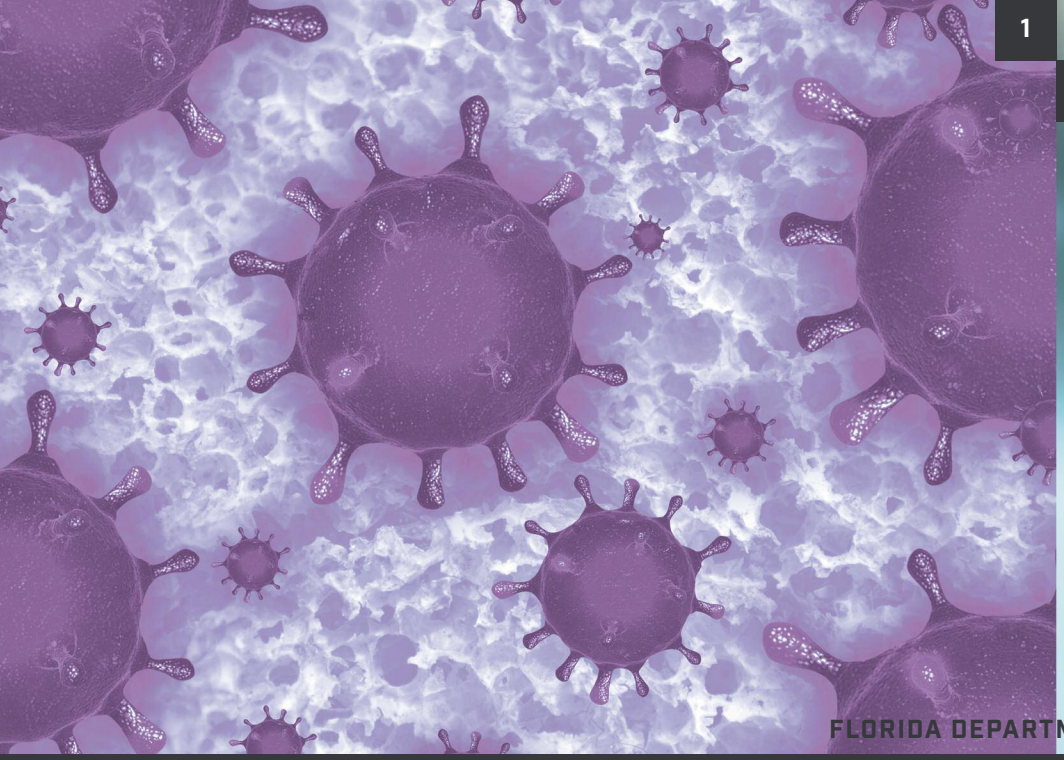

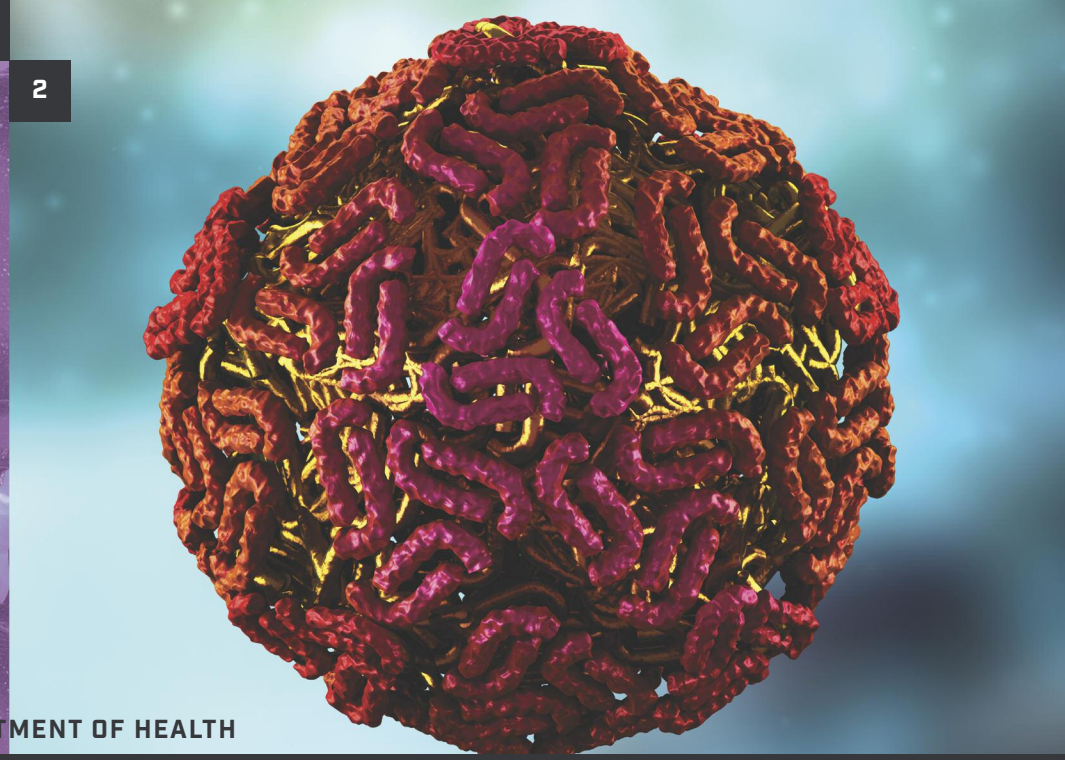

FLORIDA DEPARTMENT OF HEALTH

BUREAU OF PUBLIC HEALTH LABORATORIES

2014 ANNUAL REPORT

1. MERS 2. Chikungunya 3. Ebola 4. Influenza

Florida HEALTH

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Thanks to the *BPHL Annual Report* committee for their work on the 2014 report: Dr. Carina Blackmore, Dr. Andy Cannons, Mary Cook, Susanne Crowe, Jerry Donham, Dr. Rick France, Dr. Leah Gillis, Donna Hurr and Dr. Marie-Claire Rowlinson. Thanks to the Florida Department of Health's Office of Communications and Georgia Murphy for design and graphics.

The Bureau of Public Health Laboratories (BPHL) supports public health activities through testing of clinical and environmental samples of public health importance. Our work complements and augments laboratory services available in the private sector. All testing at BPHL is performed in close partnership with laboratorians at hospitals, universities and specialized diagnostic and environmental laboratories as well as health care providers and epidemiologists in Florida's health care system and in the state and local health departments. Public health laboratorians must be skilled and willing to learn about new tests and new technology to ensure they are ready to take on both ancient public health threats and new and emerging diseases. These important traits were highlighted in 2014, which was a year of emerging viruses in Florida.

It started with our laboratory staff diagnosing the second case of Middle Eastern Respiratory Syndrome (MERS) in the United States in a traveler from Saudi Arabia in May. Simultaneously, laboratory staff performed testing that confirmed Florida's first case of chikungunya virus in a patient who had traveled to the Caribbean. Not long after this, BPHL confirmed the first case of chikungunya virus acquired in the United States. Before the year was over BPHL staff had performed testing on most of the 508 travel-associated chikungunya cases and 12 local cases detected in the state in 2014. Later in the summer we were notified about serious illnesses associated with a relatively rare enterovirus, enterovirus D68 (EV-D68) that was causing respiratory outbreaks in the Midwest. While EV-D68 is not a new virus, until last year it had not been considered a significant health concern and few private clinical laboratories were capable of distinguishing EV-D68 from other enteroviruses. The BPHL was the only laboratory in Florida that could test for this particular strain of enterovirus during the early phases of the 2014 outbreak. In the fall we were faced with the ultimate test of emerging virus readiness, Ebola. As the tragic Ebola virus disease outbreak unfolded in West Africa, the United States responded by providing support to the affected countries whilst also preparing for the possibility of cases at home. As with MERS, chikungunya and EV-D68, a new test had to be developed, laboratorians had to learn how to perform the new test, and then implement it in their laboratories. Every step was done under strict biosafety conditions to make sure the laboratory personnel would not be at risk for contracting the virus. BPHL was one of the first laboratories in the country that gained capacity to test for Ebola and as of December 2014, all three BPHL laboratories can perform confirmatory laboratory testing for suspect disease cases. The Florida public health laboratories have also assumed a leadership role in occupational safety, and continue to consult with clinical laboratories in the state on how to safely handle suspect Ebola specimens.

Other notable events in 2014 were the implementation of critical congenital heart defect testing in newborns and the launch of our new newborn screening data management system which will help further improve our ability to provide timely, potentially lifesaving results to the health care professionals who care for them. This report describes these and other activities at the BPHL in more detail. Please take a few minutes and learn more about the work of your public health partners.

