive future.



*Featured in the photograph are the designers and builders of the Wall of Saved Babies, from the newborn screening staff: Adrienne Lockhart, Alexandra Marshall, Carolina Moreno, Amanda Parrish, Jennifer Jones and Shannon Harris (shown L to R).*

This bulletin board, located near the Newborn Screening Laboratories, is a visual representation of the importance of newborn screening for visitors and new

employees. It provides a daily reminder to lab staff that there is a tiny patient behind each specimen they handle and result they encounter. ■

*Submitted by: Dr. Sara Beckloff, PhD., Newborn Screening Laboratory Manager*



## What's Wrong with this Picture?

This lab is adhering to the safety policy by checking eyewashes, but there's a big problem! Can you identify it?

**Answer:** The eyewash is laying in the bottom of a laboratory sink. If someone needs to use the eyewash later, the risk of contamination to their eyes is very high! ■

*Submitted by: Kristy Osterhout, NCSLPH Safety Officer*

## Molecular Unit Begins Real-time PCR Testing for Shiga-toxin 1 and 2

On Aug. 7, 2017, the Microbiology Unit, in conjunction with the Molecular Epidemiology Unit of the North Carolina State Laboratory of Public Health, began testing for Shiga-toxin 1 and 2 by real-time PCR. Prior to testing by this methodology, Shiga-toxin 1 and 2 for STEC (Shiga-toxin producing *E.coli*) and *Escherichia coli* was performed using ImmunoCard, a rapid immunological diagnostic test using an immunochromatographic lateral flow principle. The decision to change methodology came about because of the need for a more sensitive test to detect Shiga-toxins produced by *E. coli* O157 and other Shiga-toxin producers. The Enteric Lab receives samples from other labs that perform culture-independent diagnostic testing. Factors negatively

affecting detection of Shiga-toxin include improper collection, storage, transport time and temperature, as well as the overall sensitivity of the test specifications itself. Often Shiga-toxin could not be recovered using the ImmunoCard, when there may be actual Shiga-toxins present. The use of real-time PCR will improve detection of STX (Shiga-toxin) because the sensitivity is greater and the sample does not have to be a viable organism.

Sensitivity was one of the areas the molecular unit focused on during the validation of the STEC PCR. According to the package insert of the ImmunoCard STAT!® EHEC has a LOD (Limit of Detection) of 1.25 ng/ml of ST 1 and ST 2. In comparison, the average LOD

for the STEC PCR was determined to be 597.85 fg/ul (femtogram =  $10^{-15}$ ). The STEC PCR procedure utilizes the Roche Compact automated extraction method with external lysis and the ABI 7500 FAST DX instrument to detect the STX 1 and STX 2 genes. This allows the molecular unit to have a rapid turnaround once samples are received from the microbiology unit, on average around two hours. The Molecular Epidemiology unit runs this test three days a week and has the capability of providing surge capacity during outbreak situations, as well. ■

*Submitted by: Chris Boner (Molecular Unit) and Jo Ann Ransom (Microbiology Unit)*

## Jump Starting a Career in Public Health Laboratory Practice Through Fellowship

For many, a career in public health science is inspired by the thrill of learning about a newly emerging infectious disease agent, like Ebola or Zika virus, or learning about novel ways to rapidly detect and treat rare, life-threatening disorders in newborn babies. However, attaining even an entry level career opportunity in a public health laboratory (PHL) can be challenging when applicants lack the basic knowledge and skills in PHL practice. Likewise, public health laboratories with an aging workforce, are often challenged to find staff with ample experience in conducting laboratory-based surveillance for infectious disease agents or the advanced laboratory skills needed to screen newborn babies to detect rare

disorders in a timely manner.

To address these concerns, the Association of Public Health Laboratories (APHL) in collaboration with the Centers for Disease Control and Prevention (CDC), has sponsored two highly competitive fellowship programs that aim to provide a high-quality training experience for a select number of individuals (approximately one out of 100 applicants) with advanced scientific knowledge and laboratory skills that can be applied to PHL practice; which in turn, provides workforce capacity to the public health community.

