# Delaware LabOrator

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## Newborn Screening Era at DPHL Comes to an End

by *Patricia Scott,* MT BT, Laboratory Manager, Delaware Public Health Laboratory

*It is impossible to understand the significance of the contributions that the Delaware Public Health Laboratory (DPHL) has made to Newborn Screening (NBS) from 1999 to 2017 without first looking back at the history of Newborn Screening in the United States and Delaware.*

### NEWBORN SCREENING IN DELAWARE

In August 1964, the U.S. Department of Health, Education and Welfare, Welfare Administration, Children's Bureau in Washington, D.C. released the results of a 29-state investigation conducted from 1962 to 1963 that looked at Phenylketonuria (PKU), an inborn error of metabolism that can lead to severe mental retardation. They concluded that PKU is not as rare as had been previously thought and occurs once in every 10,000 babies. Previous estimates had been one in every 20,000 births. The report encouraged states to ensure that testing of all newborn infants occur on a routine basis, joining New York, Rhode Island, Massachusetts, and Louisiana who had passed laws requiring the Guthrie test. Delaware heeded the call, and started a statewide voluntary PKU Screening program in 1962.

As time went by, testing for additional disorders became possible. On January 1, 1979, testing for Hereditary Metabolic Disorders was contracted out to the Maryland State Laboratory of Health in Baltimore. This allowed for expansion of the panel to include tests for Tyrosinemia (Tyrosine), Maple Syrup Urine Disease, also referred to as Branched Chain Keto Acids (Leucine, Isoleucine and Valine), Homocystinuria (Methionine), Congenital Hypothyroidism (Thyroxine [T4] and Thyroxine Stimulating Hormone [TSH]) and Galactosemia, along with PKU (Phenylalanine).

The responsibility for screening of newborns later moved from Maryland to Oregon in 1992 following a Request for Proposal (RFP) process. Oregon and Delaware testing algorithms both required two specimens on every baby. Testing responsibility remained with Oregon until 1999, when Delaware brought the screening back 'home' to the Delaware Public Health Laboratory (DPHL). After a lengthy training process, provided by the manufacture, Neometrics, the first batch of newborn screening specimens was received on June 30, 1999. At that time, about 25,000 specimens from about 12,000 newborns were tested for four disorders, Hemoglobinopathy, Hypothyroidism, PKU, and Galactosemia.

In the 18-plus years newborn screening has been performed at DPHL, upgrades were made to add newer, better, more effective, and increasingly complex testing methodologies. New protocols were implemented to benefit the newborns of the state including Congenital Adrenal Hyperplasia (2001), Tandem Mass Spectrometry (2002-2003), Biotinidase Deficiency (2006), Cystic fibrosis (2007), Molecular testing for Cystic fibrosis (2009), Severe Combined Immunodeficiency (2011), Hearing Screening, and Critical Congenital Heart Disease (2013). The last two disorders are performed while infants are still in the hospital. By 2017, the Delaware screening panel consisted of 45 disorders, listed in the *Delaware Disorder List*.

**Spring 2018**

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Division of Public Health
Laboratory

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## DELAWARE NEWBORN SCREENING DISORDER LIST

### TRADITIONAL DISORDERS

- CH - Congenital Hypothyroidism
- CAH - Congenital Adrenal Hyperplasia
- GAL - Galactosemia
  - Classic Galactosemia (GALT)
  - Galactokinase Deficiency (GALK)
  - Galactoepimerase Deficiency (GALE)
- HGB - Hemoglobinopathies
  - HbSS, Sickle Cell Disease
  - Hb S/ßTh), Hemoglobin S-beta Thalassemia
  - Hb SC, Hemoglobin SC Disease
  - Variant Hemoglobins
- BIOT - Biotinidase Deficiency
- CF - Cystic Fibrosis

### AMINO ACID/UREA CYCLE DISORDERS (MS/MS)

- PKU - Phenylketonuria
- HPHE - Hyperphenylalanemia
- MSUD - Maple Syrup Urine Disease
- HCYS - Homocystinuria
- HMET - Hypermethioninemia
- TYR - Tyrosinemia
  - Tyrosinemia Type I, limited ability to identifyTyrosinemia, Type II
  - Tyrosinemia, Type III
- ARG - Argininemia
- ASL - Argininosuccinate Lyase Deficiency
- CIT - Argininosuccinate Synthetase Deficiency (Citrullinemia)

