DELAWARE HEALTH AND SOCIAL SERVICES

Division of Public Health

Laboratory

DELAWARE LABORATOR

WINTER

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DELAWARE PUBLIC HEALTH LABORATORY SYSTEM ASSESSMENT

Jane Getchell, DrPH, Lab Director

The Association of Public Health Laboratories (APHL), in conjunction with the Centers for Disease Control and Prevention's Division of Laboratory Systems, developed the state public health (SPH) laboratory system assessment using the ten essential public health services as the measurement tool and incorporating the eleven core state public health laboratory functions. The assessment instrument is based on the work of the National Public Health Performance Standards Program (NPHPSP), APHL, and their partners. Evaluation of the capacity and capability of the SPH laboratory system involves not only evaluation of the state laboratory but of the entire system which includes those who collect the samples, those who analyze the samples, those who use the results, and those who participate in the delivery of the samples and results.

The assessment process highlights strengths and weaknesses of the system that facilitate informed, effective policy and resource decisions resulting in an improved public health laboratory system. The results gathered through this process provide an understanding of how state public health laboratories and the systems within which they are functioning are performing.

Delaware held an assessment of the SPH laboratory system on December 10, 2008 at the Smyrna Opera House. The assessment was conducted in a one day public meeting to which all partners and stakeholders were invited. For Delaware, the process was intended to spark greater coordination in the laboratory system, to identify duplication of services, inefficiencies, gaps and potential for sharing equipment, staff, and other resources. Success would be a stronger continuity of operations plan for the laboratory system, a more relevant and meaningful strategic plan for the Delaware Public Health Laboratory (DPHL) and improved mutual understanding for all system partners

Following a plenary session designed to introduce the assessment process to stakeholders, the fifty-seven individuals conducted their first assessment as a whole group and then were divided into three groups for the remainder of the essential services (ES). The breakouts were as follows:

All Attendees

Essential Service # 7: Monitor health status to identify community health problems

Group A

- Essential Service # 3: Inform, educate, and empower people about health issues.
- Essential Service # 4: Mobilize community partnerships to identify and solve health problems.
- Essential Service # 9: Evaluate effectiveness, accessibility, and quality of personal and population based services.

Group B

- Essential Service #2: Diagnose and investigate health problems and health hazards in the community.

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SPECIAL POINTS OF INTEREST

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DPHL Laboratory System Assessment

Identification of Shiga Toxin-Producing Escherichia Coli (STEC), Serotype 0157 and Non-0157 at DPHL

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Delaware Public Health Laboratory System Assessment, con't

- Essential Service # 5: Develop policies and plans that support individual and community health efforts.
- Essential Service # 6: Enforce laws and regulations that protect health and ensure safety.

Group C

- Essential Service # 1: Monitor health status to identify community health problems.
- Essential Service # 8: Assure a competent public health and personal health care workforce.
- Essential Service # 10: Research for insights and innovative solutions to health problems.

The three groups were lead by facilitators from the Division of Public Health (but not from the DPHL) and a contracted facilitator. Each group had one DPHL theme taker to record notes and observations and one DPHL laboratory resource person to provide technical input. The groups were asked to discuss the components for each essential service and give the state public health laboratory system a ranking based on the level of activity.

The Delaware State Public Health Laboratory system scored as follows:

Optimal Activity – Greater than 75% of the activity described in the question is met within the public health laboratory system.

Essential Service #2: Diagnose and investigate health problems and health hazards in the community.

Significant Activity – Greater than 50%, but no more than 75% of the activity described in the question is met within the public health laboratory system.

Essential Service # 1: Monitor health status to identify community health problems.

Essential Service # 3: Inform, educate, and empower people about health issues.

Essential Service # 5: Develop policies and plans that support individual and community health efforts.

SAVE THE DATE!!

NATIONAL MEDICAL LABORATORY WEEK— APRIL 19TH— APRIL 25TH, 2009

LAB TOURS, SPECIAL EVENTS, FUN AND FELLOWSHIP!!

Essential Service # 6: Enforce laws and regulations that protect health and ensure safety.

Essential Service # 8: Assure a competent public health and personal health care workforce.

Moderate Activity – Greater than 25%, but no more than 50% of the activity described in the question is met within the public health laboratory system.