It has been an honor for the NC SLPH to be selected by the CDC, APHL,

and incoming fellows, to serve as one of five PHLs to host Infectious Disease Laboratory Fellows to prepare them to support public health initiatives related to infectious disease surveillance and research and to be the sole PHL selected to host a fellow in the 2017 – 2019 Ronald H. Laessig Memorial Newborn Screening Fellowship program. Fellows in each of these programs receive training in bench-level PHL skills and methods, participate in distance-based training and learning activities to achieve proficiency in select PHL core competencies, and they support surveillance and implement prevention and control programs.

As many of you know by now, the state lab has enthusiastically accepted two

**Cont. on page 7**

## Jump Starting a Career in Public Health Laboratory Practice Through Fellowship cont. from page 6

outstanding young scientists to join their infectious disease team and one post-doctoral fellow to join the Newborn Screening Unit for 1-2 year terms. We can all appreciate that it takes a village to raise a well-rounded, successful public health scientist and I encourage all members of the public health family to: listen carefully to questions, answer inquiries respectfully, share your wisdom, and embrace the opportunity to “pay it forward” when you’re interacting with each of the fellows. Learning more about their past experiences and future goals can help us all to become exceptional mentors to the future leaders in public health laboratory practice.

### Introducing the 2017-2019 APHL/CDC Sponsored Fellows



**Caitlyn Daron, MS - APHL/CDC Infectious Disease Fellow**

Caitlyn earned her B.S. degree in Environmental Health and minor in Biology from East Carolina University. While at ECU, she successfully completed the honors program, served in a leadership position with the Magnolia Belles (ECU’s only all-female a cappella group), graduated Magna Cum Laude, and was awarded Outstanding Undergraduate in the Department of Environmental Health, Class of 2013. While pursuing her Bachelor’s degree, Caitlyn completed several microbiology laboratory classes, which allowed her to develop an interest in microbiology. Under the direction of Dr. Eric Anderson, she gained

undergraduate research experience in the laboratory by studying the effects of gallium exposure on biofilm formation in *Pseudomonas aeruginosa*.

After graduating in December 2013, Caitlyn worked for a brief time at Quality Chemical Laboratories as a microbiologist where she performed bioburden, microbial limits, and preservative effectiveness testing. Caitlyn went back to school and earned her M.S. degree in Microbiology from North Carolina State University. Under the direction of Dr. Hosni M. Hassan, she completed a thesis project focused on the characterization of *Lactobacillus* isolates from chickens for their probiotic potential. She was also responsible for teaching a microbiology laboratory course, which allowed her to instill her knowledge and passion for microbiology into her own students.

Caitlyn is currently an Infectious Diseases Laboratory Fellow sponsored by APHL/CDC. During her Fellowship assignment at the NCSLPH, she will rotate through various testing units of the laboratory, including: Virology/Serology, Microbiology (TB, Enteric, Atypical, Mycology, and Parasitology), Molecular Epidemiology, and Bioterrorism and Emerging Pathogens (BTEP). The bulk of Caitlyn’s fellowship will be split between the Microbiology Unit, managed by Tom Lawson and the BTEP Unit, managed by Dr. Susie Orton. Her primary goals are to be trained to work in both biosafety level two and three laboratory environments and trained to competency in the biochemical, phenotypical (using matrix-assisted laser desorption ionization- time of flight spectroscopy), and molecular characterization of microorganisms. Another fellowship goal is to participate in investigations of disease outbreaks such as those associated with foodborne illnesses and novel, emerging pathogens.



**Michael A. Mash, MS - APHL/CDC Infectious Disease Fellow**

Michael Mash was born in Akron, Ohio in 1993 and moved to Las Vegas, Nevada when he was 10. He left the Vegas chaos, casinos, and constant advertising to attend the University of Nevada, Reno (UNR). Selecting a major was difficult for Michael since he was interested in many different disciplines including psychology, statistics, computer science, biology, and medicine. This is the first sign that a career in a PHL may be a perfect fit!. However, his love for classes in molecular biology, virology, and immunology ignited his desire for a career that focused on the study of viruses infectious to humans.

