



DELAWARE LABORATOR



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NEWBORN SCREENING...
50 YEARS OF SAVING LIVES IN DELAWARE
PATRICIA SCOTT, NBS LABORATORY MANAGER

This year, the world-wide screening community celebrates the 50th anniversary of Newborn Screening (NBS). In recognition of this milestone, the Association of Public Health Laboratories (APHL) is heading a 50th anniversary national campaign designed to increase awareness among expectant parents, their families, health care providers, citizens, and policy makers about the benefits from performing newborn screening tests. Among the activities sponsored by APHL in 2013 are the creation of a book about NBS that



includes compelling stories and pictures; the development of presentations and exhibits for use at national scientific exhibits and meetings; thirteen travelling exhibits to be shown at select state public health laboratories; educational materials; social media initiatives; magazine articles; a 15-second ad to run twice per hour on the New York City Time Square Jumbotron; and a NBS event to be held in Washington D.C on September 18, 2013. The Delaware Public Health Laboratory (DPHL) will host one of the travelling exhibits during its annual open house scheduled for Thursday, April 25th, from 9:00 a.m. – 1:00 p.m. The exhibit will also be shown at Delaware's Legis-

“No child should die or suffer disabilities if a simple blood spot can prevent it.”
 Robert Guthrie, PhD, MD, 1916-1995
 Developer of the first newborn screening test

lative Hall during the week of April 15, 2013. For more information about APHL activities, please visit: <http://www.50YearsSavingBabies.org>

Mandated newborn screening efforts were implemented in Massachusetts in 1963.

Dr. Robert McCreedy, director of diagnostics at the Massachusetts Public Health Laboratory, performed a bacterial inhibition assay, developed by Dr. Robert Guthrie, as part of a mass screening of newborns, to quantify phenylalanine.

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www.dhss.delaware.gov/dhss/dph/lab/labs.html

Newborn Screening continued

During this trial, 400,000 infants in 29 states were tested, and 39 babies were diagnosed with Phenil Ketonuria (PKU). The study is detailed in a US Dept of Heath Education and Welfare press release dated August 16, 1964, and is available upon request (Contact Pat Scott at 302-223-1494 or Pat.Scott@state.de.us). Evidence also shows that Delaware performed newborn screening in 1962. In Delaware, it is generally accepted that the statewide newborn screening began early because regulations granted the director of public health department the authority to implement programs that could benefit the public's health.

These regulations were later consolidated under Title 16 Delaware Code Sec. 122 (1) and Sec. 122 (3) (h) and Title 29 Delaware Code Section 7904.

- FACT 1 Newborn screening touches nearly every baby born in the United States.
- FACT 2 Newborn screening is a public health success story
- FACT 3 Newborn screening is MORE than a test
- FACT 4 Newborn screening is a dynamic program – evolving, improving

To verify the 1962 date, a search for evidence uncovered a Memorandum

written by A. Yvonne Russell, M.D. to Floyd I. Hudson, M.D., then director of public health, dated May 8, 1967. In this document, Dr. Russell details the cases of PKU found ‘*since the beginning of the PKU Program in August 1962.*’ This memo provided confirmation that 1962 was the start of newborn screening in the State of Delaware.

Delaware’s Division of Public Health (DPH) is proud to have been at the front line of such an important public health program, which has continued for 50 years! As awareness increases, some of the most important lessons learned from this program are –

- **Newborn screening saves lives by detecting problems early.**
- **Early detection allows for early treatment** — *and a much improved quality of life.*

***WELCOME TO
DELAWARE’S NEW DIVISION OF PUBLIC HEALTH MEDICAL DIRECTOR
AWELE MADUKA-EZEH, MD, MPH***

Dr. Awele Maduka-Ezeh joined Delaware’s Division of Public Health (DPH) as medical director in July 2012. Prior to joining DPH, Dr. Maduka served as faculty in the Division of Infectious diseases and Division of Hospital Medicine at Christiana Care Health Services. Dr. Maduka received her medical degree from the University of Ibadan and holds a master’s degree in public health from Harvard University in Cambridge, MA. She completed her graduate medical education at Albert Einstein Medical Center in Philadelphia, PA, and the Mayo Clinic in Rochester MN. She is board certified in infectious diseases and internal medicine.

In January 2013, the Bureaus of Epidemiology and Communicable Diseases were moved under Dr. Maduka’s purview. With this change, Dr. Maduka will oversee DPH’s work in epidemiology, tuberculosis control, immunizations and sexually transmitted diseases, among others.

Dr. Maduka has laboratory experience acquired when she worked as a research fellow at the Mayo Clinic infectious disease research lab. Her work involved staphylococcal small colony variants and included basic bacteriology, antimicrobial susceptibility testing, pulse field gel electrophoresis, target gene amplification, electron microscopy, and 16S ribosomal RNA sequencing. She has published work in the Journal of Clinical Microbiology, Diagnostic Microbiology and Infectious Disease, the Journal of Bone and Joint Surgery, as well as several abstracts presented at infectious disease and microbiology meetings.