Essential Service # 7: Monitor health status to identify community health problems.

Minimal Activity – Great than zero, but no more than 25% of the activity described in the question is met within the public health laboratory system.

Essential Service # 4: Mobilize community partnerships to identify and solve health problems.

Essential Service # 9: Evaluate effectiveness, accessibility, and quality of personal and population based services.

Essential Service # 10: Research for insights and innovative solutions to health problems.

Next steps fell into three categories, those to be implemented by the DPHL, those to be implemented by the Division of Public Health (DPH), and those which require involvement of DPH partners. Next steps identified include:

- Develop a plan to strengthen and connect data systems to include an assessment of the capacity of DHIN (Delaware Health Information Network) to connect state-wide medical information and integrate computer systems for two-way communications.
- Finalize memoranda of understanding with partner laboratories to assure testing services are not interrupted and continuity of operations plans are completed.
- Continue focus on workforce development and efforts to make state merit system laboratory salaries competitive.
- Increase information sharing and education efforts through improved web site, LabOrator, Lab Week, press releases, etc. The DPHL customer service survey and the compilation of responses to date are posted on our website http://www.dhss.delaware.gov/dhss/dph/lab/labs.html (scroll down for survey and compilation). If you have not yet participated in the survey, we welcome your input.
- Develop advocacy groups for a state public health laboratory system (government, legislators and teachers, schools).
- Define the mission for the SPH laboratory system, determine roles and responsibilities for each partner and prepare a SPH laboratory system communication plan.
- Examine the role of the Laboratory Preparedness Advisory Committee.
- Evaluate state laws and regulations regularly to determine changes that need to be made and enforcement measures that need to be taken.
- Establish a state education training coordinator position for the public health laboratory system.

Overall, the stakeholders felt that the assessment was an effective process. As the Delaware Public Health Laboratory system does not formally exist, they recommended additional working groups and meetings with missing key stakeholders to formally develop a working system committee to include the participation of all key policy and decision makers. A follow-up meeting is being planned during National Medical Laboratory Week, April 19-25. Look for more information about this in the coming weeks.

IDENTIFICATION OF SHIGA TOXIN-PRODUCING ESCHERICHIA COLI (STEC), SEROTYPE O157 AND NON-O157 AT DELAWARE PUBLIC HEALTH LABORATORY

Mary Ann Brown, Microbiologist III And Jennifer Cascarino, Microbiologist II

Introduction

Shiga toxins are the main virulence characteristic produced by Shiga toxin-producing *Escherichia coli* (STEC) (2). More than one hundred *Escherichia coli* (*E. coli*) serotypes are able to produce Shiga toxins (3) and there are two main antigenically distinct forms of toxin, shiga toxin 1 (*stx*1) and shiga toxin 2 (*stx*2) (3).

STEC infections in humans cause a variety of illnesses: asymptomatic shedding, non-bloody diarrhea, hemorrhagic colitis and hemolytic uremic syndrome (2). STEC organisms are an important class of food-borne pathogens which are transmitted from the intestines and feces of healthy cattle by contact or contaminated food or water consumed by humans. (6) Many of these outbreaks involve raw produce, raw milk, undercooked beef and unpasteurized juices. It is estimated that *E. coli* O157:H7 causes 70,000 illnesses in the United States each year (4).

Due to the serious illnesses and large outbreaks associated with STEC, lab tests need to be both rapid and specific. Enzyme immunoassay methods can rapidly detect the presence of shigatoxin, but false-positive results can occur. New procedures involving real-time polymerase chain reaction (PCR), faster and more sensitive than conventional PCR, focus on detection of the more virulent O157:H7 STEC serotype using a highly conserved point mutation at position 93 of the *uidA* (β-glucoronidase) gene that occurs with this serotype. The new multiplex real –time PCR assay we are evaluating detects the *stx 1, stx 2 and uidA genes.*

Testing and Significance

The microbiology lab at Delaware Public Health Laboratory (DPHL) is validating extraction of DNA from patient culture isolates for subsequent testing by real-time PCR assay for detection of STEC serotype O157 and non-O157. In the past DPHL has validated STEC real-time PCR from food enrichments using a FERN (Food Emergency Response Network) protocol (1). This same protocol will be used on the patient cultures. Using real-time PCR rather than conventional culture methods to test patient specimens will drastically reduce final reporting time since we currently send STEC isolates to the Centers for Disease Control & Prevention (CDC).

