

Lab-Oratory

N.C. Department of Health and Human Services | State Laboratory of Public Health



<http://slph.ncpublichealth.com>

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Workplace
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From the Desk of the Director

With the festivities and sentiments of the holiday season so evident this time of the year, I am reminded of all that I am thankful for here at the North Carolina State Laboratory of Public Health (NCSLPH). To our staff, to our partners in public health, to those with whom we collaborate – thank you for the excellent work you do every day to ensure the safety and well-being of all North Carolinians! Together, our alliances are shaping strategic thinking and developing solutions to improve the quality of life in our state.



*Scott J. Zimmerman,
DrPH, MPH, HCLD (ABB)
Laboratory Director*

2013 has brought new faces, a new facility and new functions to the NCSLPH. Our first year in the new state-of-the-art public health laboratory building has afforded us many new opportunities to explore and implement new technologies, streamline work practices, and develop partnerships with new and innovative colleagues. We have enhanced laboratory testing in our Environmental Sciences Lab, instituted new technologies in Newborn Screening, added capabilities to support laboratory diagnoses of emerging pathogens, and applied new testing algorithms in our HIV Lab.

Our new training facility has provided our Laboratory Improvement Unit with the ability to offer new workshops and training opportunities for the North Carolina laboratory community. Expanding our distance learning capabilities is taking shape as we have begun to broadcast seminars and lectures to remote learners. With a focus on outreach and workforce development, NCSLPH partnered with the Association of Public Health Laboratories (APHL) as they held their annual meeting in Raleigh in early June 2013. As part of the

Cont. on page 2

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.

From the Desk of the Director cont. from page 1

four-day conference and exposition, NCSLPH hosted the first annual Student Day titled “Under the Microscope – A Look at Public Health Laboratory Careers.” The half-day event brought middle and high school students from across North Carolina to the lab with the purpose of promoting laboratory science careers. The experience garnered media attention, accolades from those that participated, and confirmed for APHL that this event should be replicated prior to each annual meeting.

While we celebrate the one year anniversary of the new NCSLPH, we along with public health laboratories across the United State celebrate the 50th anniversary of newborn screening – one of public health’s greatest achievements that save or improve the lives of more than 4,000 babies born in North Carolina each year. And while we celebrate the accomplishments, we remember other anniversaries. Just over a year ago, Super Storm Sandy unleashed devastation across much of the eastern United States. Yet public health laboratories were prepared to support communities with laboratory testing as prevention and remediation strategies were employed.

As I complete my first year as Director of this fabulous institution, I am proud to announce that NCSLPH has begun development of a strategic plan that will

support the mission of NCSLPH for the foreseeable future. The Plan will focus on improvements to our business process, develop our workforce, cultivate an integrated information technology infrastructure for the central support of NCSLPH labs and common business processes using industry standard technology, ensure fiscal stability, and secure a position of laboratory excellence among our peers and with our partners. And my excitement grows as I see greater opportunity with our colleagues in academia, development of relationships with our biotechnology neighbors, and cooperative efforts with our laboratory friends.

And so, as I wish each of you the best as you transition to the new year, I encourage you to keep abreast of NCSLPH’s accomplishments and take advantage of all that we have to offer.

Submitted by:

Dr. Scott J. Zimmerman

Director

*North Carolina State Laboratory of Public Health
N.C. Department of Health and Human Services*

Save the Date!

WNCPHA Annual Meeting

More information coming soon!!

May 1-2, 2014

(Lab Section will only meet on the 1st)

Lake Lure Inn & Spa

2771 Memorial Hwy. | Lake Lure, NC 28746

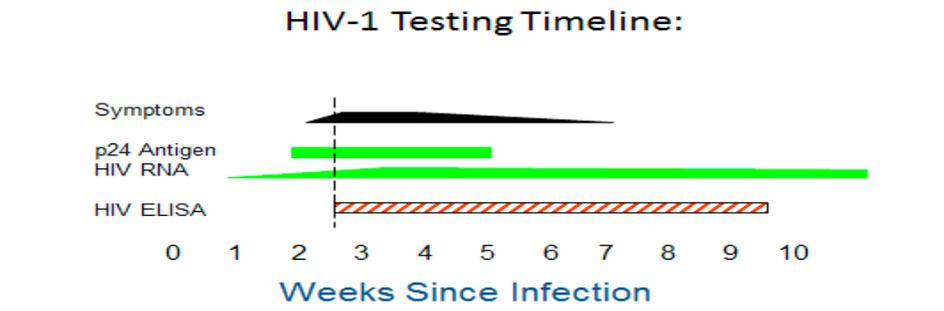
www.lakelure.com



New and Improved HIV Testing Program

The North Carolina State Laboratory of Public Health (NCSLPH) has been processing blood samples for HIV testing since 1987. A fully developed testing program at NCSLPH was in place by May 1991. A total of 32,747 HIV tests were done that year, primarily in HIV counseling and testing sites and STD clinics. New positivity rates were high at that time because testing was targeted to those at high risk of infection. HIV testing increased steadily over the next five years, and the proportion of tests from family planning and prenatal/ OB clinics increased as well. As more low-risk women were added to the testing pool, the overall HIV positivity rate declined. HIV testing levels remained relatively stable from 1996 to 2003 and then began to increase again because of expanded HIV testing recommendations and other projects. Testing levels have stabilized in recent years to the current volume of approximately 230,000 HIV tests per year.