While at UNR he was invited to join a lab run by Dr. David AuCoin. The lab focused on the development of rapid diagnostics in the form of Lateral Flow Immunoassays (LFIs), and for two years he worked on the development of monoclonal antibodies to *Burkholderia pseudomallei* (the causative agent of melioidosis) to allow for its detection in human sera. This research experience provided him with a strong scientific foundation in cell culture, microbiology, and molecular biology. Following his graduation, he entered an accelerated Master’s program, working in Dr. AuCoin’s biotech start-up, DxDiscovery; where he identified biomarkers for *Borrelia burgdorferi* (the causative agent of Lyme Disease) infections. This was a challenging

Cont. on page 8

## Jump Starting a Career in Public Health Laboratory Practice Through Fellowship cont. from page 7

project that provided invaluable scientific experience. Collectively, these three years of diagnostic development prepared him well for the opportunity to serve as a fellow in the class of 2018.

During his time at the state lab, he hopes to expand his knowledge of public health laboratory practice, combining his love for virology and diagnostic assay development. The bulk of his time will be dedicated to working within the Virology/Serology Unit, managed by Myra Brinson. In this unit, he will work to broaden his PHL skills by conducting laboratory-based surveillance for viral infections in North Carolina citizens and to enhance his knowledge of maintaining CLIA regulatory compliance. Specially, he will work to optimize and implement a protocol to confirm infections with arboviral disease agents such as Zika virus using plaque reduction neutralization assays. This opportunity will help him to solidify a career in vector-borne disease surveillance and will help the NCSLPH to enhance internal vector-borne disease surveillance capabilities and capacity.

Although virology has had a longstanding place in Michael's heart, he admits that meeting with individuals from the laboratory management team, has made him realize that public health encompasses many careers that he had never considered and he's excited to have the opportunity to explore how each unit at the state lab plays a role in keeping North Carolinians safe.



**Ellen V. Stevens, PhD - Ronald H. Laessig Memorial Newborn Screening Fellow**

Dr. Stevens' academic and industrial career has focused on the development and optimization of proteomic bioassays, drug discovery and target validation for disorders in newborns and diseases, including cancer. During her time at the National Institute of Health, she developed a novel protein microarray for detection of DNA repair pathways that are important for predicting cancer patient response to the mainstay of therapy. Subsequently, she pursued a doctoral degree from the University of North Carolina at Chapel Hill in Pharmacology and two postdoctoral fellowships at Duke University and Memorial Sloan-Kettering Cancer Center.

During the course of her graduate and postdoctoral work, she collaborated with advisors and peers alike, attended and presented at conferences, mentored students, and published research papers, book chapters, and review articles. Ellen thoroughly enjoys working in a collaborative team environment. Most recently, she has worked as a Scientist at various small biotechnology companies in Research Triangle Park, NC, focused on developing novel multiplex platforms for the diagnosis of cancer and detection of disorders in newborns.

Recently she was awarded the Ronald H. Laessig Memorial Newborn Screening Fellowship hosted at the state lab in the Newborn Unit managed by Dr. Sara Beckloff. Her primary goal is to optimize and implement the Illumina's MiSeqDx Cystic Fibrosis (CF) 139-Variant screening methodology at the state lab. This will allow for the rapid detection of CF disease-causing mutations in North Carolina newborns during the routine screening process. In addition to these activities, Ellen will work collaboratively with partnering agencies (i.e. CDC and Research Triangle Institute, RTI) to develop, optimize, and implement novel molecular assays to detect mutations associated with lysosomal storage disorders (LSD) in newborns. Supplementing traditional tandem mass spectrometry with mutational analysis will allow the newborn screening program to improve accuracy by reducing LSD false positive rates.

These activities will ultimately improve the overall well-being of babies born with life-threatening disorders by guiding earlier diagnosis and treatment options. This fellowship will be the perfect opportunity for Ellen to apply her extensive scientific background in a collaborative setting to improve the overall health of newborns through early screening.

*Introduction by Dr. Dee Pettit,  
NCSLPH Assistant Director*

*Biographies submitted by the  
respective fellows*

# A Partnership for Timely Transport of Newborn Screening Specimens

Newborn dried blood spot screening, a part of public health since 1966 in North Carolina, is not an isolated process. It encompasses many partners, with the ultimate goal of identifying affected infants before symptoms appear and cause severe or irreversible health problems. Infants with unidentified disorders may suffer from a host of complications including, but not limited to: failure to thrive, vomiting, convulsions, anemia and stroke, severe mental retardation, and coma and infant demise. Early identification and diagnosis is critical to mitigating these effects and saving lives. In 2016, over 275 North Carolina infants were identified with a disorder through the newborn screening program.