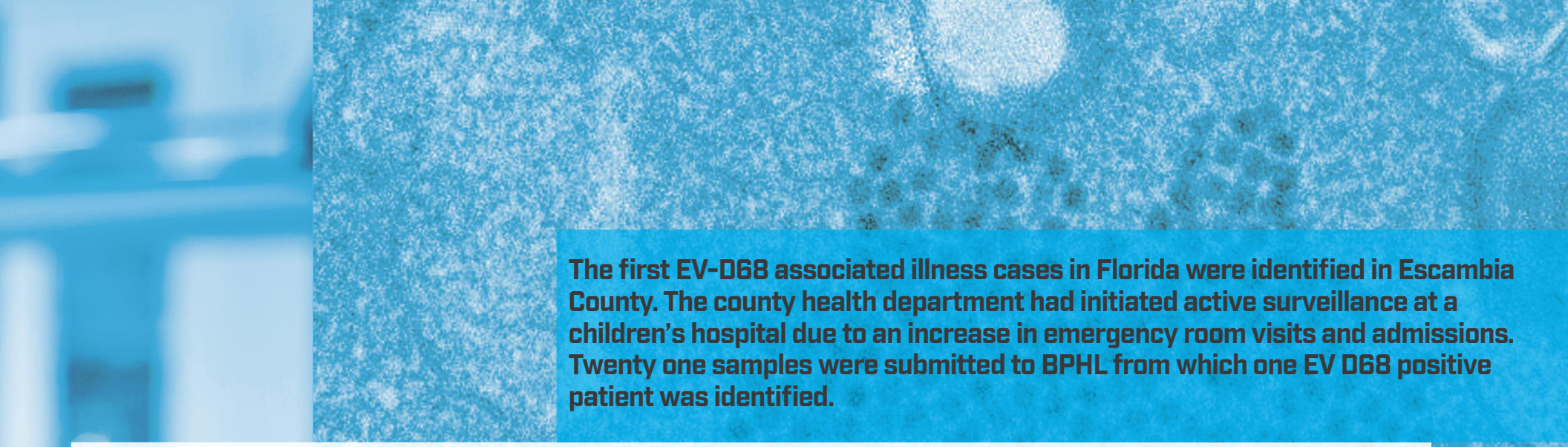
BPHL Bureau Chief and Deputy State Epidemiologist
Dr. Carina Blackmore

We are proud to contribute to a healthier Florida—one test at a time.

A Common Virus in an Uncommon Outbreak

BPHL Responds to Enterovirus D68

As summer was coming to an end in the Midwest and the temperatures were still hovering around the upper 80s to low 90s in Florida, a Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report indicated that Children's Mercy Hospital in Kansas City, Missouri had noticed an increase in patients with severe respiratory illness. Some of the patients had to be admitted to the pediatric intensive care unit. Laboratory testing detected an increase in children infected with rhinovirus or enterovirus compared to the same period in previous years. Rhinoviruses and enteroviruses cross-react in most polymerase chain reaction (PCR) assays, therefore it was unclear based on the laboratory results which virus was the etiologic agent.



The first EV-D68 associated illness cases in Florida were identified in Escambia County. The county health department had initiated active surveillance at a children's hospital due to an increase in emergency room visits and admissions. Twenty one samples were submitted to BPHL from which one EV D68 positive patient was identified.

Four days later, the CDC was again notified about an increase in the number of children with a similar, severe respiratory illness by University of Chicago Medicine Comer Children's Hospital in Illinois. The CDC Picornavirus Laboratory tested nasopharyngeal specimens from most of these patients and enterovirus D68 (EV-D68) was identified in 19 of 22 specimens from Kansas City and in 11 of 14 specimens from Chicago.

Human enteroviruses (EV) are the causative agents of some of the most common viral infections. Poliovirus is one of the well-known species in this genus of over 100 viruses and EV are the leading cause of non-bacterial meningitis in the U.S. They are named by their species letter (A, B, C, or D) and serotype number, such as enterovirus D68 or EV D68.

Infection with EV D68 is generally mild with symptoms of a runny nose, sneezing, cough, and body and muscle aches; but it has the potential to exacerbate with symptoms of wheezing and difficulty breathing. It is believed that the virus spreads from person to person through droplets released by coughs and sneezes, or by touching contaminated surfaces. The virus was first recognized in California in 1962. Typically a small number of infections are detected every year during the enterovirus season, which occurs in the summer and fall. Both the number of reported cases and severity of EV D68 associated disease were above the norm in 2014 nationwide. Most of the cases were in children who had asthma or a history of wheezing. The CDC and state public health laboratories confirmed over 1,100 infections by mid-January 2015. There were 14 reports of deaths associated with 2014 EV D68 outbreak, two of which were officially reported as caused by the virus.

Both hospital and commercial laboratories have the capability to test for enteroviruses but are not able to perform the serotyping. The BPHL has been testing for enteroviruses for many years. Both Jacksonville and Tampa BPHL have a general pan-enterovirus test that uses a real-time reverse transcriptase polymerase chain reaction (rRT-PCR) assay. They are also able to detect some of the more common types of enteroviruses by testing with specific fluorescent antibody stains. In 2003, the Tampa laboratory implemented genetic sequencing of enteroviruses to replace the tedious serum neutralization assay. Genetic sequencing allows the laboratory to identify the virus down to the serotype level which is important for identifying outbreaks. Although the genetic sequencing assay was an improvement over the previous neutralization assay, it was still a lengthy test that required growth of the virus in cell culture and subsequent sequencing steps over several days. At the start of the 2014 EV D68 outbreak, the Tampa laboratory quickly validated and implemented an improved genetic sequencing assay developed by the CDC that does not require growth of the virus in cell culture which shortens the turnaround time of results by 1–2 weeks. Furthermore, this assay can detect the virus directly from patient specimens which also helps shorten the testing procedure and improves turnaround time. By October 2014, the CDC also released a protocol for an rRT-PCR assay specific for EV D68 which was immediately implemented in BPHL Jacksonville and Tampa.

The first EV-D68 associated illness cases in Florida were identified in Escambia County. The county health department had initiated active surveillance at a children's hospital due to an increase in emergency room visits and admissions. Twenty one samples were submitted to BPHL from which one EV D68 positive patient was identified.

Because of the outbreak, the laboratories retrospectively tested recent respiratory virus surveillance specimens that had been pan-enterovirus rRT-PCR positive with unidentified serotype due to no growth of the virus in cell culture and found EV D68 positives dating back to October 2013. It is unknown at this time why EV D68 infections increased in 2014, but the CDC has indicated it was not a new strain that contributed to the increase. Enteroviruses circulate every year and it is unpredictable which will be the more common type circulating each season. However, with new testing methods in place it is nice to know that the BPHL is ready for the coming enterovirus seasons ahead.

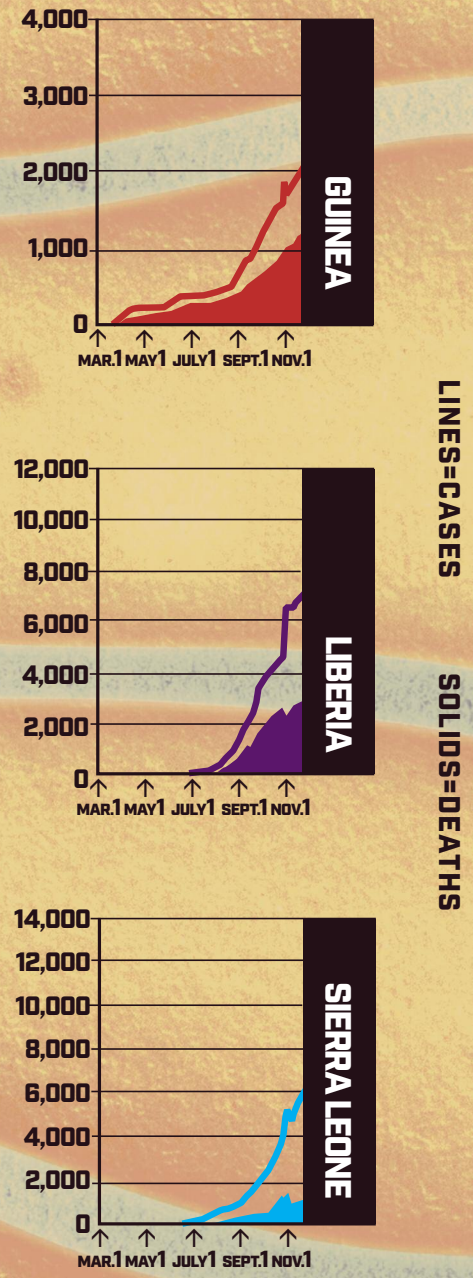
The Ebola virus disease (EVD) outbreak began in March of 2014, and devastated the countries of Guinea, Liberia, and Sierra Leone.

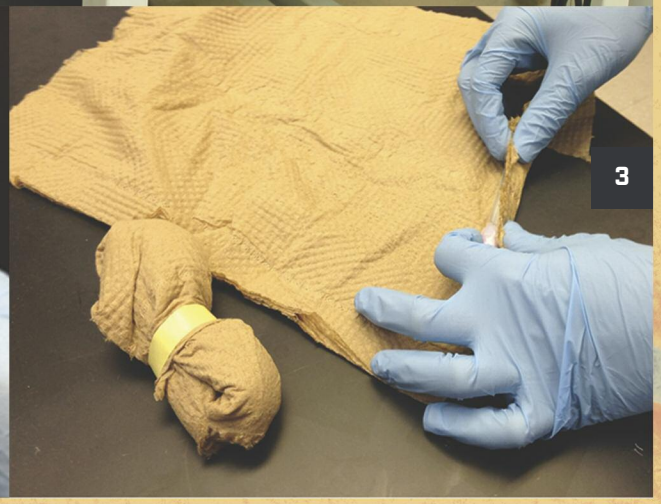
This outbreak, with a mortality rate of 41%, has seen 27,237 cases as of December 2014. The rapid spread of this outbreak, coupled with the high number of airline flights from affected areas to the United States, prompted a public health response from the Centers for Disease Control and Prevention (CDC) part of which was pushing out a rapid test for the Ebola virus to thirteen state public health laboratories. One of these thirteen public health laboratories was the BPHL-Miami laboratory which received approval and materials to perform this test in September 2014.