### ORGANIC ACID DISORDERS (MS/MS)

- GA-1 - Glutaric Acidemia, Type I
- PA - Proprionic Acidemia
- MMA - Methylmalonic Acidemia
- MCD - Multiple Carboxylase Deficiency
- IVA - Isovaleric Acidemia
- 2-MBCD - 2-Methylbutyryl-CoA Dehydrogenase Deficiency
- 3-MCC - 3-Methylcrotonyl-CoA Carboxylase Deficiency
- HMG - 3-Hydroxy-3-Methylglutaryl-CoA Lyase Deficiency
- BKT - Mitochondrial Acetoacetyl-CoA Thiolase Deficiency
- IBCD - Isobutyryl-CoA Dehydrogenase Deficiency

### FATTY ACID OXIDATION DISORDERS (MS/MS)

- MCAD - Medium Chain Acyl-CoA Dehydrogenase Deficiency
- CPT II - Carnitine Palmitoyltransferase II Deficiency
- CAT - Carnitine/Acylcarnitine Translocase Deficiency
- GA II - Glutaric Acidemia, Type II
- MADD - Multiple Acyl-CoA Dehydrogenase Deficiency
- SCAD - Short-Chain Acyl-CoA Dehydrogenase Deficiency
- LCHAD - Long-Chain Hydroxyacyl-CoA Dehydrogenase Deficiency
- TFP - Trifunctional Protein Deficiency
- VLCAD - Very Long-Chain Acyl-CoA Dehydrogenase Deficiency
- CUD - Carnitine Uptake Deficiency

### OTHER

- NH - Newborn Hearing Screening
- SCID - Severe Combined Immunodeficiency
- CCHD - Critical Congenital Heart Disease (January 2013)

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## NATIONAL RECOMMENDATIONS

**Much of the** change seen during the DPHL years was a result of national recommendations that were intended to facilitate change. One of those milestones occurred in 2006, when the American College of Medical Genetics, as commissioned by Health Resources and Services Administration released a document that would address how states add conditions to their state panels, entitled "*Newborn Screening: Towards a Uniform Screening Panel and System*." A systematic and scientific approach by experts in the field was used to look at newborn disorders and a listing of 29 primary or core disorders along with 25 secondary targets was published.

In addition, a process was set in place for additional disorders to be reviewed by the [US Health & Social Services] Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) Committee for addition to the Recommended Uniform Screening Panel (RUSP) after evidence review and vote. Many disorders have been considered with three additional disorders added to the RUSP. They are Glycogen Storage Disease, type II (Pompeii), Mucopolysaccharidosis type 1 (Hurler & Scheie syndromes), and x-linked Adrenoleukodystrophy (xALD). For inclusion on the Delaware Panel, the Delaware Newborn Screening Advisory Committee must make a recommendation and the Director of Public Health must direct that it is added.

In April 2015, another milestone occurred when the SACHDNC Committee released a report relating to timeliness of NBS in the United States. Recommendations were made regarding times from sample collection through transit, testing, and reporting. The Committee encouraged states to monitor their progress in achieving these goals and make the information readily available to providers and the general public.

DPHL accepted the responsibility for moving toward the uniform panel recommendations and for tracking timeliness and associated continuous improvement in turn-around times. The Newborn Screening lab boasted one of the shortest turn-around times in the nation for QA indicator, *Time from specimen collection to specimen receipt*. In 2007, the March of Dimes Foundation for National Leadership in Newborn Screening recognized Delaware's Newborn Screening Program. Clinical Laboratory Improvement Amendments survey officers called the Delaware program "exemplary."