When a STEC is isolated, we do PFGE and serotyping for 0157 and the six most common "O" groups: 026, 045, 0103, 0111, 0121, and 0145. This data will be uploaded to the CDC pulsenet database for comparison and detection of widespread national outbreaks. Any matches would be investigated by the Delaware Public Health Bureau of Epidemiology.

Implementing STEC real-time PCR at DPHL will be beneficial in providing patient results faster, and in providing genetic information that will allow state epidemiologists to link cases. Further infections may then be prevented by issuing recalls of incriminated foods and initiating appropriate control measures.

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

METHOD VALIDATIONS FOR THE FOOD EMERGENCY RESPONSE NETWORK

Kathleen T. Hukey, Microbiologist II, Rebekah Parsons, Laboratory Manager I, Nancy Valeski, Microbiologist II, Marion Fowler Microbiologist II, and Jennifer Cascarino, Microbiologist II

The Food Emergency Response Network (FERN) was created by the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA). It was formed to bring together the nation's food-testing laboratories for the rapid detection of foodborne pathogens in the event our nation's food supply becomes threatened by a biological, chemical or radiological agent. The Centers for Disease Control and Prevention (CDC) estimates that 76 million cases of foodborne related illnesses occur each year in the United States. Additionally, there are an estimated 325,000 hospitalizations and 5,000 deaths in the United States each year (3). The Delaware Public Health Laboratory (DPHL) joined the FERN network in 2005. In 2007-2008 DPHL received a cooperative agreement to perform two multi-laboratory validations for the detection of *E. coli* O157:H7 and staphylococcal enterotoxins A and B, and a single laboratory validation for the detection of *salmonella*.

Staphylococcal enterotoxins A and B (SEA/SEB) are produced naturally by *Staphylococcus Aureus* in food. Staphylococcal enterotoxin is a common cause of food poisoning and has the potential to be used as a biological agent to contaminate food or water supplies. These toxins can readily cause harm by inhalation of aerosols (1).

The first multi-laboratory validation compared the BioVeris platform to the Tecra kit for the detection of SEA/SEB in three different food matrices: hot dogs, canned green beans and infant formula. The BioVeris technology is a proprietary sandwich immunoassay. The Tecra Kit is an enzyme-linked immunosorbent assay (ELISA) which also uses capture antibodies like the BioVeris; however they are adsorbed to the surface of plate wells. The validation of the SEA/SEB detection methods achieved a 100% detection rate using the BioVeris, while the Tecra kit had a detection rate of 69.5%.

E. coli 0157:H7 is estimated to cause infection in more than 70,000 patients a year in the United States. According to numbers provided by the CDC, outbreaks in 2006 of *E. coli* O157:H7 in spinach and in lettuce associated with Taco Bell restaurants caused a combined total of 276 illness and 3 deaths. Foods often implicated in *E. coli* O157:H7 contamination, such as lettuce and spinach, are generally not cooked and are an optimal avenue for an intentional contamination (2).

The multi-laboratory validation for the detection of *E. coli* O157:H7 was designed as an evaluation of the dynal beadretriever's ability to isolate *E. coli* O157:H7 from three food matrices: deli meat, whole milk, and spinach. The beadretriever effectively isolated *E. coli* O157:H7 from whole milk and deli meat matrices, but failed to sufficiently eliminate competing bacteria so that E. coli O157:H7 could be easily isolated and purified from the spinach samples.

An outbreak of *Salmonella* Saint Paul in 2008 and the current outbreak of *Salmonella* Typhimurium, have demonstrated the impact a foodborne illness can have on our nation's food supply. *Salmonella* is one of five pathogens that account for over 90% of estimated food-related deaths (1). In June of 2008, tomatoes were initially implicated as the cause of the *salmonella* outbreak. It was later confirmed that jalapeño peppers were the major vehicle of pathogen transmission. Approximately 1442 persons from 43 states, including the District of Columbia and Canada were infected with the *Salmonella* St. Paul strain during the outbreak in 2008. Of those, at least 286 people were hospitalized and *salmonella* may have contributed to the deaths of two people (4). The ongoing *Salmonella* Typhimurium outbreak has been traced back to a plant which manufactures

peanut butter and peanut paste (5).