The introduction of testing for Ebola virus presented several logistical problems for the BPHL-Miami laboratory. The preparedness staff developed updates to their biosafety and incident response plans to accommodate testing for the virus. This included additional personal protective equipment (PPE), above and beyond the standard biosafety level 3 PPE and ensuring two qualified staff members were present during manipulation of all specimens. Also, staff focused on the new chemical used in the assay, as combining this chemical (Trizol) with the standard waste, which contained bleach, would result in the production of toxic fumes. Other BPHL laboratories were prepped in December of 2014 (BPHL-Jacksonville and BPHL-Tampa) and the Miami laboratory provided their experience to expedite facility readiness.

The BPHL assisted with Florida's overall EVD response when the state activated the EVD incident Management Team (IMT) in early October. The IMT focused on identification, testing, and containment. The IMT identified several weaknesses in the testing component, specifically pre-testing or shipping supply availability and appropriate packaging and shipping training for hospital and county health department staff. The BPHL, with the BPHL-Miami laboratory director acting as head of laboratory operations, assisted with these deficiencies by first identifying the critical supplies needed for the proper shipment of specimens. A procedure for shipment, including identifying appropriate courier mechanisms was developed by BPHL and distributed to hospital laboratories. The IMT also, in conjunction with BPHL, distributed shipping supplies to 59 county health departments. The BPHL-Miami then developed a refresher seminar to ensure that the target staff at the appropriate healthcare providers would be prepared in the event of a suspect EVD person under investigation. These seminars began in November and continued into 2015 to ensure adequate training.

The streamlined workflow developed by BPHL-Miami, including sample collection and testing, bolstered the state of Florida's response to the EVD public health threat. With the coordinated efforts of BPHL staff and the IMT, BPHL-Miami was able to begin testing just two weeks after the CDC request in August 2014. By November, the IMT had distributed the necessary supplies and training had begun across the state. This rapid development and deployment serves as a model for public health laboratories in combating future public health threats.





1: Dr. Leah Gillis (left), laboratory director, and Dr. Aaron Monroy, BT coordinator, review test results in the BPHL-Miami Molecular Laboratory.
Photo: Bob Sullivan

2 and 3: Demonstration pictures for wrapping and shipping suspect Ebola specimens to the testing laboratory used as part of the training sessions.
Photo: Bob Sullivan

BPHL Works Around the Clock for **Accurate MERS Diagnosis**

Middle East Respiratory Syndrome (MERS)—a viral respiratory illness that is new to humans and was first reported in Saudi Arabia in 2012—has caused severe illness and even death in people from several countries. The virus spread globally, and reached the U. S. on May 2, 2014. During the two years between initial identification of MERS and its arrival in the U.S., federal, state and local health departments worked tirelessly to ensure the illness could be quickly detected, diagnosed, treated and contained. Diagnostic capabilities within our public health laboratories were essential to these preparations.

6/5/2013

On June 5, 2013, the Food and Drug Administration (FDA) authorized emergency use of a CDC test for MERS in clinical respiratory, blood, and stool specimens. The BPHL was among the first state public health labs to receive this test. Over the next nine months the laboratory tested specimens for seven cases that met the MERS case criteria. Information technology staff also updated the lab's Laboratory Information Management System (LIMS) to ensure accurate results were reported to CDC. LIMS was established using Public Health Emergency Preparedness (PHEP) cooperative agreement funds and enables secure reporting of results regarding biological threats.

5/9/2014

A week after the first MERS case in the U.S. was diagnosed, the Florida State Investigations Unit Manager and Epidemiologist alerted BPHL-Tampa that there was an Orlando hospital patient suspected of having MERS. The patient's blood and respiratory swab samples arrived at the Tampa lab at 5:00 pm on Friday, May 9. By 9:00 pm the same day the samples arrived, the initial testing was complete. The lab used a method that looks for two genetic targets in the virus. This testing method detected one of these targets in the blood sample. Testing for detection of a third target is required to confirm presence of the virus. The third target tested negative, which CDC calls an equivocal (i.e., unclear), result. The BPHL Tampa Laboratory Director called CDC's Emergency Operations Center at 11:30 pm to discuss the case with the subject matter experts (SMEs) on duty. CDC staff advised to try and get a sputum sample for further testing and this request was forwarded on to the on-call epidemiologist at midnight the same day. At 3:00 pm on Saturday, May 10, the sputum sample arrived to the Tampa lab. By 9:00 pm, testing was complete and the sample was positive for all three genetic targets. At 11:30 pm, the laboratory consulted with the SMEs at CDC, who agreed that the U.S. was likely facing its second confirmed case of MERS.

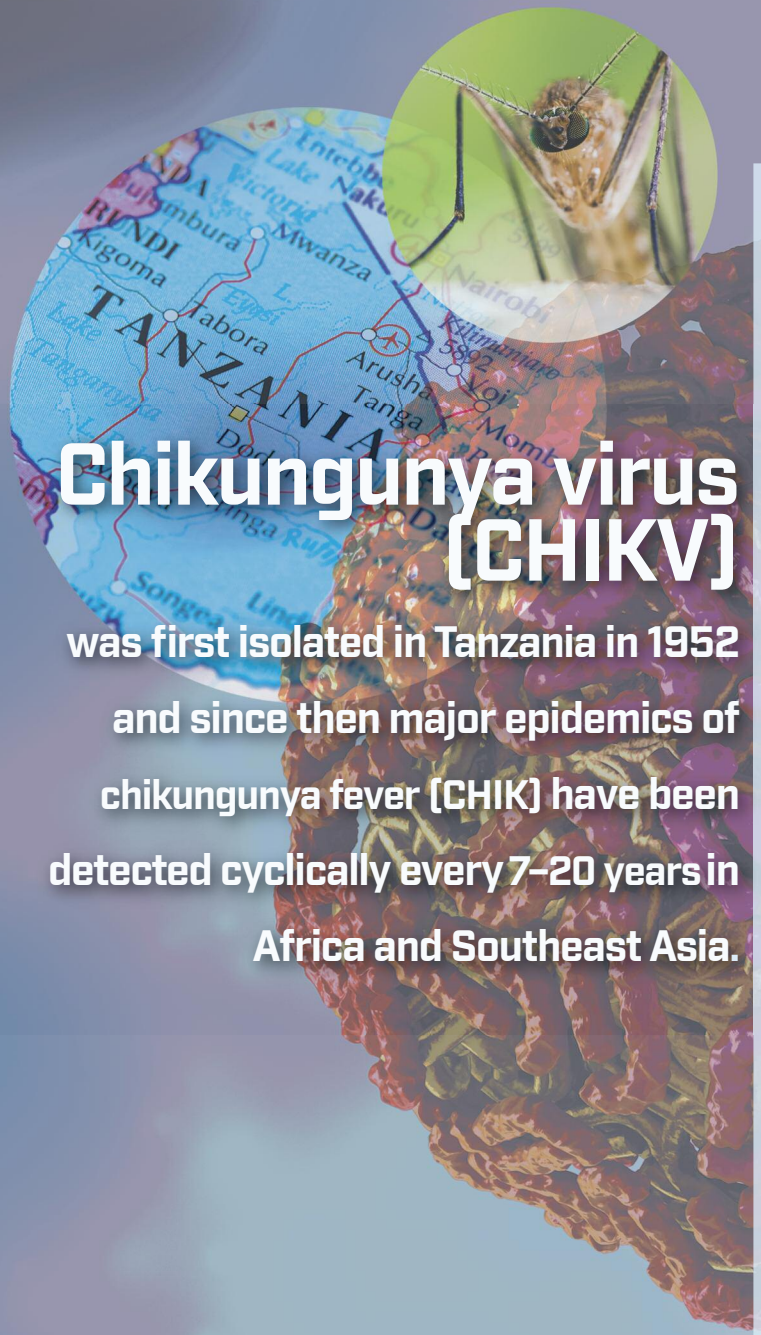
5/11/2014

CDC requires diagnostic confirmation by its own labs on samples that test positive. On Sunday, May 11 at 1:00 pm, a courier picked up the sample from BPHL-Tampa. The sample was securely flown to Atlanta and was delivered to CDC at 7:30 pm that evening. By 10:45 pm CDC lab staff confirmed that the sample was positive for MERS.

5/12/2014

Advanced preparations by the public health lab in Tampa ensured that when called upon, it was ready to respond. On Monday May, 12, after demonstrating success in diagnosing MERS, the lab received about 25 sample swabs from close contacts of the Orlando hospital patient. Samples from other people exposed to the patient confirmed to have MERS were sent to the lab for testing. Also, as news of the diagnosis spread through the community the Tampa lab experienced an increase in samples they received for testing. All patients symptomatic with respiratory illness, and meeting the case definition, were tested to rule out MERS. The few weeks following the confirmation of MERS in Florida, BPHL-Tampa lab tested over 130 samples for MERS.

The MERS event required well trained staff, testing agents, and adequate testing equipment. The PHEP cooperative agreement is instrumental in ensuring a successful response infrastructure is in place to afford public health laboratories the ability to accommodate sudden increases in testing for both established and novel emerging threats.