Testing methodologies for HIV infection have also evolved over the past 30 years of the HIV epidemic. The first generation of enzyme immunoassay (EIA) tests utilized a whole viral lysate antigen. HIV test specificity was improved in second generation EIA tests by the change to synthetic peptide and recombinant protein antigens, thus reducing the number of false positive results. The accepted testing algorithm during this time was to screen with an EIA and confirm repeatedly reactive samples with HIV-1 Western Blot. In 2008,



NCSLPH moved to a more sensitive third-generation EIA capable of detecting both IgG and IgM antibodies to HIV-1 (including Group O subtypes) and HIV-2. Use of the HIV-1 Western Blot for confirmation became problematic in cases of early infection because it was less sensitive than the improved EIA tests and often required additional testing for HIV-1 RNA to ascertain the true HIV infection status of the patient.

Since 2002, the NCSLPH has participated in the N.C. STAT (Screening and Tracing Active Transmission) program for the identification of acute HIV infections. Acute HIV is defined as the very early stage of HIV infection when viral load is extremely high but there are no detectable HIV antibodies. At this time, an infected individual is most infectious, but may be asymptomatic or present with a non-specific influenza-like syndrome.

A multistage, pooled testing strategy was employed, in which all HIV antibody-negative patients were combined into B pools representing 80 samples each and tested for HIV-1

RNA by nucleic acid amplification testing (NAAT). If the pooled serum sample was NAAT negative, all 80 samples comprising the B pool were considered to be negative for HIV-1 RNA. If HIV-1 RNA was detected in the B pooled sera, the B pool was then broken down into 10 smaller A pools, representing eight samples each, and tested by NAAT. The NAAT positive A pool was then further broken down into the eight individual samples that comprised it and the samples were tested individually to identify the positive sample. Although this testing strategy successfully detected more than 300 cases of acute HIV during the 12-year period, pooled NAAT was laborious and time-consuming, resulting in long turn-around times for both negative and positive HIV results. NAAT was also used during this time to resolve the HIV infection status of patients who tested antibody-reactive but either Western Blot nonreactive or indeterminate. Samples that tested reactive by EIA but were both nonreactive or indeterminate by HIV-1 Western Blot and negative by HIV-1 NAAT

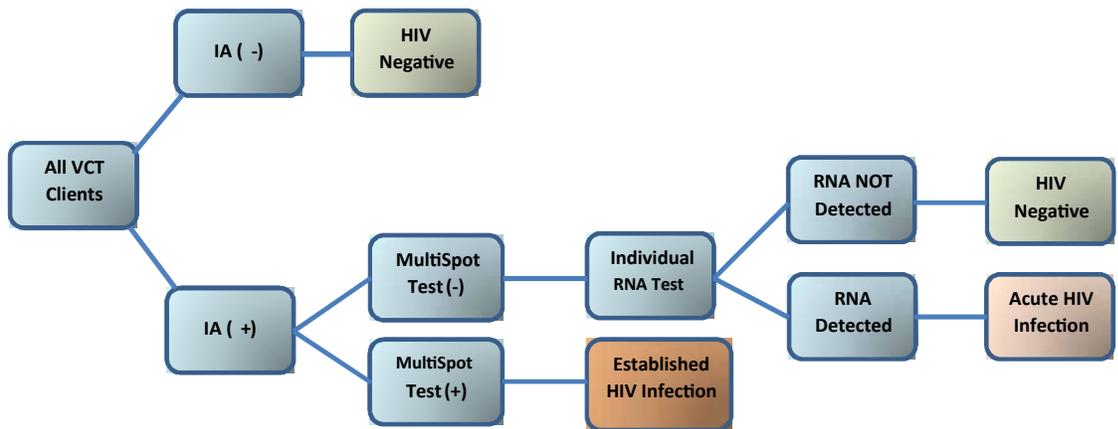
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were further tested with the Multispot rapid discriminatory assay to rule out infections because of HIV-2.

In 2010, the first fourth-generation HIV screening assay, referred to as an HIV antigen/antibody combination assay, was approved for use in the U.S. Immunoassays (IAs) maximize sensitivity and specificity by using synthetic peptide and recombinant protein antigens to detect IgM and IgG antibodies. They also incorporate a component that detects viral p24 antigen, an early serological marker of HIV infection present in blood prior to detectable HIV antibodies. On November 1, 2013, NCSLPH converted from using third-generation EIA tests for HIV screening to the fourth-generation screening IA, or chemiluminescent microparticle immunoassay (CMIA) by Abbott Laboratories, Inc.