As of January 28th, 2009, approximately 529 persons from 43 states and Canada have been infected with the *Salmonella* Typhimurium strain. This total includes 8 deaths (5). These outbreaks illustrate that rapid detection and traceback ability are necessary to improve food safety. Outbreaks from foodborne illness have been documented on every single continent demonstrating the public health significance of these diseases.

The last validation study of the 2007-2008 grant year was the single laboratory validation for the detection of *salmonella* in a variety of food matrices, including lettuce, tomatoes, jalapeño peppers, broccoli, creamed corn, frozen spinach, alfalfa sprouts, watermelon, cantaloupe, strawberries, orange juice, hot dogs, chicken, ground beef, vegetable burgers, milk, liquid eggs, peanut butter, baby oatmeal and cat food. The dynal beadretriever was used to recover the organism from food matrices spiked with a gradient of *salmonella* concentrations. The lightcycler foodproof *salmonella detection* kit was used in conjunction with the LightCycler 2.0 (Roche) Carousel-Based System, which amplifies the target DNA.

Our studies showed that the FSIS/FERN method for the Staphylococcal A and B on the bioveris platform was an excellent and efficient method. In addition, the *E. coli* O157:H7, despite being tedious, also produced clear results, especially when there were no competing bacteria. The *salmonella* validation showed that, if needed, testing can be done on a food matrix in approximately 24 hours. The importance of the work being done at DPHL and other public health and agricultural laboratories across the country to develop increased sensitivity, rapid detection and target-specific assays for monitoring foodborne contamination can be easily illustrated by the recent outbreaks. Delaware was the first state to report the "fingerprint" pattern of the Taco Bell associated *E. coli* strain thanks to our involvement in the *E. coli* validation process. Delaware was the first state to isolate *Salmonella* agona

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Method Validations for the Food Emergency Response Network, cont'd

from puffed wheat from a nationwide outbreak associated with cereal, and DPHL is prepared to detect *Salmonella* Typhimurium in peanut butter associated with the current outbreak.

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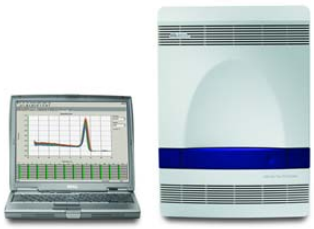
INFLUENZA MOLECULAR METHOD TRANSITION

Rebekah Parsons, Lab Manager I

With molecular testing becoming more and more prominent in public health laboratories, federal agencies are implementing regulations to assure quality and integrity of testing. Presently, the Delaware Public Health Laboratory (DPHL) performs a molecular real-time Reverse Transcriptase Polymerase Chain Reaction assay (rRT-PCR) for the detection of respiratory viruses on an Applied Biosystems 7500 Fast real-time PCR instrument. The current rRT-PCR assay is comprised of analyte specific reagents (ASRs) acquired through various sources making the assay a "home-brew" assay. The method allows for the detection of seasonal influenza strains, including influenza A and influenza B, and novel influenza strains, including the highly pathogenic influenza A (H5N1) virus. Although biannual proficiency testing is performed to assure the competency, accuracy, and reliability of the analysts, methods and equipment, the assay was not previously a US Food and Drug Administration (FDA)-cleared assay. Consequently, the current rRT-PCR assay is used for surveillance purposes only and the 7500 Fast instrument is deemed to be a "Research Use Only" (RUO) platform.

In September of 2008, the FDA cleared a Centers for Disease Control and Prevention (CDC) developed method called the Human Influenza Virus Real-Time RT-PCR Detection and Characterization Panel (rRT-PCR Flu Panel). A collaborative effort between the CDC, Applied Biosystems and the Association of Public Health Laboratories (APHL) facilitated the progression toward FDA clearance. The standardized assay and reagents will strengthen the accuracy, consistency, and comparability of test results across qualified laboratories and rapidly distinguish between strains of seasonal and novel influenza. The DPHL sent a microbiologist to the CDC for training on Molecular Methods in April of 2008 which paved the way for DPHL to become a CDC-qualified laboratory. CDC-qualified laboratories are to be the pioneer roll-out sites for the FDA cleared methods and instrument upgrades. The Applied Biosystem's 7500 Fast Dx real time PCR diagnostic instrument was also FDA cleared for "in vitro diagnostic use" as opposed to the previous classification of "research use only."