Chikungunya virus (CHIKV)

was first isolated in Tanzania in 1952 and since then major epidemics of chikungunya fever (CHIK) have been detected cyclically every 7–20 years in Africa and Southeast Asia.

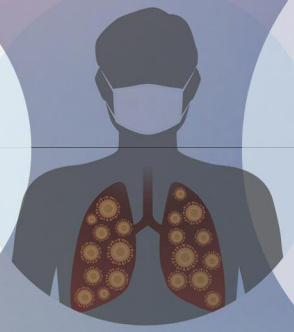
The virus generated additional interest among public health officials in 2004 when a large outbreak, which started in Kenya, rapidly spread to countries in the Indian Ocean region and India. The outbreak had significant social and economic impact in both impoverished and economically developed areas and over the following three years more than 1,000 American and European travelers to the region were diagnosed with the disease upon their return home. Another wave of CHIK outbreaks started in the Republic of Congo in 2011. As before outbreaks were recorded throughout Africa, Southeast Asia and the Pacific. In December 2013 virus transmission was also documented on the Caribbean Island of St. Martin. This was the first documented evidence of autochthonous CHIKV transmission in the Americas. The outbreak has spread to 44 other countries throughout the Caribbean, Central and South America. In 2014 more than 1.3 million suspected or confirmed cases were reported from the Americas.

The principal vectors *Aedes aegypti* (the house mosquito) and *Aedes albopictus* (the Asian tiger mosquito) are common in the subtropics. Both mosquito species are found in Florida. *Aedes albopictus* breeds throughout the state while *Aedes aegypti* is more common in urban environments in the southern part of Florida as well as in the Florida Keys. Chikungunya virus is transmitted back and forth between mosquitoes and people. This is a different transmission cycle than that seen for other arboviruses currently endemic to Florida (eastern equine encephalitis virus, St. Louis encephalitis virus and West Nile virus). These endemic viruses are maintained in nature by *Culex* species mosquitoes; birds, humans and other mammals such as horses, serve as incidental hosts.

Chikungunya fever presents as a non-specific flu-like illness and patients with an abrupt onset of fever, typically greater than 102 F, and severe joint pain. The joint pain is typically symmetric affecting joints in both legs. The pain can be intense and debilitating, most often affecting joints of the extremities (ankles, wrists, hands and feet). Other symptoms may include headache, back pain, muscle pain, arthritis, a maculopapular rash, nausea/ vomiting and conjunctivitis. The incubation period is short, typically between 3–7 days (range 1–12 days). Symptoms generally resolve after about a week. Migratory, erratic, relapsing joint pain most often in the small joints of the hands, wrists, ankles and feet can be seen among adults and infrequently among children. Mortality has been observed, primarily among older adults. Treatment is symptomatic and includes rest, fluids and non-steroidal anti-inflammatory drugs.

Upon confirmation of the first CHIK cases in St Martin, the BPHL immediately requested and received primers from CDC to set up Real-Time RT-PCR testing. Serology testing for chikungunya (IgM and IgG ELISA) was implemented in March, 2014. As is often the case with emerging viruses, the BPHL was the first clinical laboratory in Florida to offer chikungunya testing as it was not available in commercial laboratories at the time. The first Florida CHIK case with travel to the Caribbean was diagnosed in May 2014. Subsequently Department epidemiology and BPHL staff identified another 507 travel-associated and 12 locally acquired CHIK cases in 2014. The BPHL test load was significant. Our Jacksonville and Tampa virology teams performed a total of 1,600 tests for CHIKV or CHIKV antibodies last year. In addition, since CHIK and dengue present with similar clinical signs, the two viruses share the same mosquito vector and can sometimes cause co-infections, most samples submitted for CHIK testing were also analyzed for dengue. In 2014, the work of Department epidemiologists and laboratory staff resulted in 83 reports of travel-associated dengue, three locally acquired cases and 20 co-infections of CHIK and dengue.

FLORIDA BPHL



January

Cuban Oysters

The BPHL identified *Vibrio cholerae* 01 serotype Ogawa in a sample submitted by a Miami-Dade hospital from a 49-year-old patient. The county epidemiologists determined that the patient likely acquired the infection from eating raw oysters while traveling in Cuba. There has been an outbreak of cholera in Cuba since July, 2012, the first since well before the 1959 revolution.

February

Rocky (Raccoon) vs. Tony (Tiger)

The BPHL identified rabies in a raccoon that was found pestering a tiger at the Big Cat Rescue at Citrus Park. This is the second positive raccoon found in this area prompting DOH-Hillsborough Country to release a rabies alert for the area.

March

Arsenic Poisoning?

The Pinellas County Sherriff's office was working on a case involving a victim of arsenic poisoning and inquired about the BPHL's capability to test for arsenic in juice. The BPHL Chemistry Department performed the testing and analysis revealed the juice and milk samples did not contain higher than normal arsenic levels.

April

Laboratory Exposure

The BPHL Biological Threat (BT) Laboratory identified *Brucella* in an isolate submitted from a clinical laboratory. Following a biosafety risk assessment it was determined that several laboratorians were exposed while working on the open bench. Medical evaluation was provided and exposed individuals were offered post-exposure prophylaxis and serological monitoring.

May

Ready to Respond

The BPHL received specimens from a suspected Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV) case in Orange County. Within 48 hours of when the specimens were received the results were identified as positive and confirmed by the CDC. This was the second confirmed imported case of MERS-CoV infection in the United States.

June

Exercise for Preparedness

The BPHL BT coordinators participated in a U.S. Postal Service full-scale exercise for their Biohazard Detection System (BDS). A simulated BDS alarm indicated the detection of *Bacillus anthracis* in the mail processing and distribution center. Exercise participants included the FBI, Jacksonville Sheriff's Office, Jacksonville Fire and Rescue Department Hazardous Materials teams, and the Florida Department of Health Duval.

2014 TIMELINE

July

Emerging Infectious Disease

Locally-acquired chikungunya infections were detected in a Palm Beach County resident and also a St Lucie County resident. As part of disease surveillance, eight Palm Beach County residents, who lived in proximity to the chikungunya infected individual, were tested and all were negative.

August

Malaria in Travelers

The BPHL identified *Plasmodium falciparum* from a patient who was hospitalized in Clay County and had history of travel to Senegal. The patient was a pilot. *Plasmodium falciparum* is the parasite that causes malaria and is transmitted by mosquitos.

Sept.

Kissing Bugs

The BPHL Microbiology Laboratory forwarded a serum submitted from a 43-year-old female in Collier County to the CDC. The specimen was confirmed as positive for *Trypanosoma cruzi*. *T. cruzi* is the causative agent for Chagas disease. Chagas disease is caused by a protozoan parasite transmitted from "kissing bugs" and is endemic in Latin America. Chronic Chagas disease can damage the heart and central nervous system.

Oct.

Fingerprinting

Pulsed-field gel electrophoresis (PFGE) fingerprinting assay showed that two *Campylobacter jejuni* isolates had an identical pattern. This indicated that the two patient infections were most probably from a common source. This information was communicated to epidemiologists and helped them to further investigate the source.

Nov.

Rare Infant Disease

Cronobacter sakazakii was isolated from a medical examiner blood culture specimen from an infant. *Cronobactor* infections have been associated with infant formula. The laboratory and the CDC performed testing on both the powdered formula and a reconstituted sample. However, neither the BPHL nor the CDC found any *Cronobacter sakazakii* in formula samples.

December

Holiday Surprise

The BPHL performed testing on samples from a potential food contamination incident from a holiday party in Orange County. The laboratory isolated *Staphylococcus aureus* from both a patient and food sample and the fingerprint by pulse-field gel electrophoresis (PFGE) determined they were the same strain. Testing by the CDC revealed *Staphylococcus* enterotoxins in the turkey and in the green beans. Additionally, *Bacillus cereus* hemolytic enterotoxin was found in the green beans.

100-Years Celebration

MIAMI LAB

On November 12, 2014, the BPHL-Miami opened its doors to the community in celebration of 100 years of improving public health in the State of Florida.

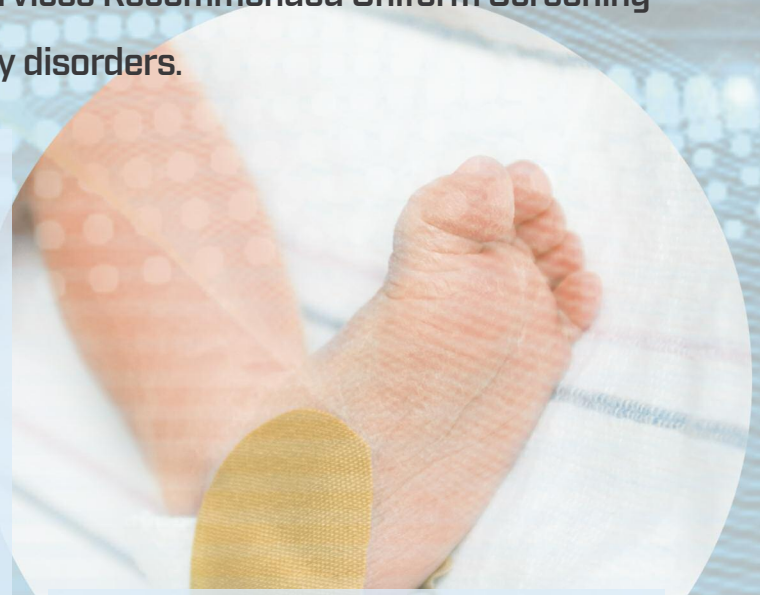
In 1914, the State Board of Health, now the Florida Department of Health, established the Public Health Laboratory in Miami. The laboratory, originally established to provide diagnostic screening to the State Board of Health and private physicians, has evolved through the years as hospital and commercial laboratories were created and disease challenges changed. In 1914, the laboratory performed rudimentary testing looking for organisms under the microscope and performing simple serology and blood tests. Today, the laboratory performs a range of complex tests using advanced instrumentation and molecular methods to detect a whole range of disease-causing organisms.