PREPAREDNESS LABORATORY AND SELECT AGENT UPDATE***FEBRUARY 2013******DEBBIE RUTLEDGE, MBA(ASCP)
BIOTERRORISM LABORATORY COORDINATOR
INFECTIOUS DISEASE LABORATORY MANAGER II***

The Centers for Disease Control and Prevention (CDC) Select Agent Program regulates the possession, use and transfer of biological agents and toxins that can pose a threat to public health and safety (select agents). This program, which is managed by the Division of Select Agents and Toxins (DSAT), located in CDC's Office of Public Health Preparedness and Response (OPHPR), has greatly enhanced our nation's capability to manage select agent safety and security. In Delaware, the Select Agent Program promotes laboratory safety and security by:

- Developing, implementing, and enforcing select agent regulations;
- Providing guidance to the regulated community;
- Inspecting facilities that work with select agents;
- CDC is working closely with the Animal and Plant Health Inspection Service (APHIS) in the U.S. Department of Agriculture (USDA) and the Criminal Justice Information Services Division (CJIS) in the Department of Justice. APHIS regulates the possession, use, and transfer of select agents that can pose a severe threat to animal or plant health and/or animal or plant products. CJIS conducts security risk assessments of non-federal entities and of personnel who have access to select agents.

APHIS/CDC Select Agent Regulations Changes

The U.S. Departments of Health and Human Services (HHS) and the USDA published final rules (42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121) in the Federal Register on October 05, 2012. All provisions of the final rules supersede those contained in the previous final rules.

Changes to the final rules include tiering of some select agents. Laboratories that wish to maintain Tier 1 select agents must meet additional safety, personnel, and security measures. Details for these changes are provided in guidance documents (see references on page 4) developed by the Select Agent Program. They are designed to help entities meet the requirements of the new regulations. Other changes call for laboratories that do not apply for Tier 1 select agent classification to transfer or destroy agents, beyond Tier 1, within 7 days.

Available guidance documents include:

- Guidance for Meeting Training Requirements of the Select Agent Regulations
- Guidance for Suitability Assessments
- Guidance on the Inventory Requirements for Select Agents and Toxins
- Incident Response Plan Guidance Document
- Information Systems Security Control Guidance Document
- Occupational Health Program Guidance Document for Working with Tier 1 Select Agents and Toxins
- Responsible Official Guidance Document
- Security Guidance for Select Agent or Toxin Facilities

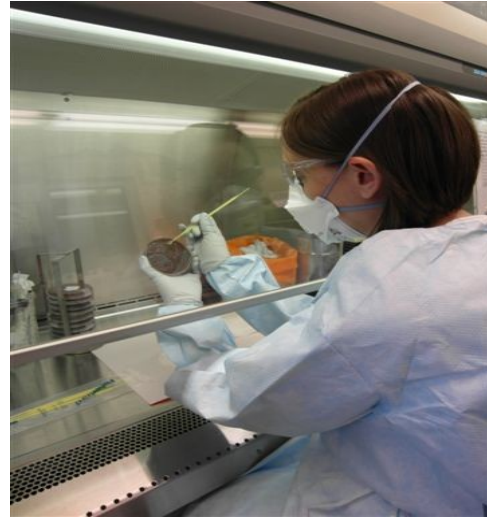
In general, any lab that is classified as Tier I must implement additional security precautions, undergo more rigorous training, and institute personnel reliability assessments for new and existing personnel. While intended to strengthen biosecurity, these requirements are more practical for research and larger institutions. As part of the Laboratory Response Network (LRN-B) mission, having Tier I status is not necessary since it can result in unnecessary costs and efficiency burdens.

Preparedness continued

Because of increased CDC requirements in safety, security, personnel screening, and “tiering” of Select Agents, the Delaware Public Health Laboratory (DPHL) only maintains Tier 1 select agents. This change was announced in October 2012. Destruction of select agents beyond Tier 1 was completed in November 2012 and an amendment to the registration documents was submitted to CDC prior to the December 4, 2012 deadline. This decision does not impact the laboratory’s ability to confirm select agents in the event of an incident.



From left to right: Debbie DeRocili, Brenda Chandler, Bela Patel, Diane Hindman and Jordan Hudson from DPHL



Jessica McKnight from DPHL

The annual DPHL internal Select Agent and Toxin Inspection was conducted during the week of November 13 – 16, 2012. This was an intensive inspection that focused on plans, training, protocols, practices, and adherence to DPHL and CDC Division of Select Agent and Toxin Program regulations and checklists. In this program, there are two alternate responsible officials (ARO): Debra Rutledge and Tara Lydick; a biosafety officer, Fred Franze; and a lead bioterrorism (BT) staff member, Jessica McKnight. They inspected the Bioterrorism/Tuberculosis (BT/TB) Suite and the Biological Preparedness Laboratory (BPL) Suite. A final inspection report was completed in December 2012 and recommendations were successfully completed in January 2013.