The new CDC-endorsed HIV testing algorithm was also initiated, eliminating the use of the HIV-1 Western Blot for confirmation of a reactive HIV screening test, and instead employing the Multispot rapid discriminatory assay as a secondary supplemental test. With the use of the Multispot, all IA-positive specimens are tested specifically

NCSLPH HIV Testing Algorithm (Proposed)



for HIV-2 antibodies. Samples that yield discordant results on the two tests (CMIA reactive; Multispot nonreactive) are further tested for HIV-1 RNA to rule out acute HIV infection.

Using the new fourth-generation HIV screening test and new testing algorithm provides many advantages. Improved combination IAs allow for the detection of both virologic and serologic markers of HIV infection, reduce indeterminate test results, and eliminate the need for pooled NAAT to identify acute HIV-1 infections. The new testing algorithm also eliminates the HIV-1 Western Blot, a subjective assay which has always been difficult to interpret and is no longer useful as a confirmatory assay for the ultra-sensitive fourth-generation

HIV IA. Turnaround times for negative HIV results (including acute HIV) will be reduced from two to three weeks to two days. Positive results could be available in as few as three to four days. New instrumentation has been put into place in the laboratory that will provide increased testing capacity for the future growth of the NCSLPH HIV testing program. As the 30-year HIV epidemic continues to evolve, NCSLPH moves forward to meet the challenge of rapid diagnosis of both acute and established HIV infections by using the newest testing strategies and methodologies.

*Submitted by: Myra Brinson,
Manager, Virology/Serology Unit*

Updated Newborn Screening for Galactosemia

In September, the Newborn Screening laboratory implemented an expanded testing panel and reporting algorithm for galactosemia. Prior to this update, all specimens were tested for total galactose and a sub-set only for the enzyme galactose-1-phosphate uridytransferase (GALT). A deficiency of GALT enzyme activity is indicative of classical galactosemia, and partial enzyme activity is seen with patients

with a variant form of the disorder. Prior to September, the GALT assay was done only on elevated total galactose results, but with the purchase of two new analyzers, the GALT assay is now performed on all samples. If GALT or total galactose is abnormal, then third tier testing, consisting of a three DNA mutation panel analysis, is performed. The three-mutation panel includes Q188R (the most common mutation in the Caucasian population), N314 D (the most common mutation in patients with Duarte variant) and S135L (the most common mutation in those of African descent).

The Prosystem® analyzer, from Astoria-Pacific International, includes a liquid handling system, robotic manipulator arms, a microplate absorbance reader, and offers complete walkaway automation. This analyzer can perform overnight and weekend testing without technologist supervision. Automation significantly improves throughput from five to 18 assayed plates in one day, allowing for a potential 774 samples to be tested per day. Automation also eliminates the potential for errors that can occur during manual



*Galactosemia Laboratory staff in front of the new ProSystem®.
First Row: Chris Tinsley, Radish Persaud, Juanita Singleton
Second Row: Heather Boston, Krystal Plemmons, Pamela Deloatch*

operations, reducing the need for repeat testing, and maintenance time is also significantly reduced. The simultaneous testing of both total galactose and GALT activity greatly reduces the turnaround time (TAT) for galactosemia testing. The Newborn Screening laboratory can now provide the galactosemia results to healthcare providers within five days of receipt of the samples.

The DNA mutation analysis is performed by the State Laboratory's Molecular Diagnostics and Epidemiology Laboratory with a short TAT of 24 hours.

In summary, the new instrumentation, in conjunction with new tests and reporting protocol, improves the sensitivity of galactosemia testing, increases the efficiency and effectiveness of the workflow, decreases TAT and ultimately provides more timely and accurate results so that newborns in our state are promptly diagnosed and treated for galactosemia.

If you have questions about the new testing for galactosemia or reporting of results, contact Radish Persaud, FIA/GAL Supervisor (919-733-3937) in the Newborn Screening Program.

*Submitted by:
Radish Persaud, Supervisor, FIA/GAL Laboratory
Dr. Shu Chaing, Manager, Newborn Screening Unit
Ann Grush, Newborn Screening Laboratory Consultant*

What Does It Take to Move the Bioterrorism and Emerging Pathogens Unit?

Moving company hired?
Yes.

Ample numbers of boxes,
rolls of tape and moving
containers?
Check.

A plan to disassemble and
decontaminate the Biosafety
Level 3 (BSL-3) laboratory
used for the testing for the
causative agents of diseases
such as anthrax, plague and
brucellosis?
Absolutely!