In honor of the celebration a proclamation from the Miami Dade County Office of the Mayor and Board of County Commissioners was presented declaring Wednesday, November 12, 2014 as the 100 Year Anniversary of the Bureau of Public Health Laboratories-Miami. The BPHL-Miami decided to use the 100 Year Anniversary Celebration as an opportunity for community outreach. One component in reaching out to the public was the creation of posters showcasing each BPHL-Miami test department, detailing work performed and providing informative data for sharing during the guided tours of the BPHL-Miami during the celebration. The Department in Miami-Dade County and the Department's Office of Communications became important collaborators in the planned outreach, through the organization of an on-site health fair and the provision of a web-accessible video, respectively. These important collaborations were key elements in our celebration and greatly enhanced our connection with the public.

Shinesha Chowdhury, BPHL-Miami Molecular Biologist, loading and operating autoclave.
Photo: Bob Sullivan

For more about the celebration, visit www.floridahealth.gov/newsroom/2014/11/111214-miami-lab.html; Additional Resources; Miami Laboratory: 100 Years.

The Newborn Screening (NBS) department at the BPHL performs genetic and metabolic testing for all newborns in Florida. Laboratory tests include 31 disorders recommended by the United States Department of Health and Human Services Recommended Uniform Screening Panel, and an additional 22 secondary disorders.



Florida testing is performed only at the BPHL laboratory facility in Jacksonville. Each day newborn blood specimens from hospitals, clinics, birthing centers and midwives arrive at the laboratory where they are sorted, evaluated, processed and tested. All results are reported back to the submitting offices, with Children's Medical Services (CMS) staff monitoring and coordinating the notification of hospital and clinical specialty staff to further evaluate babies identified to be at risk for genetic and metabolic disorders.

The NBS department implemented an updated Laboratory Information Management System (LIMS) through Perkin Elmer, called "Screening Center" in fall 2014. This system improves the linking of test result data and patient information from the laboratory to CMS who provides oversight for the management of clinical cases. The system update went into production in October 2014 and continues to be customized to meet the needs of the Florida NBS program.

In addition, the laboratory had two key changes in staffing in 2014. Dr. Bonita Taffe joined BPHL as acting directory for the NBS laboratory. The workflow in the data entry section at the laboratory was reorganized under an Operations Manager, Mrs. Sherry Ray. This reorganization of staffing and workflow have increased productivity and the flow of patient information (demographic data) from specimens that are received in the laboratory. The customer service side of the department has also improved, with closer relationships between NBS staff and the hospitals in the state to assure that specimens and the accompanying patient information are received in a timely manner.

In the coming year the laboratory is restructuring part of the laboratory testing space to create a molecular section as recommended by the Association of Public Health Laboratories and Centers for Disease Control and Prevention (CDC) Molecular Assessment Program. This recommendation arose from the review of the Florida NBS laboratory as reported in the *2013 BPHL Annual Report*. Planned laboratory modifications will improve specimen handling, and testing and analysis for both the (soon to be implemented) updated Severe Combined Immunodeficiency (SCID) test and the molecular Cystic Fibrosis (CF) test.

The BPHL and the NBS Program will continue to provide the best service possible and implement improvements where necessary for healthier babies in the state of Florida.

1965 The program began in Florida—required the Florida Board of Health to promote the testing of all newborns for phenylketonuria. At the time, 20% of testing was performed by hospitals and 80% was performed by the BPHL in Jacksonville and Miami.

1978 Congenital hypothyroidism, maple syrup urine disease (MSUD) and galactosemia were added to the NBS panel.

1984 The program was expanded to identify infants at risk for hearing impairment and those with birth defects.

Jan. 1985 MSUD was deleted from testing due to the lack of any detected case in 500,000 births but was added back in January 2006.

Aug. 1988 Testing for hemoglobinopathies was added.

March 1995 Identifying infants at risk for hearing impairments and birth defects was discontinued.

April 1995 Testing for congenital adrenalhyperplasia was added.

Oct. 2000 Hearing screening was mandated per Florida Statutes 383.145.

2002 The NBS Task Force was created by House Bill 817 to evaluate the program and make recommendations for improvement

Oct. 2005 Biotinidase deficiency was added to the NBS panel for a total of nine disorders.

Jan. 2006 Implementing tandem mass spectrometry added 25 new disorders to the NBS panel including amino acid disorders, organic acid disorders, and fatty acid oxidation disorders—for a total of 34 disorders including hearing.

Sept. 2007 Cystic fibrosis was added to the NBS panel. A total of 35 disorders screened.

Jan. 2009 Physicians were able to register and obtain NBS results through the Florida NBS Results website.

Jan. 2011 The Department's Genetics and Newborn Screening Advisory Council recommended adding severe combined immunodeficiency disease (SCID) to the NBS panel.

Oct. 2012 SCID was added to the NBS panel and the first baby was identified on October 29, 2012.

Dec. 2013 Critical congenital heart disease screening, using pulse oximetry testing by the hospitals or birthing centers prior to discharge, was added to the NBS panel.

Shiga-Toxin Producing E. coli (STEC)
Improved Detection Methods

Shiga-toxin producing Escherichia coli (STEC) can cause food-borne related illness. The Centers for Disease Control and Prevention (CDC) estimates that STEC bacteria are responsible for 37,000 illnesses, 1,100 hospitalizations and 30 deaths annually in the U.S.

The most common STEC that causes illness in the U.S. is *E. coli* O157:H7, but there are other kinds (or serotypes) that can also cause disease. In 2012 the U.S. Department of Agriculture (USDA) identified a further six serotypes which it deemed to be adulterants in meat (which is identified as commonly being at risk for harboring *E. coli* bacteria). These serotypes are known as the "big six" (*E. coli* O26, O45, O103, O111, O121, O145) and are sometimes referred to as "non-O157 STEC." Like O157, the "big six" STEC are known to cause foodborne illness.

The symptoms of STEC infection can vary but tend to include stomach cramps, diarrhea (sometimes bloody) and vomiting. Most infections resolve within five to seven days and are mild; however, some infections, particularly in the young, elderly and immune compromised, can be severe or even life-threatening. About 5–10% of STEC infections cause a potentially life-threatening complication called hemolytic uremic syndrome (HUS). Patients with HUS should be hospitalized due to the increased potential for damage to their kidneys or other serious outcomes, including death.

The diagnosis of STEC generally relies upon detecting shiga-toxin in stool by an antigen-detection method that is neither highly sensitive nor specific and requires additional follow-up testing for isolation and characterization of an isolated organism. The BPHL receives patient stool in broth that has tested positive for shiga-toxin by this antigen method. Prior to 2014, BPHL would then confirm this result by the same method and perform testing to isolate *E. coli* O157 organisms. However, it was determined that we may be missing some toxin-positive samples and missing outbreaks caused by non-O157 serotypes.

In 2014, BPHL implemented a new algorithm for STEC testing that improves:

a) The initial detection of STEC
b) The ability to culture an isolate from the specimen
c) The enhanced characterization of STEC isolates to determine if cases are related (outbreak detection).

The new changes in 2014 have meant that instead of using an EIA method to determine whether shiga-toxin is present in these broth specimens, now BPHL tests to detect four virulence genes that, if any or all are detected, indicate the presence of a shiga-toxin producing organism. The four virulence genes, *stx1*, *stx2*, *eae* and *ehxA*, are detected by Polymerase Chain Reaction (PCR) which detects DNA. This PCR method is a more sensitive assay than the EIA so we are able to detect STEC in more specimens.