## ELECTRONIC DATA IMPROVEMENTS

**Of the many** disorders added to Delaware's Neometrics data system during this period, the most impactful was the addition of Tandem mass spectrometry (MS/MS) technology allowing for the measurement of 29 analytes with a single method. Delaware was one of the first labs to include all MS/MS analyte results in their data system and our work was presented at the 2013 Newborn Screening Symposium. Over the years, additional connections between data systems were being made, including vital statistics (birth records), immunizations (Hepatitis B), hearing screening data systems, and Healthy Women, Healthy Babies. In 2015, the Neometrics data system was expanded to include the technical programing (LOINC codes) for electronic messaging of the NBS report and electronic receipt of hearing data, direct from hospitals. Preparations were being made to allow access to NBS data through DHIN, Delaware Health Information Network.

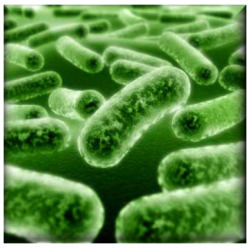
## FINAL GOODBYE

**Alas, in 2016**, with an economy in recession, and increasing expenses forecasted, the pressure and cost to add additional disorders and additional staff needed to expand to six-day-a-week testing (to improve timeliness); the impending replacement of the original MS/MS equipment; and increasing costs associated with contracting out metabolic follow-up services, Public Health officials made the very difficult decision to contract out Newborn Screening laboratory and follow-up services. An RFP was published and awarded to A.I. DuPont Hospital, with a sub-contract with PerkinElmer Genetics for laboratory testing, effective January 1, 2018.

The last 18 years have allowed DPHL staff the opportunity to directly impact the health and lives of babies, ensuring a healthy start for more than 200,000 babies. The work has been both humbling and rewarding for staff and a public health success story as thousands of babies were identified before major damage or death occurred and were introduced to proper follow-up care. DPHL is proud to have shepherded this program through the heavy growth years to where it stands today. Understanding that change is necessary, DPHL wishes success to the Delaware NBS program as it progresses on its new pathway.

## Epidemiology and Laboratory Tabletop Exercise

by *Camille Moreno Gorrin,* MS, Epidemiologist, Office of Preparedness



**On December** 6, 2017 the Emergency Medical Services and Preparedness Section, Office of Preparedness conducted a tabletop exercise to test the process and communication between epidemiologists and laboratory staff during an infectious disease emergency. The exercise was held at DPHL and the main objectives were based on DPHL testing and Public Health surveillance and epidemiological investigation capabilities.

Twenty-two people attended the exercise, which included epidemiologists from various areas of expertise (infectious diseases, chronic diseases, and maternal and child health), DPHL scientists, and DPH nurses. A plausible scenario was presented and divided into five different modules that were handed out individually as discussion progressed.

The first module introduced information about current infectious diseases outbreaks in other countries generating discussion about situational awareness tools currently available to epidemiologists. Subsequent modules presented reports about atypical number of illness in hospitals, diagnosis of an imported infectious disease, and possible local transmission of the disease in Delaware. These scenarios triggered discussion about the different levels of response that will be put into action based on the situation.

Specific topics that surfaced during this exercise included discussion about epidemiological surveillance tools, enhancing communication between the Office of Infectious Disease Epidemiology and DPHL, requirements for specimen testing, State Health Operations Center activation processes, and inclusion of non-infectious diseases in epidemiologists' infectious disease investigations. Valuable recommendations were made to improve processes in place and enhance public health investigations.

## Bioterrorism Update

by *Debra Rutledge,* MT (ASCP), MBA, Infectious Disease Laboratory Manager II

**Last fall,** DPHL had the opportunity to work with real Select Agents. On September 29, the laboratory received two emu brains for testing for West Nile Virus (WNV) and Eastern Equine Encephalitis (EEE). DPHL received the brains from two emus that had become ill and died in Virginia on October 2. Both birds tested positive for EEE. The flock of emus associated with this case reside in Bloxom, Virginia. The sick birds did not spend time in Delaware. The flock owner in Virginia heard that the University of Delaware's Georgetown Laboratory had a pathologist who could diagnose the mortality they had been seeing over the past month. The pathologist traveled to Bloxom to diagnose and do the necropsies in Virginia. The brains were brought back to the Delaware Department of Agriculture. DPHL was contacted about the possibility of running EEE and WNV tests. EEE was the suspected clinical diagnosis. Virginia does not have a lab on the shore; the closest lab is located in Richmond, Virginia. DPHL assisted by performing these tests. EEE is considered a select agent by the Centers for Disease Control and the samples were destroyed.