In a continual effort to improve timeliness of newborn screening, the NC State Laboratory of Public Health (NCSLPH) seeks to fulfill federal timeliness goals:

- Initial newborn screening specimens should be collected in the appropriate time frame for the baby's condition, but no later than 48 hours after birth. Initial specimens should not be collected at less than 24 hours of age.
- Specimens should be received at the laboratory ideally within 24 hours of collection.
- Presumptive positive results for time-critical conditions should be reported to the healthcare provider within five days of life. However, if the first two goals are not achieved, this goal may not be attainable.
- All presumptive positive results for time-sensitive conditions should be reported to the healthcare provider within seven days of life. Again, timely collection and transport will impact the speed at which the results are reported to the healthcare provider.
- All results should be reported within seven days of life.

Given these timeliness goals, NC SLPH has looked at ways that transport can be improved, so that more specimens arrive at the lab for testing as soon as possible. One way is to standardize the specimen carrier, and another is to reduce the cost barrier of overnight delivery of specimens.

Beginning February 2017, the state lab partnered with United Parcel Service (UPS), whereby UPS was the sole transporter of newborn screening specimens, with pick-up at pilot facilities Monday through Saturday and delivery was made to the lab on each of these days. In addition to establishing assured pick-up at these birthing facilities six days a week, the lab began covering the costs of the overnight delivery. UPS and the state lab conducted training webinars for submitters before the rollout so that they could ask questions and have training on using the UPS CampusShip online shipping portal. The pilot group included birthing hospitals, a military hospital, and three free-standing birthing facilities. Before the beginning of the pilot program, these facilities' average transit time (the average time, in days, from collection to receipt at the state lab) was three days. By July, the pilot facility's transit time had decreased to 2.4 days. With this improvement, the lab decided to roll out UPS transport of newborn screening specimens statewide in two additional phases.

The second phase began June 26 and added 41 more birthing hospitals using UPS delivery for their specimens; this now encompassed over one-half of initial screening specimens each month. Training webinars were expanded and recorded, so that those not able to attend could learn and share with others in their hospital. With this group of hospitals, dramatic improvement in transit times was observed, with one



hospital decreasing their transit time over three days from June. During the webinars, participants were urged to have their transit time "number" sent to them monthly so that they can track improvement in timeliness, or investigate why their "number" is not decreasing.

The UPS partnership is entering its final phase, incorporating the remaining birthing hospitals and adding midwives. Focused education is being developed for midwives in North Carolina, as they do not necessarily have the materials management infrastructure of a birthing facility.

There have been snags to this change in transport of newborn screening specimens, even with UPS pick-up and costs being borne by the laboratory. Some hospitals, while enthusiastic about overnight delivery costs being paid by NC SLPH, are not as quick to change their internal processes to maximize the number of specimens sent daily. In some facilities, not all relevant staff knew about the UPS program, and envelopes of specimens were not readied for pickup each day. A lack of staff communication and education also lead to envelopes not being labeled for delivery at the state lab on Saturdays.

As birthing facilities are added to the NC SLPH-UPS newborn screening partnership they are more cognizant that if there is only one newborn screening

**Cont. on page 11**

# Regulations and Guidance Affecting the North Carolina State Laboratory of Public Health

In recent years, we have seen an explosion in the number of laws, regulations, rules, and accreditations that impact and govern clinical, environmental, and public health laboratories. The scope of these regulations is broad and their relationships to one another are complex. Most of these requirements focus on two important components of laboratory practice: quality and safety.

It is important to clearly understand the difference between regulations and accreditation. Regulation is governmental oversight and control of a laboratory's operations and practices that is governed and enforced by laws. These may be federal, state or local laws. Failure to comply with governmental regulations may result in civil and criminal penalties. Accreditation is a process by which a laboratory's practices are surveyed and approved by an entity that promotes standards of practice; accreditation is voluntary and failure to comply is not typically grounds for civil or criminal action.