The new STEC algorithm improves:

The **initial detection** of STEC

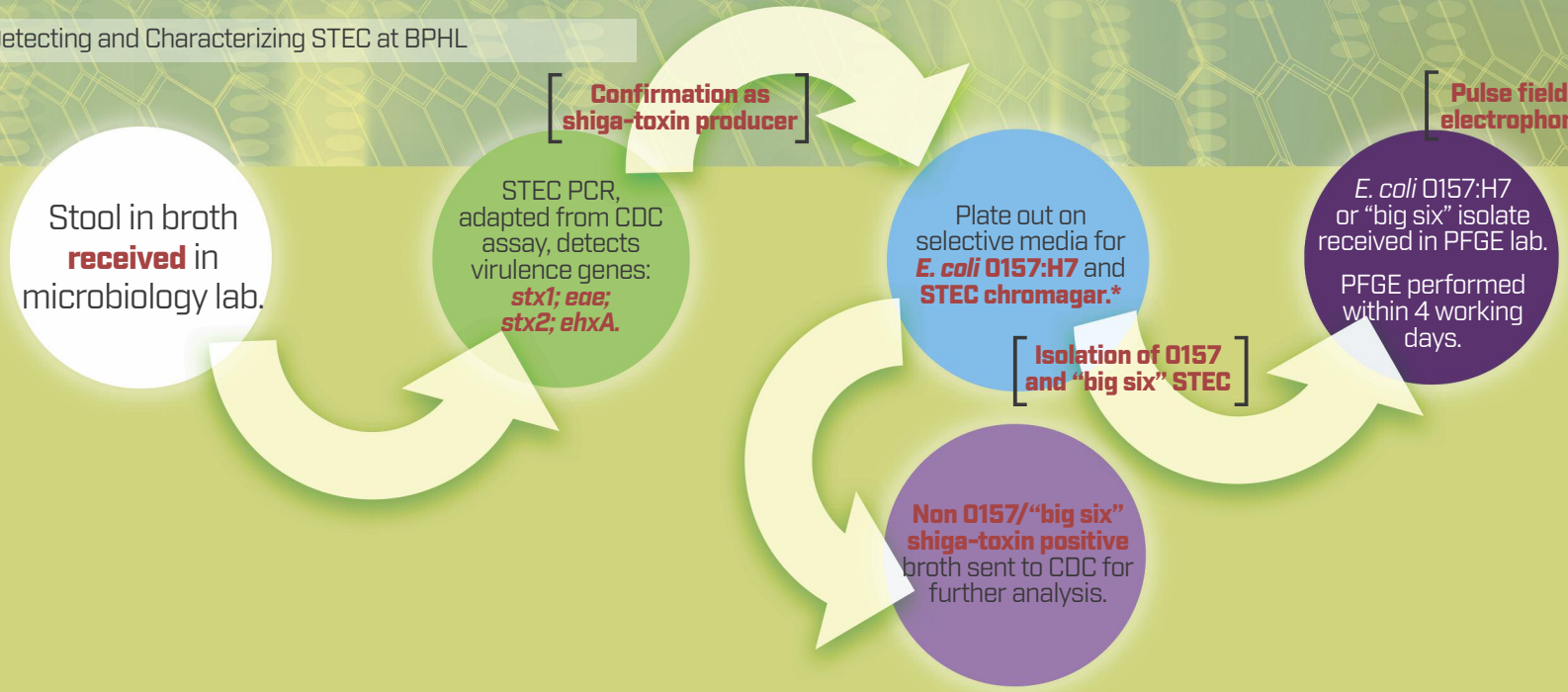
The ability to **culture an isolate from the specimen**

The **enhanced characterization of STEC isolates** to determine if cases are related—outbreak detection.

Once we have confirmation that STEC is present in the stool in broth specimens, we can plate the specimens onto selective agar media to isolate the *E. coli* organisms and determine whether they belong to the seven serotypes of greatest concern. Getting the *E. coli* organisms to grow and obtaining a culture on media is very important in confirming that STEC bacteria are indeed present in the specimen and also permits additional characterization of the isolate. We use specialized media which enables us to grow and select for STEC bacteria. If we are able to get an STEC isolate we can see if it is serotype O157:H7 or one of the "big six" serotypes (O26, O103, O45, O111, O121, and O145). After determining the serotype, we characterize the isolate even further by performing Pulsed-Field Gel Electrophoresis (PFGE). The PFGE process, which was covered in our 2013 report, is a fingerprinting method that enables us to determine whether one strain is related to another. Closely related strains are more likely to have come from the same source. This is important information for the Department's epidemiologists and food and waterborne disease experts who identify and respond to outbreaks.

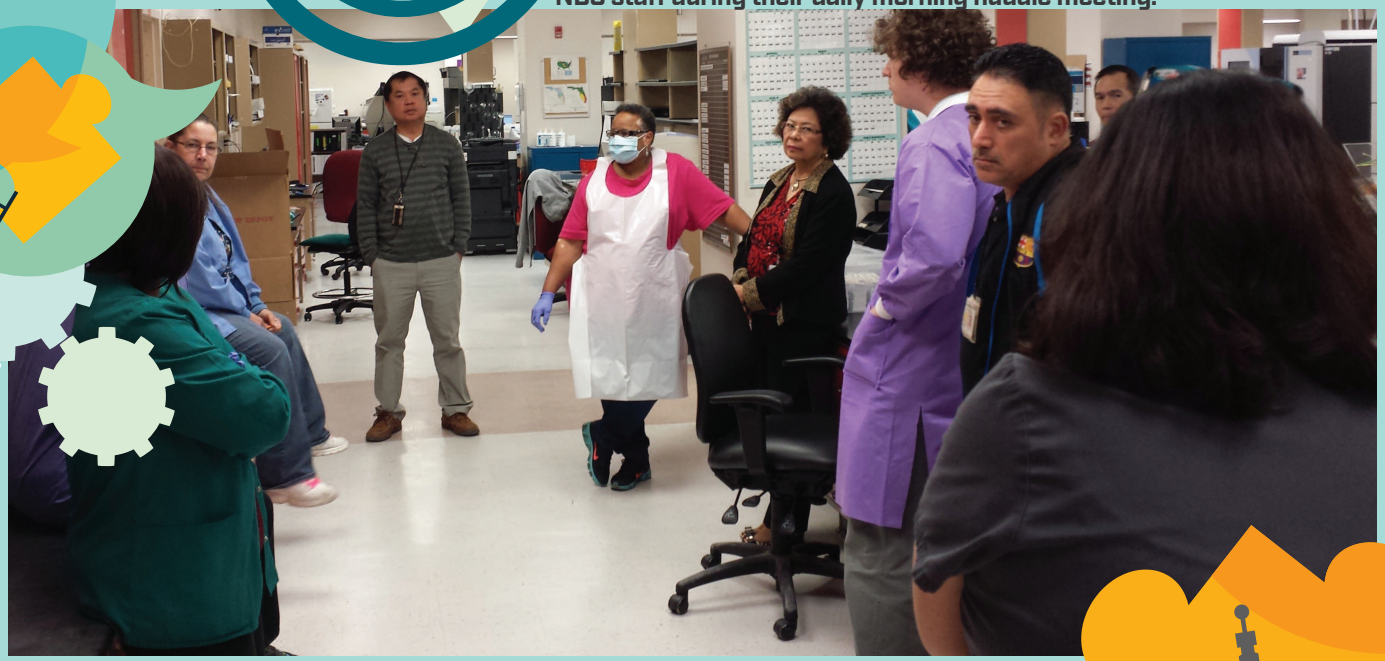
In 2014, BPHL identified two cases of STEC serotype O45. Although there were no commonalities identified between the two patients, these are two cases that would not have been identified (or at least not in a timely enough manner to initiate useful investigation) without the changes to our testing algorithm.

Figure 1: Detecting and Characterizing STEC at BPHL



LEAN in the Laboratory

LET THE TRANSFORMATION BEGIN



NBS staff during their daily morning huddle meeting.

Lean is a management philosophy that focuses on reducing waste and improving efficiency and quality. It can be applied to any business or any process. Although historically Lean principles have applied to manufacturing processes, Lean can be applied in the laboratory to improve test performance and test turnaround time while maintaining test quality and enabling cost savings.

LEILA FILSON, BPHL SAFETY OFFICER, WAS NOMINATED TO TAKE PART IN A LEAN TRAINING PROGRAM. The program was initiated by the Association of Public Health Laboratories' (APHL) National Center for Public Health Laboratory Leadership (NCPHLL), and the APHL Quality Team who contracted with a medical technology company, Becton Dickinson (BD), to provide Lean quality improvement training and certification. In addition to Leila, four other public health laboratory participants from around the U.S. were enrolled in this year-long training culminating in "Lean Leader Certification". To gain the certification Leila was required to complete three projects within a year and present her findings and improvements using specific Lean practices to APHL, the BD trainer and her public health laboratory colleagues.

The first project for Leila, as part of her training, focused on the newborn screening area and data entry turnaround times in this section. Leila focused on reviewing and improving the process for receiving samples for Newborn Screening (NBS) testing and the follow-up notification of hospitals if unsatisfactory samples had been submitted.