In November, 2017, DPHL received an isolate for rule-out testing from a local hospital on November 6, 2017. A 24-year-old female had been bitten on the hand by a stray cat and was started on rabies vaccinations while in the emergency room. The patient returned to the emergency room several days later and noted that the stray cat had died and the bite wound had become infected. The wound was cultured and drained. The culture grew slow-growing colonies that were suspicious for *Francisella tularensis*. The culture was transported to DPHL for rule-out and confirmatory testing. Real-time polymerase chain reaction was completed by the end of the day, and it was positive for "tularemia or rabbit fever" (*Francisella tularensis),* which can be found in ground squirrels or rabbits. It is highly virulent and can cause an ulceroglandular infection on the skin or if inhaled, can cause a pneumonic disease which can be lethal without treatment. *F.tularensis is* considered a select agent and only registered laboratories can maintain possession of select agents. The samples and isolates were reported to CDC and destroyed.

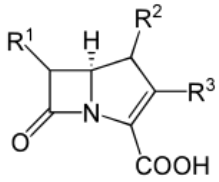
For a list of select agents, visit https://www.selectagents.gov/.

# Antimicrobial Resistance Laboratory Network (ARLN) Update

by *Debra Rutledge,* MT (ASCP), MBA, Infectious Disease Laboratory Manager II

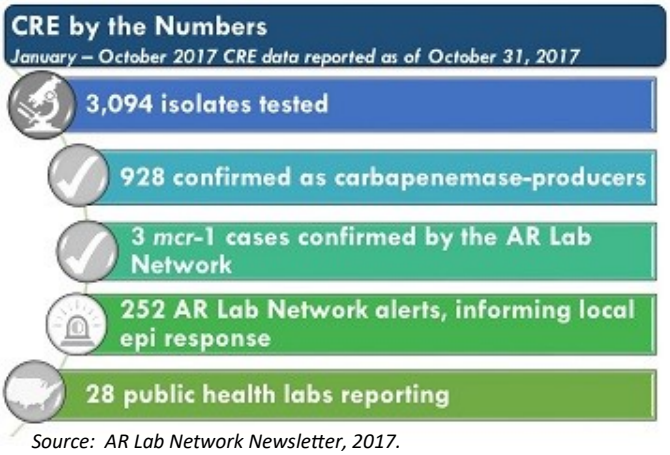
In December 2016, the Centers for Disease Control (CDC) formed the Antimicrobial Resistance Laboratory Network (ARLN) to create and support nationwide laboratory capacity to identify, notify, and provide prompt local response and containment to prevent disease spread. In 2016, the CDC established ARLN to support nationwide laboratory capacity to rapidly detect and inform local responders regarding antibiotic resistance in health care, in food, and in communities. Responders could then take appropriate measures to prevent the spread of organisms.

ARLN includes seven regional laboratories; the National Tuberculosis Molecular Surveillance Center (National TB Center); laboratories within the 50 U.S. states; and with laboratories in five cities and Puerto Rico. As a whole, laboratories in the ARLN monitor and track changes in organism resistance. This helps to rapidly identify organisms and to quickly respond to disease outbreaks, In effect, the network serves to build effective response and containment capabilities to control emerging infectious outbreaks.




In the latter part of 2016 and into 2017, laboratories received funding to add testing capabilities to detect and confirm carbapenemase-resistant organisms. This included performing whole genome sequencing on all Salmonella isolates obtained from clinical specimens.

The Maryland Department of Health and Mental Hygiene Laboratory became the regional reference laboratory in the mid-Atlantic region. Currently, ARLN laboratory staff




*Source: AR Lab Network Newsletter, 2017.*

monitor for carbapenemase-resistant organisms including *Neisseria gonorrhoeae* resistance. This year, all regional laboratories also worked on new grant initiatives that focus on susceptibility testing, particularly for Candida auris.