Moving from one facility
to another is nothing like
moving from one house
to another. When
considering the scope of
work that is performed
by the Bioterrorism and
Emerging Pathogens (BTEP)
Unit at the North Carolina State
Laboratory (NCSLPH), simply
wrapping items in newspaper
and placing them in boxes for
the movers to transport is not a
plan that can be applied to the large
undertaking of moving the contents
of a BSL-3 laboratory.

As a whole, the old NCSLPH facility
located in downtown Raleigh
operated as a Biosafety Level 2
(BSL-2) laboratory, as does the new
laboratory, and maintained a BSL-3
laboratory for use by the BTEP Unit
for the testing of both clinical and
environmental samples suspected
of containing possible agents of
bioterrorism. Biosafety Level 2



The BSL-3 area at the Bath Building in downtown Raleigh

laboratories are those that are suitable
for work involving agents that pose
moderate hazards. BSL-2 organisms
include Hepatitis A, B, and C and
HIV. Standard safety practices
for working in a BSL-2 include
hand washing after working in the
laboratory and no eating, drinking
smoking or applying cosmetics while
in the laboratory. Work surfaces
can be decontaminated with the use
of a 10 percent bleach solution or a
facility-approved disinfectant and
must be performed at the completion
of work and after any spill or splash
of potentially infectious materials. In
BSL-3 facilities, work is performed
with those organisms that may cause
serious or potentially lethal disease
usually by way of inhalation.

Laboratory personnel must
receive specific training
annually in handling
dangerous organisms such as
Bacillus anthracis (anthrax)
and *Yersinia pestis* (plague).
All procedures involving
the handling of infectious
materials must be performed
within a Biosafety Cabinet.
All BSL-3 laboratories are
designed as to be easily
cleaned and decontaminated
in the cases of gross
contamination or facility
relocation. Seams, floors,
walls and ceiling surfaces
are sealed with smooth
finishes and the spaces
around doors and ventilation
openings have the
capability of being sealed
to aid with space decon-
tamination. Chairs used
in the laboratory must be

non-porous so that they can easily be
cleaned and decontaminated, and all
windows must be sealed. A ducted
HVAC system is required and must
provide directional airflow. Both
BSL-2 and BSL-3 spaces within the
laboratory required decontamination
before moving, but the BSL-3 process
is much more involved because of the
scope of work that is performed.

Prior to the BSL-3 suite
decontamination, all samples and
reagents were packaged and placed
into refrigerators and freezers
provided by the moving company.
Select agents, including control
strains of *Bacillus anthracis* and

Bioterrorism and Emerging Pathogens Unit cont. from page 6

Francisella tularensis, were destroyed. All extraneous and outdated files, books, materials, etc. were autoclaved and discarded. The BSL-3 office space was organized, and the contents of the desk and other unit essentials were packed in containers for shipment to the new facility. Moving the smaller items prepared the space for decontamination.

To ensure decontamination of the BSL-3 space, a Vaporized Hydrogen Peroxide (VHP) decontamination procedure was performed in the BSL-3 suite of the old facility. VHP is produced in generators specifically designed for the purpose of space decontamination. It is produced from a solution of liquid hydrogen peroxide and water. VHP is registered by the Environmental Protection Agency as a sterilant or substance that destroys all forms of microbial life including bacteria, fungi and their spores, and viruses. This chemical is approved for decontamination of anthrax spores and was used during the 2001 anthrax letters attack to decontaminate buildings. An advantage to using the VHP system is that the end products of the procedure are simple water and oxygen that are non-toxic.



The BSL-3 area at the new District Drive location

The VHP procedure included the rooms, exhaust ductwork and exhaust HEPA filter housings of the BSL-3 suite. The BSL-3 laboratory is classified as a “high risk” area that required a longer room injection time. That is, a longer contact time was performed for the space. All cabinet doors, incubator doors, etc. were left open during treatment to aid the decontamination process. BSL-3 suite door louvers were sealed on the outside of each door. Chemical indicator test strips were placed in all corners of the rooms to verify good distribution of the vapor, and each room was individually sealed during treatment.

At no time during decontamination did airborne hydrogen peroxide levels exceed the regulatory limits. The entire floor where the BSL-3 laboratory was located was empty of employees during the whole procedure, and warning signs were placed on all entries and elevators. At the conclusion of the procedure, a surface decontamination of

supplies was performed with laboratory-approved disinfectant solution.

Following the VHP procedure, large pieces of equipment were physically decontaminated. Freezers were decontaminated with bleach for 20 minutes and then soaked with an approved disinfectant for 20 minutes prior to drying. No

materials left the BSL-3 suite without either undergoing the VHP procedure or physical decontamination with bleach and the approved disinfectant solution. Cleaning materials were autoclaved at 121°C at 15psi for one hour.