THE CHALLENGE

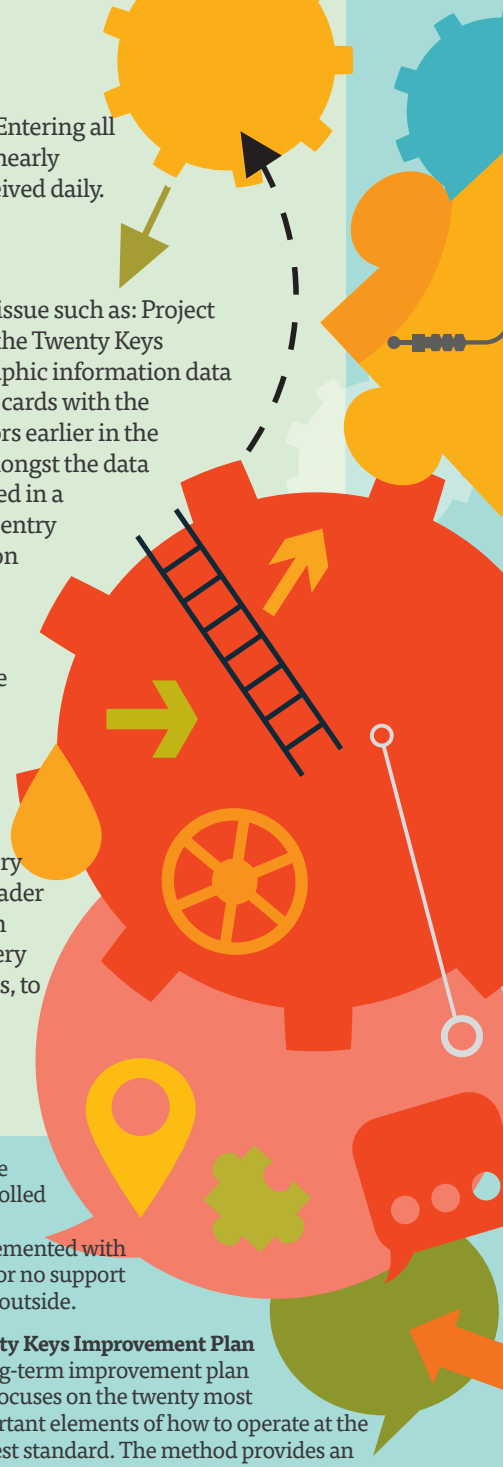
Leila and the NBS staff determined that a significant delay in the entry of patient information, or *demographics*, affected the ability of the NBS laboratory to provide timely notification to submitting providers if the samples were unsatisfactory for testing. Ideally, unsatisfactory samples should be reported back to the hospital within 24 hours, as the baby may still be there allowing for another sample to easily be collected. Once the baby has left the hospital, it is much more difficult and sometimes impossible to receive a second sample. Removing barriers from sample collection and newborn screening testing is very important because it saves lives!

In reviewing the NBS laboratory processes, Leila and the NBS staff noted that samples were received at the laboratory around 10:00 am and that the paperwork with patient information associated with each sample was handed to the data entry operators between 1:00 or 2:00 pm for entry into the computer system. This three- to four-hour delay in time caused an unnecessary time crunch for the data entry operators since unsatisfactory sample submissions needed to be reported out by 3:00 pm each day in order for providers—to be able to collect another specimen. Entering all patient demographic information by 3:00 pm was nearly impossible due to the large number of samples received daily.

THE SOLUTION

Leila used several standard Lean tools to tackle the issue such as: Project Charter, Huddle meetings, Primary Visual Display, the Twenty Keys Improvement Plan. To reduce the delay in demographic information data entry the NBS laboratory staff delivered the patient cards with the demographic information to the data entry operators earlier in the day. The way that patient cards were distributed amongst the data entry staff was also modified. These changes resulted in a reduced specimen card processing time in the data entry section and earlier availability of patient information associated with unsatisfactory specimens. Overall, implementing this project improved team building between departments and with outside partners. Consistent with the practice of Lean, all parties were enlisted and engaged to provide the best solution.

Leila presented back to her colleagues in summer 2014 and received her Lean leader certificate. Since then she has provided training to other BPHL staff on Lean practices, has implemented projects in other areas of the laboratory and has presented on her experiences. The Lean Leader Certification program increased proficiency in Lean practices among the APHL membership and was very beneficial to BPHL. We are now able, on a daily basis, to take advantage of the tools that Leila implemented and shared with others.



What is Lean?

Lean, sometimes termed Lean Manufacturing or Office Kaizen is the name of a process by which standardized methods can be used to minimize waste and maximize efficiency. Lean supports the concept of continuous improvement using a long-term approach that systematically achieves incremental changes in processes to improve efficiency and quality.

Project Charter

This is the official document that outlines a process improvement project. It is the first step in a Lean project and usually includes the following elements: Business Case, Problem Statement, Goal Statement, Team Members/Roles, Constraints/Boundaries and Project Scope.

Lean Daily Management System

This is a management system that encompasses various management elements.

System Examples

Primary Visual Display A graphic indicator that can visually communicate important information in the workplace. This is a 'lean visual control' and means that a system can be easily monitored and controlled with e.g. a "visual control chart." It can also display the group's performance and be updated on a daily basis.

Daily Workgroup "Huddle" Meeting When the group gets together each day to discuss the plan for the day, review results from the previous day/week/month, and provide an opportunity for adjustments and improvements in daily work practices. It brings the workgroup together and generates a sense of ownership through a brief, though highly productive, five- to ten-minute meeting.

Kaizen Action Sheet System A method for capturing small, low-tech improvements that can be controlled and implemented with little or no support from outside.

Twenty Keys Improvement Plan A long-term improvement plan that focuses on the twenty most important elements of how to operate at the highest standard. The method provides an assessment of current performance and recognition of priority areas for improvement followed by a plan and vision for the future.

Work Published in National Scientific Journals & Publications, 2014

"Bioterrorism: A Laboratory Who Does It." Craft DW, Lee PA, Rowlinson MC. J Clin Microbiol. 2014 Jul;52(7):2290–8.

"First confirmed cases of Middle East respiratory syndrome coronavirus (MERS-CoV) infection in the United States, updated information on the epidemiology of MERS-CoV infection, and guidance for the public, clinicians, and public health authorities-May 2014." Bialek SR, Allen D, Alvarado-Ramy F, Arthur R, Balajee A, Bell D, Best S, Blackmore C, Breakwell L, Cannons A, Brown C, Cetron M, Chea N, Chommanard C, Cohen N, Conover C, Crespo A, Creviston J, Curns AT, Dahl R, Dearth S, DeMaria A, Echols F, Erdman DD, Feikin D, Frias M, Gerber SI, Gulati R, Hale C, Haynes LM, Heberlein-Larson L, Holton K, Ijaz K, Kapoor M, Kohl K, Kuhar DT, Kumar AM, Kundich M, Lippold S, Liu L, Lovchik JC, Madoff L, Martell S, Matthews S, Moore J, Murray LR, Onofrey S, Pallansch MA, Pesik N, Pham H, Pillai S, Pontones P, Pringle K, Pritchard S, Rasmussen S, Richards S, Sandoval M, Schneider E, Schuchat A, Sheedy K, Sherin K, Swerdlow DL, Tappero JW, Vernon MO, Watkins S, Watson J. Centers for Disease Control and Prevention (CDC). MMWR Morb Mortal Wkly Rep. 2014 May 16;63(19):431–6.

"Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations." Branson BM, Owen SM, Wesolowski LG, Bennett B, Werner BG, Wroblewski KE, Pentella MA, CDC Guideline. MMWR Morb Mortal Wkly Rep. 2014 Jun 27;63(25):537.

National Meetings & Presentations, 2014

2014 Spring Chemical Laboratory Response Network (LRN-C) Level 1 Meeting, hosted by BPHL Chemical Threat Preparedness Program (CT), April 15–17, Jacksonville.

Representatives from 20 state public health laboratories were in attendance along with members from the CDC, the FBI, the Association of Public Health Laboratories and the FDA making up to 70 total attendees. BPHL CT staff members from Tampa, Pensacola and Jacksonville laboratories were in attendance. There were 30 scientific presentations over the course of two and a half days. Three group discussions were held at evening to discuss analytical chemistry methods employed in the LRN-C laboratories. Several informal discussions took place about quality assurance protocols to align with Clinical Laboratory Improvement Act regulations. Funding for this meeting was provided by the PHEP cooperative agreement grant from the CDC.

Clinical Virology Symposium, April 27–30, Daytona Beach:

"Virology and Women's Health Testing for Public Health," Pre-conference Workshop, oral presentation, B. Bennett

"Clinical and Public Health Laboratories: An Essential Partnership in Patient Care," oral presentation, M-C Rowlinson

"Outbreak of Locally Acquired Dengue Virus in Florida," poster presentation, L. Heberlein-Larson, V. Mock, P. Colarusso, S. York, J. Ambrose, A. Cannons, S. Crowe, M-C Rowlinson, S. Moody-Geissler, K. Peck

"Performance Evaluation of Puritan Unitranz Universal Transport System for the Detection of Respiratory Viruses," poster presentation, D. Lee (CDC/APHL Fellow)

"Dried Blood Spot Testing with the Bio-Rad GS HIV Combo Ag/Ab EIA and Bio-Rad Geenius™ HIV-1/2 Supplemental Assay," poster presentation, B. Bennett

American Society for Microbiology General Meeting, May 17–20, Boston:

"Stuck in the Middle with You: Do Clinical Labs have a responsibility for Public Health testing?" Session Convener M-C Rowlinson

"Solve the Outbreak: Bioterrorism or Nature," learning lab, oral presentation, M-C Rowlinson

Florida Society of Environmental Analysts, May 21–23, Clearwater Beach:

"Microbiology On Site Assessment Findings," oral presentation, S. Arms

"Subcontracting of Assessors Lessons Learned," oral presentation, S. Arms

"Meet the New FDOH Private Party Assessors," panel discussion, S. Arms, C. Kircher and Florida Environmental Laboratory Certification Program assessment contractors

Association of Public Health Laboratories Annual Meeting, May 31–June 4, Little Rock:

"An LRN (Laboratory Response Network) Reference Laboratory Investigation and Analysis of Blood and Blood Donor Products as Source of Putative Brucella abortus Infection in a Patient," poster presentation, S. White, A. Mitulinsky, E. Quaye, L. Gillis

"Demystifying 'What We Do' in the Public Health Laboratory with Powerful Posters," poster presentation, A. Cannons, R. France

"A Shared Services Model for HIV Nucleic Acid Amplification Testing for Public Health Laboratories Utilizing the Proposed HIV Laboratory Diagnostic Algorithm," poster presentation, B. Bennett