Candida auris is an emerging multi-drug resistant fungus first identified in the U.S. during 2013. As of January 2018, it has been identified 10 ten states with the majority of cases in New York and New Jersey. The organism is very difficult to treat once it colonizes in a person. It is also very difficult to destroy once it takes up residence in hospital rooms and objects.

Since this organism was found, the New York, Wadsworth Center, collected specimens from the first human cases of *C.auris* and used these to develop a Real Time Polymerase Chain Reaction (RT-PCR) method for use as a confirmation test.

**Figure 1. Confirmed cases of C. auris, U.S., January 2018**

| State | Number of Clinical cases reported | |
|---|---|---|
| | **Confirmed** | **Probable** |
| California | 1 | 0 |
| Connecticut | 1 | 0 |
| Florida | 2 | 0 |
| Illinois | 19 | 2 |
| Indiana | 1 | 0 |
| Maryland | 2 | 0 |
| Massachusetts | 7 | 0 |
| New Jersey | 52 | 22 |
| New York | 129 | 4 |
| Oklahoma | 1 | 0 |
| TOTAL | 215 | 28 |

*Source: Centers for Disease Control and Prevention*

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It is concerning that tests commonly used in diagnostic laboratories may not be fully able to identify C. auris. Five of seven cases tested were either misidentified or identified to genus level (Candida) rather than to species level (C. auris). The CDC recommends that all Candida isolates obtained from any sterile source (e.g., blood-stream, cerebrospinal fluid) be identified to the species level so that prompt treatment can be initiated based on species susceptibility patterns.

C. auris can be misidentified by a number of commercial systems (see chart below). Laboratories can send suspect yeast isolates that cannot be ruled out as C. auris to the regional laboratories. In Delaware, contact Debra

**Figure 2. Common misidentifications based on the identification method used**

| Identification Method | Organism C. auris can be misidentified as |
|---|---|
| Vitek 2 YST | Candida haemulonii<br>Candida duobushaemulonii |
| API 20C | Rhodotorula glutinis (red color not present)<br>Candida sake |
| BD Phoenix yeast identification system | Candida haemulonii<br>Candida catenulata |
| Microscan | Candida famata<br>Candida guilliermondii*<br>Candida lusitaniae*<br>Candida parapsilosis* |

*Source: Centers for Disease Control and Prevention*

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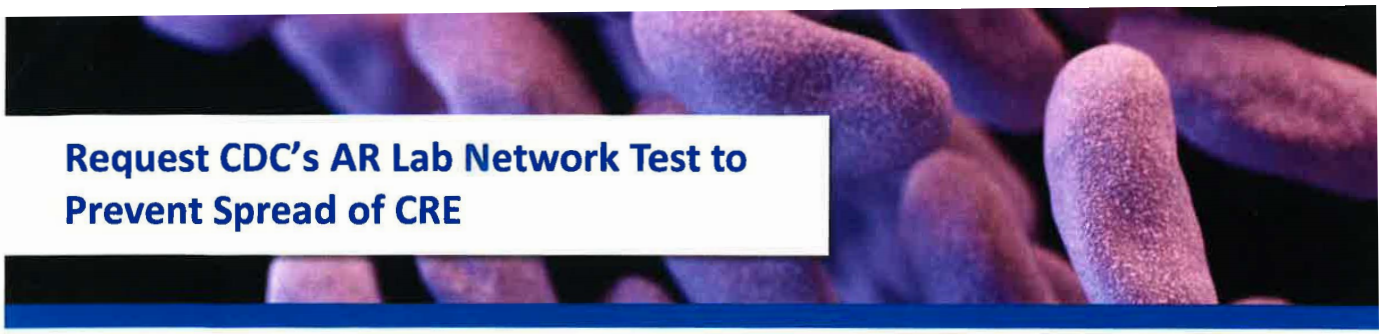
AR Laboratory Network Newsletter, September 2017: http://www.magnetmail.net/actions/email_web_version.cfm?ep=yycKLGVkKKVI2GNAMAAqt5wwBjeUKo5MnppKwpJbeMXvdohxcQS9TFBXWet91gXMzlYXNnSL7hXF2kbQUlMiRpkm5Kjyb8pd0xLDC644GEWwlQhqC57K5KsQOxJYQqY2