Finally, the BSL-3 in the Bath Building was swabbed in more than 25 different locations using moistened sterile swabs. The swabs were swiped using several different motions to ensure that the areas were properly being sampled. The swabs were then processed in the Bioterrorism and Emerging Pathogens Unit’s Mecklenburg Regional Response Laboratory in Charlotte. Each swab was processed and sheep blood agar plates inoculated to determine if any viable potentially hazardous organism remained in the decontaminated space. Molecular testing was performed on each swab for the presence of *Bacillus anthracis* DNA.

Bioterrorism and Emerging Pathogens Unit cont. from page 7

Because *Bacillus anthracis* spores are very resistant and able to survive extreme environmental conditions, this organism was selected specifically for testing. No *Bacillus anthracis* DNA was detected on any of the swabs with environmental contaminants growing on just two of the more than 25 plates. Proper decontamination of the space had been achieved. At this point, the movers were able to safely pack all instrumentation contained within the BSL-3 suite to deliver it to the new, pristine District Drive facility.

All members of the BTEP team, including regional laboratory employees, participated in the successful preparation and execution of the BSL-3 laboratory move from the Bath Building to the District Drive facility.

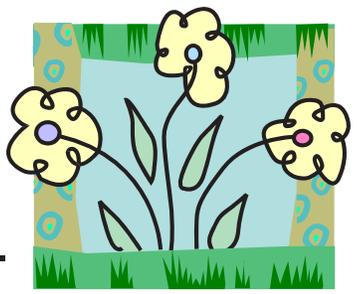
Next article: *What Does It Take to Bring a BSL-3 Laboratory Online for Testing of Biological Threat Agents?*

Submitted by:
La'Vonda Benbow, BS, MLT(ASCP)cm
*Laboratory Improvement Consultant/
 Training Coordinator*
*Bioterrorism and Emerging
 Pathogens Unit*



Winter/Spring

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



**January-May
 2014 WORKSHOP SCHEDULE**

DATE	TITLE	APPLICATION DEADLINE
January 15, 2014	Microscopy: Viewing & Reviewing	December 15, 2013
January 16, 2014	Examination of a Vaginal Wet Mount	December 16, 2013
February 5-6, 2014	Laboratory Methods in the Diagnosis of Gonorrhea	January 6, 2014
February 18-20, 2014	Bacteriological Methods for the Analysis of Drinking Water (Abbreviated version)	January 20, 2014
March 18-21, 2014	Process Control Chemistry	February 21, 2014
April 10, 2014	Bioterrorism Preparedness for Clinical Laboratories	March 10, 2014
April 16, 2014	Microscopy: Viewing & Reviewing	March 16, 2014
April 17, 2014	Examination of a Vaginal Wet Mount	March 17, 2014
May 14-15, 2014	Basic Microbiology	April 15, 2014

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

<http://slph.ncpublichealth.com>

9th Annual Clinical Laboratory Day

Clinical Laboratory Day is an annual event celebrating the laboratory professional. The Laboratory Improvement Unit of the North Carolina State Laboratory of Public Health (NCSLPH) has co-sponsored this event with the Texas Health Institute since 2005. Originally called Clinical Lab Tech Day, this event has evolved over the years to be a valuable source of continuing education for clinical laboratorians across the state. Each year the conference features topics that meet the needs and concerns of the laboratory and its personnel. This year's Clinical Laboratory Day theme was titled "Embarking on a New Era in the Laboratory" and highlighted many of the recent changes at the state laboratory.

After months of planning and promotion, the event hosted close to 130 participants. The program was held on the Raleigh main campus of Wake Technical Community College, attracting laboratory professionals working in public and private sectors, as well as educators, students, safety officers, nurses, nursing assistants and medical office staff.

Opening the event this year was Dr. Scott Zimmerman, the new state laboratory director. In keeping with this year's theme, Dr. Zimmerman discussed how NCSLPH is embracing a new facility full of new faces as we carry out new functions for the state. In the presentation, he illustrated that the public health lab has 11 core functions:

- disease prevention, control and surveillance
- integrated data management
- reference and specialized testing
- environmental health and protection
- food safety
- lab improvement and regulation
- policy development
- emergency response
- public health related research
- training and education
- partnership and communication



His final remarks reminded us that public health labs are often the front line of communication with the emerging changes in our communities, and public health organizations must be prepared to assist in every way possible.

During the day, participants attended a choice of educational sessions. Topics ranged from cultivating communication skills to solving baffling microbiology case studies. In Session One, attendees could either learn how to enhance customer service skills to reduce conflict or receive the latest updates on rapid influenza testing. Session Two introduced the state laboratory's new assistant director, Dr. Dee Pettit, to discuss responses to infectious disease threats, with the second option being an overview of waived testing and good laboratory practices. Session Three presented an exciting exploration of clinical microbiology case studies as well as a discussion on keeping phlebotomy skills on target. Participants were able to visit and explore vendor displays, showcasing varying new laboratory technologies and supplies from exhibitors. Everyone had an opportunity to meet, mix and network at sponsor-arranged refreshment breaks and lunch. Throughout the day, there were several chances to win prizes and acquire samples from exhibitors.