"Action Plan for Approaching Academic Institutions about Developing a Doctoral Program in Public Health Laboratory Science and Practice (PHLSAP)," poster presentation, A. Cannons, L. Gillis

"Public Health Leadership in Action: Impactful Communications with State Legislatures," Session Moderator A. Cannons

"The Role of 4th Generation HIV Combo Immunoassays in the New HIV Diagnostic Algorithm: Impact on Timely Diagnosis and Linkage to Care in Florida's Public Health Population" Industry Workshop, oral presentation, B. Bennett

The Council of State and Territorial Epidemiologists Annual Conference, June 22–26, Nashville:

"Emergence of a Dominant Clone of Neisseria meningitidis Serogroup W135 in Southeast Florida, 2008–2012," poster presentation, S. Pritchard, P. Fiorella, A. Mejia-Echeverry, E. Rico, P. Jenkins, D. King, B., E. Merlo, L. Gillis

Environmental Measurement Symposium, Aug. 4–8, Washington, DC—the combined meetings of the NELAC Institute (TNI) and EPA's National Environmental Monitoring Conference:

"A NELAP Accreditation Body's First-Year Experience Using Contract Assessors: Lessons Learned in Florida," oral presentation, S. Arms

"Relevance of Measurement Traceability Standards to Environmental Testing Laboratories," oral presentation, C. Kircher

"The Changing Face of Accreditation," panel discussion, S. Arms

Southeastern Microbiology Summit, Sept. 6–7, Ponte Vedra:

"The Role of Public Health Laboratories in the Detection and Surveillance of Antibiotic Resistance," oral presentation, M-C Rowlinson

American Council of Independent Laboratories Annual Meeting, Oct. 5, Chicago—Environmental Sciences Section:

"A National Environmental Laboratory Accreditation Program (NELAP) Accreditation Body's Experience Using Contract Assessors." oral presentation, S. Arms

National Stakeholders' Workshop, Oct. 6–9, Leesburg, VA:

"Sample prioritization and laboratory surge: Making or Breaking the Response," oral presentation, L. Gillis

"Investigation of PCR Inhibitors Affecting Amplification of Nucleic Acid from Southeast Florida Air Samples," poster presentation, L. Gillis

Florida Society of Environmental Analysts, Oct. 22–24, Ft. Lauderdale:

"Establishing Acceptance Criteria and Concentration Ranges for NELAC Proficiency Testing," oral presentation, C. Kircher

"Regulatory Forum," panel discussion, S. Arms, C. Kircher

Southeastern TB Controllers Meeting, Oct. 23–25, Deerfield Beach:

"Laboratory Diagnosis of Mycobacterium tuberculosis complex" oral presentation/panel discussion, M-C Rowlinson

18th Annual Infectious Disease and HIV/AIDS Conference of Northeast Florida, Nov. 14, Jacksonville:

"The New HIV Diagnostic Algorithm: Impact on Timely Diagnosis and Linkage to Care," B. Bennett

Boards & Committees

Association of Public Health Laboratories

Informatics Committee: S. Crowe (2012–2015)

Workforce Development Committee: L. Gillis, A. Cannons (TERM)

Public Health Preparedness and Response Committee: A. Cannons (TERM)

Knowledge Management Committee: R. France (2014–2017)

Infectious Diseases Committee:M-C Rowlinson (2014–2015)

HIV/HCV Sub-Committee: B. Bennett (2006–2016)

Arbovirus Sub-Committee: V. Mock (TERM)

Network of Laboratory Leadership Alumni (NOLLA)

M-C Rowlinson, chair-elect; L. Gillis, A. Cannons and M. Ritchie, members

American Society for Microbiology

Committee on Post-graduate Education Program: M-C Rowlinson, board member

FDA Partnership for Food Protection

Laboratory workgroup: A. Cannons, co-chair

The NELAC Institute (TNI)

Board of Directors: S. Arms, past chair,

Advocacy Committee: S. Arms, chair

Nominating Committee: S. Arms, chair

NELAP Accreditation Council: S. Arms

Non-Governmental Accreditation Body Working Group: S. Arms

National Environmental Filed Activities Program Executive Committee: C. Kircher

Laboratory Accreditation System Executive Committee: C. Kircher

Accreditation Body Expert Committee: C. Kircher

International Organization for Standardization

ANSI International Conformity Assessment Committee: C. Kircher

ISO CASCO Technical Interface Group: C. Kircher

Florida Public Health Association:

Executive Board: B. Bennett, member-at-large

Board of Directors: R. France, second vice president (board member/co-chair of Legislative Committee)

Florida Consortium on HIV/AIDS Research

Executive Advisory Board: B. Bennett

Jacksonville Area Microbiology Society

B. Bennett, president ; M-C Rowlinson, vice-president; B. Burden, secretary; M. Schimenti, treasurer

Florida State College

Medical Laboratory/ Histotechnology Program Board: C. Healan

Medical Laboratory Technician Advisory Committee: B. Bennett

University of South Florida

Institutional Biosafety Committee: D. Wingfield, A. Cannons

University of North Florida

Medical Laboratory Scientist Advisory Committee: S. Crowe, B. Bennett

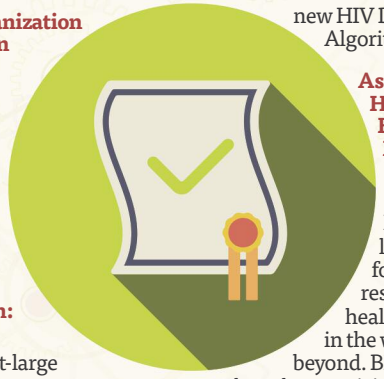
Awards

Prudential Productivity Awards:

C. Bonner—Cost Savings for the Bureau of Public Health Laboratories and State Taxpayers.

Newborn Screening and Shipping staff—Improved Ordering and Shipping of Newborn Screening Cards.

Retrovirology Testing Section staff — Evaluation and Implementation of a new HIV Diagnostic Algorithm



Association of Public Health Awards—Healthiest Laboratory, Honorable Mention

Recognizes laboratories that foster environmental responsibility and healthy personal choices in the workplace and beyond. BPHL was awarded based on participation in the state-wide Healthiest Weight initiative and the 10,000 step challenge. Initiatives have been spearheaded by Bonnie Hardy.

Florida Public Health Association Awards

Lylah Seaton, Serology/Arbovirus Testing Section, BPHL-Tampa, received the Homer D .Venters Award. Awarded annually to a public laboratory worker and FPHA member with less than 10 years public health experience.

Dr. R. France, BPHL-Tampa, assistant laboratory director, received the FPHA Presidential Award.

U.S. Department of Homeland Security's Office of Health Affairs—Laboratory Award

Public Health Laboratory Quality Assurance Award

Awarded to BPHL-Miami at a national conference in Oct. 2014.

Grants

***Neisseria Gonorrhoeae* (GC) Susceptibilities Project**

BPHL was awarded funds to support a GC susceptibilities project with APHL/CDC. The project looked at inter-laboratory reproducibility of testing 200 GC isolates to antibiotics by the E-test susceptibility method. Florida BPHL was one of eight laboratories awarded funding for the project.

Graduates

Matthew Schimenti

Medical Laboratory Scientist III, BPHL-Jacksonville, Master of Public Health, University of Florida.

Marshall Cone

Medical Laboratory Scientist I, BPHL-Tampa, Master of Public Health, University of South Florida.

Leila Filson

BPHL Safety and Training Coordinator/Safety Officer, Lean Leader Certificate. Filson completed a year-long program with the Association for Public Health Laboratories where she learned how to apply the Lean principles that focus on reducing waste and improving efficiency and quality.

Patent

Detection of Salmonella Species

Tatavarthy, A, Heller, L and Cannons, A (2014) Novel PCR Target for the Detection of Salmonella Species: Outer Membrane Porin F (Ompf). U.S. Patent No, 8895248 B1. Issued December 2014.

Thank You For Your Service

The Bureau of Public Health Laboratories is staffed by a team of highly qualified and dedicated individuals. In 2014, several staff members were acknowledged for their service:

40 Years

Nancy Pickens, Jacksonville

30 Years

Marek Pawlowicz, Jacksonville

25 Years

Susanne Crowe, Jacksonville
Carol Brazet, Jacksonville
Karen Jones, Jacksonville
Estrel Callao, Jacksonville
Pat Onasanya, Jacksonville
Tracey Ricks, Jacksonville
Nancy Kerr, Jacksonville

20 Years

Vita Avena, Jacksonville
Lillian Dela Torre, Jacksonville
Judy Barber, Jacksonville
Tanya Kuramoto, Jacksonville
Josephine Griffin, Jacksonville
Kim Williamson, Jacksonville
Joy Cipriano, Jacksonville
Edward Howell, Jacksonville
Theresa Young, Jacksonville

Contact Information

Bureau of Public Health Laboratories
904-791-1500; FAX, 904-791-1567

Florida Department of Health
Bureau of Public Health Laboratories
1217 N. Pearl Street
Jacksonville, FL 32202

Branch Locations

BPHL-Jacksonville
904-791-1500; FAX, 904-791-1567

BPHL-Miami
305-324-2432; FAX, 305-325-2560

BPHL-Tampa
813-974-8300; FAX, 813-974-3425

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