AR Laboratory Network Newsletter, November 2017: http://www.magnetmail.net/actions/email_web_version.cfm?ep=iEwlDpaFeO4qFEP_NyJSzutSo7bouTMCMytU9i3fFSKs2jDDhntOUydWINuYl0OJXdU2i5SYxFCpNRLf2M_kmV9K0Rs8ZjEx39QUjLjH9Y7ow2dCFpES2u2uqHJTlta

CDC website: https://www.cdc.gov/fungal/diseases/candidiasis/recommendations.html
https://www.cdc.gov/fungal/diseases/candidiasis/tracking-c-auris.html



# Request CDC's AR Lab Network Test to Prevent Spread of CRE

## CRE Colonization Screening can stop "nightmare bacteria" from spreading.

Carbapenem-resistant Enterobacteriaceae (CRE) are a serious threat to public health. Infections with CRE are difficult, and in some cases impossible, to treat. Because patients move throughout the healthcare system, CRE in one facility can spread to other facilities in the region. CDC's new CRE Colonization Screening, offered through the AR Lab Network, detects gastrointestinal colonization with carbapenemase-producing CRE and other important healthcare threats, like *Pseudomonas* and *Acinetobacter*. Screening is a CDC-recommended intervention that can help stop the spread of CRE.

**1. Alert your HAI Coordinator and request CRE Colonization Screening.**
Laboratories and facilities should immediately contact their clinical and infection prevention staff to ensure timely implementation of control measures.

**Find your HAI Coordinator:** www.cdc.gov/hai/state-based

**Find CDC's CRE guidance:** https://www.cdc.gov/hai/pdfs/cre/CRE-guidance-508.pdf

**2. Send CRE swabs to your regional lab.**
Your HAI Coordinator will help connect you to your CDC AR Lab Network regional lab who will conduct CRE colonization testing and send results to your facility, your HAI coordinator, and the state public health laboratory within two days.

**3. Implement infection control.**
Adjust infection control measures based on test results. Follow procedures in the CRE Control and Prevention Toolkit.

**CRE Colonization Screenings:**

- Uncover hidden reservoirs of CRE
- Are performed after a confirmed infection
- Detect the bug among epi-linked patients, high-risk contacts, and people who recently received healthcare outside of the U.S.

CDC's AR Lab Network can also test:

- Drug-resistant *Candida*, like *C. auris*
- *Pseudomonas aeruginosa* (CRPA)
- Emerging threats, like *mcr* (plasmid-mediated colistin resistance)
- *Clostridium difficile*
- *Mycobacterium tuberculosis*
- Drug-resistant *Neisseria gonorrhoeae*

☑ **Shipping and testing are free**
☑ **Results in 2 days or less**

**YOUR STATE & REGIONAL LAB WORK TO:**
DETECT RESISTANT SPECIES & NEW THREATS | PERFORM SUSCEPTIBILTY TESTING TO TRACK RESISTANCE | HELP RESPOND TO OUTBREAKS


## About CDC's AR Lab Network

The AR Lab Network can rapidly detect antibiotic resistance in healthcare, food, and the community, and inform local responses to prevent spread and protect people. The AR Lab Network supports lab capacity in 56 state and local labs, including 7 regional labs and the National TB Center. The regional labs provide core testing, including *Candida* testing and CRE colonization testing, for states in their region. Some perform additional screening for *Streptococcus pneumoniae, Neisseria gonorrhoeae,* and *Clostridium difficile.*

**www.cdc.gov/DrugResistance/Solutions-Initiative/AR-Lab-Networks**

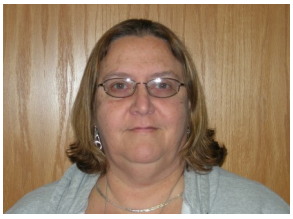
ARLABnetwork

CDC

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

# Employee News

## Congratulations, Nancy!



**Nancy Valeski.** Join DPHL in congratulating Nancy Valeski on her promotion to Microbiologist III with the Clinical Microbiology Section. Nancy graduated from the University of Delaware with a B.S. in Health Sciences (Medical Technology). Since then, she has furthered her education, taking classes for fun (quilting and Chinese cooking), and earned a certificate in molecular diagnostics. Nancy likes to spend her free time going out with her friends from work and attending concerts.