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9th Annual Clinical Laboratory Day cont. from page 9

The day ended with a discussion on the capabilities of the Chemical Terrorism and Threat (CTAT) Unit of NCSLPH presented by unit manager, William “Tex” Parks. Tex’s discussion focused on current testing methods, how to contact the CTAT Unit, and the types of samples that are appropriate to send for testing.

By the end of the program, many participants reported that they appreciated the information obtained from the various breakout sessions, exhibits and interaction with their peers. Gaining a better understanding of the capabilities and functions of the state laboratory and learning about overall improvements to lab practices will hopefully allow participants to take information back to their facilities for further advancement of their labs. By offering informative updates on topics pertinent to today’s healthcare communities, NCSLPH and its Laboratory Improvement Unit used creative collaborations and partnerships to present a full day of effective, empowering education.

Submitted by:

*Michaela Harvey-Creech, BSLAS, BSMT
Laboratory Improvement Consultant*



Who's Certifiable?

It's simple...the Environmental Services Certification Office at the North Carolina State Laboratory of Public Health (NCSLPH) has two primary responsibilities: 1) to certify laboratories to test drinking water compliance monitoring samples for programs governed by the EPA Safe Drinking Water Act (SDWA) and 2) to certify laboratories and analysts for FDA defined testing of milk and dairy products for compliance with the *Grade 'A' Pasteurized Milk Ordinance (PMO)*. Simple, right?

In 1978, the U.S. EPA implemented a certification program for laboratories performing analyses on drinking water compliance samples. The EPA recognized North Carolina as a primacy state responsible for establishing, maintaining, and enforcing the requirements set forth by the EPA for certification of public and private laboratories wishing to analyze compliance samples. The Certification Office is charged with the responsibility of overseeing the drinking water laboratory certification program and works closely with the North Carolina Public Water Supply Section (NC PWSS) and EPA to meet these responsibilities. The Certification Office provides consultation and teaching services as needed. The office is staffed with two Chemist II positions, one Processing Assistant IV, and the Supervisor. The NCSLPH has four Laboratory certification officers who have completed week-long EPA certification-officer training courses in microbiology, inorganic chemistry, and organic chemistry, and two in radiochemistry, all courses with rigorous competency exams. The North Carolina program has 228 laboratories, both from within North



Members of the Environmental Services Certification Office brainstorm about ways to become certifiable! Left to right: Chris Goforth, Mamie Harris, Michele Andrews, David Livingston

Carolina and from other states who may report data on North Carolina compliance monitoring samples. These include commercial laboratories, municipal water treatment plants, academia, military, and local health departments. The certified water laboratory breakdown is as follows: microbiology - 203, inorganic chemistry - 93, organic chemistry - 35, and radiochemistry - 13.

A program audit of a certified drinking water laboratory in the state of North Carolina consists of both a document review and a visit to the laboratory facility. An integral part of the North Carolina certification program is the actual on-site laboratory visit which is performed to determine if the laboratory has adequate facilities, necessary equipment and proper sample handling and test protocols for the analytes for which certification has been granted. During the audit, the documents provided by the laboratory and evaluated prior to the audit will be further discussed and reviewed with technical staff. Laboratory evaluations are performed for initial certification and at least every three years thereafter. We strive for evaluations every two years, and even more frequently if questionable practices are observed or suspected. Laboratories in other states must also be reviewed to assure they are conforming to specifics in the North Carolina rules and regulations. Another heavy time-consumer of the Certification Office is the maintenance of the Proficiency Testing (PT) program. To maintain certification, a laboratory must prove proficiency by analyzing samples where the analyte and concentrations are unknown to the laboratory. North Carolina requires a full study once a year for all analytes and methods that

Who's Certifiable? cont. from page 11

the laboratory is certified to report, and a second study in the third quarter for acute health hazards. All PT samples are entered into a database and reviewed by certification officers looking for unacceptable proficiency analyses. When unacceptable records are found, the certification officers must begin the process of decertifying laboratories. The Drinking Water Laboratory Certification Office is also responsible for maintaining the laboratory component of North Carolina's SDWIS database. This responsibility includes notification of the N.C. PWSS representatives when new laboratories enter the program. Additionally, the certification status of each individual laboratory is tracked by the Certification Office with additions and deletions entered as appropriate.