Currently, the North Carolina State Laboratory of Public Health (NCSLPH) is certified by four (4) agencies that oversee laboratory regulations and one (1) accreditation agency:

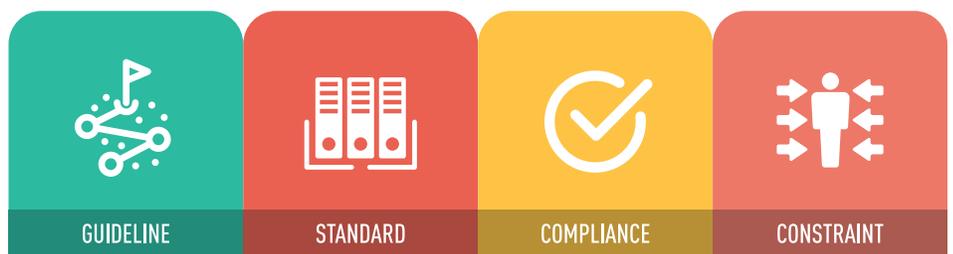
1. The **Clinical Laboratory Improvement Amendments of 1988 (CLIA "88)** include federal standards that apply to all United States (US) laboratories that test human specimens for diagnosis, prevention, or treatment of disease. CLIA establishes quality standards for clinical laboratory testing of specimens from humans including blood, body fluids, and tissues. The

standards establish the conditions that all laboratories must meet to perform testing on human specimens. These standards are designed to focus on a laboratory's ability to provide accurate, reliable and timely test results. Assessment of this ability utilizes an outcome-oriented survey conducted by trained inspectors that assess the laboratory's practices and functionality. This survey process occurs biennially (every two years), or more frequently, if necessary.

2. The **US Environmental Protection Agency (EPA) Safe Drinking Water Act (SDWA)** includes the certification of laboratories that analyze drinking water from public water systems (PWSs). Certified laboratories use laboratory methods approved by the EPA to analyze water from PWSs and provide

them with reliable information on water quality. On-site audits are conducted at least every three years, or more frequently, if necessary.

3. The **US Food and Drug Administration Grade "A" Milk Safety Program** evaluates and approves milk laboratories. The FDA measures analyst performance in milk laboratories, using on-site surveys of techniques and proficiency testing. These evaluations are intended to enhance greater uniformity, accuracy and precision of microbiological and chemical analyses. This survey process occurs every two years, or more frequently, if necessary.
4. The **Federal Select Agent Program (FSAP)** oversees the possession, use and transfer of biological select agents and toxins, which have the



## REGULATIONS



Cont. on page 11

## Regulations and Guidance Affecting the North Carolina State Laboratory of Public Health cont. from page 10

potential to pose severe threat to the public, animal or plant health or to animal and plant products. The FSAP is jointly comprised of the Centers for Disease Control and Prevention (CDC) Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service (APHIS) Agriculture Select Agent Services. CDC/APHIS inspects all entities that possess, use or transfer select agents to ensure that all individuals who work with these agents undergo a security risk assessment performed by the Federal Bureau of Investigation and that regulated entities are compliant with federal regulations. Inspections may be announced or unannounced and are conducted for the purposes of renewal of certification (every three years), evaluation of new facility space, resolution of prior inspection deficiencies, compliance issues or other incidents.

5. The *American Industrial Hygiene Association (AIHA)* is a non-profit organization devoted to achieving and maintaining standards for occupational and environmental health. AIHA accredits laboratories performing analysis of lead in environmental samples including

paint, soil, dust wipes, composited wipes and air to assure compliance with the EPA National Lead Laboratory Accreditation Program (NLLAP). Accredited laboratories perform analyses related to lead-based paint and matrices contaminated with lead-based paint and meet EPA requirements. AIHA accredits the laboratory facility, not individuals. Site assessments of laboratories are conducted by trained, experienced assessors and generally take place once every two years, unless additional site assessments are deemed necessary.