7500 FAST Real time PCR System

The DPHL has three 7500 Fast platforms which are scheduled for software upgrades during February 2009. The upgrade of the 7500 Fast real-time PCR instruments to 7500 Fast Dx involves the installation of new software and an extensive service contract. The new service contracts include the stringent maintenance and calibration specifications necessary to be compliant with the FDA regulations for performing the CDC diagnostic assay.

The 2008-2009 Influenza season began on October 1st, 2008. To date, 709 tests have been performed for influenza with 41 resulting in the detection of influenza. The influenza A:H1 strain has been the prominent strain circulating in Delaware during this influenza season. The real-time 7500 Fast PCR instruments are also used at the DPHL to perform testing for Norovirus, West Nile Virus, and many pathogens which have the potential to be used as Bioterrorism agents. The 2008-2009 Norovirus season which is occurring concurrent to the Influenza season has produced 54 tested specimens of which 29 have been positive. The transition to the ABI 7500 Dx platform and diagnostic protocol is set to occur in the spring of 2009 and will be implemented for the 2009-2010 influenza season.

APHL is strongly supporting and encouraging the upgrade of equipment, software and reagents in order to significantly improve surveillance, credibility and turn around time of specimen results associated with public health laboratories. The DPHL is proud to be included among the public health laboratories participating in the transition from the assay for Research Use Only (RUO) to the FDA cleared assay for *In Vitro Diagnostic* (IVD) Use.

For more information, visit: www.cdc.gov

EMPLOYEE NEWS

We say a fond farewell to **B.J. Scott** and thank her for 30 years of service to the State of Delaware. Her continued skills as a laboratory technologist enhanced the lives of Delawareans from our very oldest (BJ began her career with the Delaware Hospital for the Chronically Ill (DHCI) to the youngest. After leaving DHCI, B.J. joined the DPHL team in the newborn screening section. We wish her happiness in her retirement.

Congratulations!! We'll miss you.

B. J. Scott

The DPHL thanks **Pat Scott** for her service as the out going chair of the Employee of the Month Committee. She has worked hard and tirelessly in getting the nominations and making the trump card and certificates each month. She has also offered her support to the committee in the future when needed and you will be needed, Pat!

Congratulations to **Tara Lydick** who is the lab's Employee of the Month for January and nominee for the Division Employee of the Quarter. The laboratory performs complex testing for the state and for the federal government and undergoes many certification and inspection reviews. These certification and inspection processes require coordination of state personnel and different sections within the laboratory. Tara has undertaken a major role in supporting the laboratory through these reviews. The most recent review the laboratory underwent was the select agent inspection. Tara was outstanding in coordinating the sections and personnel for the inspections. She ensured all the materials (e.g., training records, inventory logs, policies and procedures for security, etc.) were accurate and ready to go on the day of the inspection. Her attentiveness to details and to all aspects of the review process were outstanding. She provided foresight and willingness to accomplish all tasks presented to her. She was a tremendous help to us and to the success of the inspection. We sincerely congratulate her on a job well done.

In addition to the inspection assignment, Tara played an important role in another critical event for the DPHL. The laboratory conducted a program to assess the public health laboratory system in Delaware. Tara stepped up and took a lead position in compiling results, presenting, and writing down key points during the assessment program. This was no small task. In the current climate of "making do with less", Tara has demonstrated herself as a model state employee showing how resolve and hard work get the job done.

DELAWARE'S DIVISION OF PUBLIC HEALTH LABORATORY

Delaware Public Health Laboratory

30 Sunnyside Road
Smyrna, DE 19977
302.223.1520
Fax: 302.653.2877

Built: 1990

Business Hours: 8 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
- Lead
- Epidemiology
- Newborn Screening
- STD prevention
- TB Elimination
- Drinking water
- Preparedness

DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health
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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 liz.moore@state.de.us.

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

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