The Certification Office actively assists the Laboratory Improvement Unit with two weeklong environmental workshops: *Bacteriological Methods for the Examination of Drinking Water* and *Process Control Chemistry*, which includes preparation of course materials, lectures and demonstrations, and assistance to students during the laboratory sessions. The *Bacteriological Methods* workshop is scheduled three times a year with 24 to 30 students in each class, and *Process Control Chemistry* is held twice yearly with a maximum of 12 students per session. The Certification Office also assists with the N.C. Waterworks Operators Association (NCWOA) Schools held in Morganton (spring) and Raleigh (fall), teaching approximately 12 hours at each school. These weeklong workshops are designed to provide a review for water treatment plant personnel preparing to take the various levels of the operator's exams. *Laboratory Technology Day* is held every May in Raleigh. This is a day-long educational experience for water plant personnel, commercial laboratories, and wastewater personnel. The entire Certification Office is used to make the day a success, from registration of 150+ attendees, emceeding the Drinking Water session and setting up the presenters to helping with vendor participation and presentation of participation certificates.

In 1984, the state of North Carolina adopted the U.S. Public Health Service/ Food and Drug Administration's *Grade 'A' Pasteurized Milk Ordinance* (PMO) as a governing document covering sanitary

production, transportation, processing and distribution of Grade 'A' dairy products. As part of the laboratory component of the PMO, a Laboratory Evaluation Officer (LEO) is required to monitor plants and public sector laboratories that report compliance data. North Carolina currently has five large processing plants and eight small producer/processors facilities, and more than 70 analysts in the Grade 'A' milk program. Each tanker of milk, upon receipt at the processing plant and before transfer to a milk silo or holding tank, is tested for antibiotic residues, and raw milk and finished products may also be tested for various quality indicators. All compliance testing must be conducted by analysts who have been certified by the LEO, and each laboratory must be approved by the LEO. This requires an on-site visit to the laboratory biennially to observe each analyst perform the methods for which they are certified to run and to evaluate equipment and records, as well as supplemental visits when new analysts are hired or new methods are added. To maintain certification, each approved analyst must test a series of split-milk samples annually for each method they are certified to perform. Results of this testing are returned to the LEO who will evaluate the results and the analysts' performance based on established acceptance criteria. The Certification Office supports the Grade 'A' milk program by providing a technical position which serves as the LEO. This individual must successfully complete an FDA training course and an audit check by an FDA auditor every three years. The LEO also works with the Environmental Sciences Microbiology Laboratory as needed on the milk program and acts as the primary contact between the North Carolina laboratories and the FDA for issues related to the laboratory community.

As you can see, there is a lot for the Certification Office to keep up with ensuring that federal and state guidelines and requirements are met. It is an on-going job that keeps us away from the office much of the time, and when we are in the office, we are usually working on the various paperwork trails that must be rigorously maintained.

Submitted by:
Michele Andrews
Laboratory Certification

Career Choices Highlighted for Genetic Counseling Students

A single phone call or fax at work may seem a routine part of the work day. But the communication between medical technologists at the State Laboratory of Public Health's Newborn Screening program and genetic counselors in the Women's and Children's Health Section can signal the start of a medical journey that may result in the diagnosis of a disorder with life-long consequences. The enormity of one communication between these two public health groups was conveyed recently to a visiting group of UNC-Greensboro genetic counseling students.

Meeting at the new State Laboratory of Public Health, the students learned about the role of the Newborn Screening testing program in North Carolina, as presented by manager Dr. Shu Chaing. Dr. Chaing's focus centered on the disorders for which the laboratory screens, testing methods used and how abnormal results from the laboratory are conveyed to genetic counselors. Depending on the disorder, these infants may suddenly be admitted to an emergency room with life-threatening symptoms that could lead to coma and death. The laboratory works closely with genetic counselors within the Department of Health and Human Services' Women's and Children's Section to notify them of results that need immediate action. Two of these genetic counselors, Lara Percenti and Ginny Vickery, are responsible for short term follow-up of certain disorders and are certified genetic counselors. During their presentations, they described their work in notifying healthcare providers of abnormal results for congenital hypothyroidism, congenital adrenal hyperplasia, cystic fibrosis, biotinidase deficiency, and galactosemia. Rapid contact to the provider is crucial in newborn screening and begins immediately upon receipt of the laboratory result. The genetic counselors continually communicate with the healthcare provider and a medical specialist until the infant is confirmed with a disorder or not.

The Genetic Counseling program at UNC-Greensboro is the only such program in our state. Students complete a rigorous 21-month program, after which they are



*UNC-G First Year Genetic Counseling Students, **First Row:** Alexandra Henshaw, Juliann Koenig, Briana Lubben **Second Row:** Taylor Zuck, Lauren Baldwin, Caitlin Troyer, Samantha Caldwell and Elizabeth Decker*

employed in a variety of careers across our state and nation. Following graduation, these students also begin study for the national certification exam. This educational outreach exposes the students to the work of genetic counselors within public health.

Students enter this program with undergraduate degrees from schools across the nation, with majors in biology and psychology being frequent; many of these first-year students were double majors. During an interview, the students shared their influences to study genetic counseling. One student had a family member with a genetic disorder, and many were exposed to genetic counseling during their undergraduate years. The Genetic Counseling program is one way to integrate an interest in science and a healthcare serving profession.