## Congratulations, Pat!

**Pat Selg**. DPHL would like to congratulate Pat Selg on her promotion to Senior Accountant. Pat has been with DPHL since 2007. She started as an operations specialist and then moved into the Administrative Specialist III position. Throughout her time at DPHL, Pat has demonstrated exceptional customer service and has provided assistance to the previous senior accountant. The experience gained in that role provided her the background with which to qualify for the senior accountant. Her previous knowledge has helped her transition into this new position. Join us in congratulating Pat on her promotion.

## Welcome, Becca!

**Rebecca Savage.** We welcome Rebecca Savage as our new Microbiologist II with the Molecular Virology Section. Rebecca is working on her Master's degree at the University of Delaware and received her bachelor's degree in pre-veterinary medicine at UD. Becca spends her free time powerlifting, eating, napping, cuddling with her two cats, and going to concerts with friends.

## Welcome/Congratulations, Jerry!

**Jerry Clark.** Join us in welcoming Jerry Clark to DPHL and congratulating him on his promotion to Administrative Specialist III. He started with the lab this past November as an Operations Support Specialist and within this short time he was promoted to his new position. Jerry comes from an extensive background in educational publishing, customer service, and administrative support. He enjoys traveling, cooking, outdoor music festivals, and spending time with family. Jerry is a recreational Texas Hold'em player and has self-published two books on the subject.

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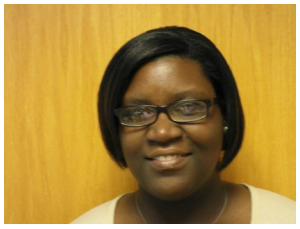
# Employee News *(continued)*

## Congratulations, Ria!

**Ria Allman.** DPHL congratulates Ria Allman in her new position as a Microbiologist III in the Molecular Virology section. She has worked at DPHL since November 2015 and took on the new position in November 2017. She has baby-crested geckos.

## Congratulations, Nikia!

**Nikia Green.** Congratulations to Nikia Green! She recently accepted a position as a Microbiologist II within the Environmental Laboratory. Nikia has worked in the Environmental Laboratory as a Laboratory Technician III since August 2015. She has performed chemical testing such as Routine Metals, Mercury, pH, Anions, Turbidity, and Alkalinity analysis on drinking water samples. She also performs bacteriological testing on drinking water samples. In her new position, she will take over responsibilities in the Media Prep and Washroom and also start learning other chemical testing methods in the near future.



## Welcome, Paul!

**Paul Browning** recently moved from Harrisonburg, Virginia where he worked as a quality manager for an organic chicken company. Although he enjoyed the challenge of working as a quality manager, his true passion is working in a laboratory as a microbiologist. The interest started when he worked at New Mexico State University under a Food and Drug Administration (FDA) contract validating new methods for the detection of pathogens such as *E. coli* O157:H7, *Salmonella*, *Listeria,* and other organisms. Paul also tried his hand at working as a manager of a food testing lab for a major laboratory and built a new laboratory in Fresno, California. However, he soon decided that he wanted to return to his real passion: working as a microbiologist. He returned to New Mexico State University and worked there until the FDA grant was completed. Paul is very excited about working with the team at DPHL. He looks forward to broadening his horizons and continuing work as a molecular biologist. Paul enjoys being outdoors, rock hounding, and surf fishing.

## Welcome, Nick!

**Nick Rapp.** A Dover native, Nick currently works as a contract microbiologist in the Virology Department, where he runs nucleic acid extractions, polymerase chain reactions, and rabies testing. He received his B.S. in Biology from Dickinson College in Carlisle, Pennsylvania in 2013 and was hired at DPHL after graduating. In his free time Nick enjoys running, skiing, weight lifting, cooking, and traveling. In the fall, Nick will be starting medical school with a special interest in emergency medicine.