References:

<http://www.cdc.gov/phpr/dsat.htm>

<http://www.selectagents.gov/>

http://www.selectagents.gov/Guidance_Documents.html



Jordan Hudson from DPHL

LIMS ELECTRONIC DATA MESSAGING

KATHY GRAY, LIMS ADMINISTRATOR

Delaware's Division of Public Health (DPH) and the Delaware Public Health Laboratory (DPHL) are in the midst of a "digital revolution" when it comes to the conveyance of laboratory test results. Beginning with influenza and continuing with all clinical data, DPHL is expanding capabilities through the transfer of data at both local and national levels.

Last Spring DPHL began electronic messaging of influenza data. Currently, all influenza test results are automatically sent to the Centers for Disease and Control Prevention (CDC) from our Laboratory Information Management System (LIMS). Staff no longer have to manually assemble weekly data and enter it into the CDC website. This saves time and reduces errors. Following this, the DPHL initiated a Laboratory Response Network (LRN-B) message so that data could be automatically transmitted to the CDC when tests are completed. LRN-B messages differ from the current influenza messages in that LRN-B involves the results from multiple tests and multiple organizations. The set of criteria for these messages is established at the national level so that all communication standards are maintained in the electronic transfer of information between Delaware and the CDC as well as between states. This change represents a significant improvement in the process of data and information sharing within the U.S. Some of the different message types include:

- PHIN Direct Alerting
- PHIN TB Case Notification Message - Send
- PHIN Varicella Case Notification Message - Send
- PHIN Cascade Alerting
- PHIN Generic Case Notification Message – Send

Another project is the integration of the LIMS with the state's new Electronic Medical Record system (EMR) called CX360. Data and test requests will be made in the CX360 system and transmitted to LIMS for sample processing. Results will be recorded in LIMS and transmitted back to the EMR. Currently users have to do extra work to input data into the EMR and LIMS, separately. With the completion of the interface, workloads will be reduced by 50 percent. Reports will be automatically transmitted to the EMR once testing is complete. This eliminates the need for time to print reports from LIMS and then scan them into the EMR.

A third project that is underway is the transmission of data to the Delaware Health Information Network, also known as DHIN, which is a repository for health information about individuals. A participating physician will be able to log into DHIN and receive lab results or other test results such as x-rays without having to search for paper reports. Most of the hospitals, commercial reference labs, and many doctors' offices already participate in DHIN. The integration of DPHL with data from various DPH programs into DHIN enables physicians to have a more comprehensive view of their patient's health data. This will save time to treatment, reduce the costs from repeat testing, and help to improve the overall health of Delawareans.

EMPLOYEES NEWS



Leah Wingard joins DPHL as our environmental health laboratory fellow and will be tasked with expanding our biomonitoring testing program. During this yearlong fellowship, she will be indulging her love of instrumental techniques developing new mass spectrometry methods. Leah earned her doctorate in chemistry from the University of North Carolina

Chapel Hill and her Bachelor of Science with a major in chemistry from Rhodes College. She has traveled nationally and lived in China for three years. She is an avid reader, a consummate knitter, and loves cooking with her latest focus on bread making.

WELCOME TO THE LAB!

Shemeeakah Powell is the new bioterrorism (BT) contractor under the Public Health Emergency Preparedness (PHEP) grant. She has a Bachelor of Science with a major in biochemistry from Seton Hall University and a Master of Science in chemistry from Rutgers University. Prior to coming to DPHL, she worked at both Memorial Sloan-Kettering Cancer Center in New York City and the Howard Hughes Medical Institute in New Jersey. In her spare time she lobbies to get her name spelled correctly, likes to sew, cook, make jewelry, and teach belly dance.



DELAWARE'S DIVISION OF PUBLIC HEALTH LABORATORY

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Built: 1990

Business Hours: 8:00 a.m. – 4:30 p.m.

Purpose: The Division of Public Health Laboratory currently offers consultation and laboratory services to state agencies, Delaware Health and Social Services and Division of Public Health programs including:

- HIV surveillance and prevention
- Immunization
- Epidemiology
- Newborn Screening
- STD prevention
- TB Elimination
- Drinking water
- Preparedness

Karyl Rattay, MD, MS
Director, Delaware's Division of Public Health

Christina Pleasanton, Deputy Director,
Delaware Public Health Laboratory

If you have questions regarding these articles or would like to receive a hard copy of this newsletter, contact the Delaware Public Health Laboratory at 302.223.1520. To receive this newsletter by email, contact Pat Selg, Editor, at pat.selg@state.de.us

"To Protect and Enhance the Health of the People of Delaware"