The role of genetic counselors in public health is an atypical career choice, and the students had little previous awareness of the Newborn Screening program before the presentations and tour of the laboratory. Careers in genetic counseling are more frequently found in prenatal and pediatric fields, research, and genetic testing laboratories. This outreach by the laboratory and follow-up genetic counselors brought to light new

Genetic Counseling Students cont. from page 13

and different career paths in public health for these aspiring genetic counselors. In a new setting, they learned that the partnership role of a genetic counselor and a laboratory can affect the very lives of newborns in North Carolina.

*Submitted by: Ann Grush,
Newborn Screening Laboratory Consultant*

Appreciation is expressed to Ms. Nancy Callan, UNC-G Genetic Counseling Program Director, for information about the program, and to the students for providing insight into their educational and career choices.



The State Laboratory welcomes the following new employees:

- Microbiology** – Jason Clinton, Vilma Gonzalez, Dominique Torrence
- Virology/Serology** – Tiana Beard, Lisa Smith
- Molecular Diagnostics** – Katja Manninen
- Operations** – Richard “Rick” Yeager, Louie Allen
- Chemical Terrorism and Threat** – Lindsey Parker
- Newborn Screening** – Katelyn Van Meter

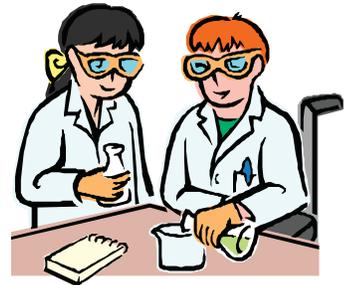
CUSTOMER SERVICE TIPS

Don't make excuses. If a customer's issue is your fault, SAY SO. Don't blame the customer, circumstance or the vendor. If a problem is your fault or your staff's fault, take full responsibility. Admit that an error has been made, and let the customer know that you will do your best to resolve the issue. If you are not able to come up with a solution, let the customer know that you will personally forward the problem to your supervisor or someone that is more capable of giving them a satisfactory solution in a timely manner. Honesty and accountability are always appreciated!

The Safety Corner

Laboratory Safety's Top Ten List: Opportunities for a Safer Workplace

Personal Protective Equipment



Believe it or not, we are at the end of our Top Ten List! Last, but certainly not least, let's discuss personal protective equipment.

Personal protective equipment (PPE) is our last line of defense for protecting ourselves from hazards in the laboratory. Once engineering controls and work practice controls have been put in place, we must do a hazard assessment and determine what PPE is necessary. If these assessments have never been done in your facility, evaluate tasks performed in your lab and determine if the PPE used is acceptable. Look at gloves, lab coats and eye protection to determine if these items are used appropriately and as often as needed. For example, during a specific laboratory safety assessment, we found the lab coats were not sufficient for the tasks at hand. Employees were using short lab coats which did not protect their legs from splash hazards. They corrected the situation by purchasing longer, knee-length lab coats.

Once you have determined what PPE is necessary, the next and possibly most difficult step is ensuring your employees wear the PPE. Lab coats and gloves must be worn in the laboratory at all times. If nursing staff wear lab coats as part of their 'uniform' and it is worn outside of the lab, this is not considered PPE. In this situation, they must place a disposable apron or coat over their 'uniform' while performing tests in the lab. All items considered personal protective equipment should be removed before leaving the lab. Employees must also wear closed-toed shoes in the laboratory, as this is an OSHA requirement.

Make sure employees are also wearing the PPE *correctly*: A lab coat is not protecting you at all if it's unbuttoned. Single-use gloves should never be reused. Safety glasses do not protect your eyes if they are sitting on top of your head. Just keep an eye out for these types of things, and make sure everyone is complying with your PPE policy. If there are complaints, tell them the rules are there to protect them, not to make them miserable!

A few other items to remember about PPE include:

- Personal protective equipment should be provided at no cost to the employees. This also includes PPE maintenance such as laundering.
- Ensure employees are trained in the proper use, types, and locations of personal protective equipment.

If you have any questions regarding safety, please contact Kristy Main at kristy.main@dhhs.nc.gov or (919) 733-7186.

*Submitted by:
Kristy Main, BS
Laboratory Improvement Consultant*

Webinar Announcement

Developments in Newborn Screening

March 13, 2014

NCLTN

(North Carolina Laboratory Training Network)

This program will be presented in Adobe Connect format.

WEB CONFERENCE DESCRIPTION

Newborn Screening has been an integral part of public health in North Carolina for almost 50 years. During this time much has changed, from the disorders screened for to a new facility to house this laboratory.

This web conference will highlight developments and changes to the testing program in the past year. Topics will include additions to the testing panel, changes in reporting algorithms, new reports, and plans for future testing in North Carolina.

Be on the lookout for registration information in early 2014!

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