It is often a challenge for the individual laboratory scientist to be familiar with all the regulations that pertain to laboratory operations; therefore, it is vital that there be a strong institutional capacity regarding the details of these rules. Albeit, all laboratory employees must be familiar with the principal provisions and concepts of the most important laws and regulations that impact laboratories. Both laboratory managers and employees must recognize that violation of regulations not only may pose risks to that patients we test, the laboratory and surrounding community, but can also result in serious consequences including the imposition of civil penalties

NCSLPH maintains a strong culture of quality and safety; our Quality Assurance Office assures that the laboratory is compliant with all quality-related requirements and our Safety Officer and Biosecurity Official oversee biological, chemical and radiological hazard safety programs. Commitment to an institution-wide culture of quality and safety assures that NCSLPH maintains compliance with all federal, state, and local laws, regulations, and rules. ■

*Submitted by: Dr. Scott J. Zimmerman, Laboratory Director, NCSLPH*

## A Partnership for Timely Transport of Newborn Screening Specimens cont. from page 9

specimens ready for transport, it should be transported as soon as possible; this is an important clinical specimen. UPS has been a partner with the Laboratory every step of the way with this timeliness program, from initial logistical planning, webinar training, and extensive follow-up with submitters once each phase went live. To quote a UPS team member, “The UPS envelope is not just a package, it’s a patient!” ■

*Submitted by: Ann Grush, Newborn Screening Laboratory Consultant  
Sara Beckloff, Newborn Screening Laboratory Manager*



# Fall/Winter

**LABORATORY IMPROVEMENT**  
**State Laboratory of Public Health**  
**NC Department of Health and Human Services**

**NOVEMBER 2017 – MARCH 2018 WORKSHOP SCHEDULE**

DATE	TITLE	APPLICATION DEADLINE
November 1-3, 2017	Bacteriological Methods for the Analysis of Drinking Water	October 3, 2017
November 16, 2017	Evaluation of a Stat Male Smear	October 16, 2017
December 7, 2017	Bioterrorism Preparedness for Clinical Laboratories	November 7, 2017
January 10, 2018	Microscopy: Viewing and Reviewing	December 10, 2017
January 11, 2018	Examination of a Vaginal Wet Mount	December 11, 2017
February 7-8, 2018	Lab Methods in the Diagnosis of Gonorrhea	January 8, 2018
February 20-22, 2018	Bacteriological Methods for the Analysis of Drinking Water	January 22, 2018
March 6-9, 2018	Process Control Chemistry	February 9, 2018

**Disclaimer: These Workshops are not intended to replace formal education but to enhance skills and promote use of recommended standard techniques.**

**For more information, consult our website or contact Lab Improvement at 919-733-7186 or <http://slph.ncpublichealth.com>**

# New Additions and Kudos!

During recent months, the State Lab has had the privilege of welcoming many new employees. They bring unique talents and skills to all areas of the laboratory, and we are so excited they have joined us! We congratulate the following on their new positions:

**Virology-Serology** – Ebonee Shire, Sara D'Arcy, Anne Payne  
Newborn Screening - Henry Persons, April Burrell, Alvin Liao

**Pre-Analytical** – Kristina Busbin, Latia Armstrong, Denise Lewis, Adenna Cox

**Microbiology** – Ashleigh DaGrosa, Mame Lemine, Yashmin Marsan

**Operations** – Daris Tart

**Retirement congratulations** are extended to **Debra Springer** from Microbiology who retired at the end of July with 25 years of service and **Carol Ludwig** from IT who retired in June. Debra plans to enjoy retirement spending time with her family. Carol and her husband, who is also retired, plan to move back to her hometown of Boone.

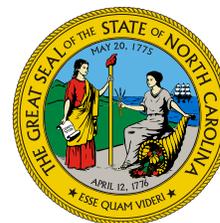
## Kudos to Employees of the Quarter!

**La'Vonda Benbow**, the Mycobacteriology Laboratory Supervisor has been chosen as the Employee of the Quarter for the third quarter. La'Vonda was recognized for her incredible leadership during the TB lab's relocation due to facility malfunctions. She was able to develop a plan of action, coordinated communications and activities, and ensured that her team would still be able to meet the needs of the citizens of NC during this transition. Thank you to La'Vonda and her team! ■

*Compiled by: Angie Bradley, Laboratory Improvement*

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