DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health
Laboratory

DELAWARE LABORATOR

Winter 2012
Vol. 36, Issue 3

NEW & IMPROVED TRICHOMONAS TESTING

LINDA POPELS, LAB MANAGER I

Gen-Probe has developed the first nucleic acid amplification test (NAAT) for *Trichomonas vaginalis,* called the APTIMA® *Trichomonas vaginalis* assay. The assay is far superior to traditional wet mount and culture techniques for Trichomonas screening, which have approximately 60% and 75% sensitivities respectively. The new test has close to 100% sensitivity and uses the Tigris automated system that the Delaware Public Health Laboratory (DPHL) is currently using for other sexually transmitted disease (STD) testing. With the low sensitivity of current testing techniques, many patients may not be properly diagnosed. In addition, 50% of infected women and most men are asymptomatic for Trichomonas, further complicating detection and treatment of this STD. The APTIMA® Trichomonas assay is FDA approved for women only at this time, although both men and women can be infected with Trichomonas.

According to Gen-Probe press release 4/20/11, "Trichomonas is a sexually transmitted parasite that causes vaginitis, urethritis and cervicitis in women. If left untreated, complications can include premature labor, low-birth-weight offspring, and premature membrane rupture in pregnancy. The US Centers for Disease Control estimate that 7.4 million American men and women are infected with Trichomonas annually."

DPHL will use the APTIMA® assay due to the improved sensitivity of the test and the public health implications of Trichomonas infection and the shocking prevalence rates presented in recent studies. Based on research conducted by Charlotte Gaydos, DrPH, from Johns Hopkins University School of Medicine, 13% of women in their 50s were infected, 11.3% of women in their 40s were infected, 7.9% of women in their 30s were infected and 8.3% of women in their 20s were infected. In addition, 20.2% of African-Americans and 5.7% of Caucasians were infected. In certain populations, especially women in their 40s and 50s

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and African-American women, there are extremely high infection rates and we cannot ignore the need to conduct routine screening for Trichomonas.

Currently, DPHL is completing validation studies so the assay can be used for both females and males. We anticipate starting Trichomonas testing in February 2012. The test can be performed on the same specimens as those taken for chlamydia and gonorrhea testing.

OPERATION LOOSE PACKAGE

DEBRA RUTLEDGE, LABORATORY MANAGER II

Operation Loose Package, held November 8-10, 2011,was a multi-agency full scale exercise centered around activation of the Bio Detection System (BDS) from a letter potentially containing anthrax processed at the Hares Corner Postal Distribution Center in New Castle, DE. Participants included; the United States Postal Service and Inspectors Service HazMat Team (Hares Corner, DE and NJ), DNREC Laboratory and Emergency Response Branch, New Castle County Technical Decontamination Team and Emergency Management, Goodwill Fire Co., 31st Civil Support Team (Delaware National Guard), Delaware State Police, the Federal Bureau of Investigation, St. Francis Hospital, DE Medical Reserve Corp., Delaware Academy of Public Safety and Security, Delaware Public Health Laboratory (DPHL), Office of Drinking Water (ODW), Public Health Preparedness (PHPS), Health Systems Protection (HSP) and the Office of Health Risk and Communication.

The first day of the exercise began with the activation of the BDS alarm, 911 notification, evacuation of the facility, HazMat response, extraction of the BDS cartridge, decontamination of employees, and simulated treatment for prophylaxis. Student volunteers from the Delaware Academy of Public Safety and Security served as volunteers for medical surge at St. Francis Hospital. ODW was alerted of a report of an individual dumping powder into the public water storage tanks near the post office. Bulk water was collected and tested for bioterrorism (BT) agents, while a second incident unfolded involving the Civil Support Team at a nearby location. Over two days, three different samples were transported to DPHL for analysis. DPHL received, triaged and analyzed samples per appropriate protocols.

Overall, the exercise was a huge success. All of DPH programs and partners worked well together. DPHL was successful in confirming *Bacillus anthracis* from the post office sample and chromium chemical contamination in the tampered water supply. Communication and relaying information to an actual person seemed to be challenging and will be a focus for future improvement.

Improper packaging and transport of one sample led to biological exposure of four laboratory personnel. A multi-agency hot wash was held to identify areas that need to be improved. The laboratory would like to acknowledge Tara Lydick for all her effort and dedication in planning and implementing this full scale exercise. DPHL wishes to thank all those who volunteered, planned or participated in this important exercise.

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

SEVERE COMBINED IMMUNODEFICIENCY TESTING UPDATE JANUARY 2012

PATRICIA SCOTT AND CLOVER CARLISLE, DELAWARE NEWBORN SCREENING LABORATORY

There has been significant progress made by the Delaware Public Health Newborn Screening Program and the Delaware Public Health Laboratory (DPHL) to initiate a newborn screening for a 39th disorder, Severe Combined Immunodeficiency (SCID), sometimes referred to as 'Bubble Boy' disease. The technology used for identifying SCID-related disorders involves the identification of T-cell receptor excision circles (TRECs) and uses molecular technology.

SCID is a group of disorders characterized by a deficiency of the T-cell lymphocytes in the immune system. Infants affected by SCID develop recurrent infections resulting in death by two years of age. SCID affects a minimum of one in 100,000 newborns, however some studies estimate that the actual number is closer to one in 40,000. While SCID is the most significant of the disorders identified when looking for decreased TREC levels, several other disorders are likely to be identified, including DiGeorge Syndrome, Jacobsen Syndrome, or other unspecified T-cell lymphopenia. The overall incidence of T-cell lymphopenias requiring bone marrow transplant is 1in 38,000.

The following is the timeline of activities in the development of the Newborn Screening SCID testing program.

May 2010 – Kathleen Sebelius, Secretary of the US Department of Health and Human Services, asked states to adopt the national uniform screening panel as recommended by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC). This panel now includes SCID as a core disorder.

October 2010 – The Delaware Newborn Screening Advisory Committee heard testimony from Donna and Tim Sawyer about their children, both born with the deadly disease but with very different outcomes. The committee voted unanimously to send a recommendation to Dr. Karyl Rattay, Director of Public Health, to add SCID to the Delaware newborn screening panel.

October 2010 – Two staff members, one from the newborn screening follow-up program and one from the laboratory, attended a two-day training in Atlanta, Georgia entitled "Newborn Screening for Severe Combined Immunodeficiency, Implementation, Challenges and Updates". In addition the lab analyst also had the opportunity to participate in a wet-workshop and hands-on SCID method demonstration at the Molecular Biology branch laboratory at the Centers for Disease Control and Prevention (CDC). This event was sponsored by the Association of Public Health Laboratories (APHL) and the National Newborn Screening and Genetics Resource Center (NNSGRC).

February 2011 – The Division of Public Health (DPH) whole-heartedly supported the addition of SCID to the Newborn Screening panel and directed the DPH Newborn Screening laboratory and program to move forward with plans to establish screening for SCID during 2011.

May 2011 through July 2011 – An Invitation to Bid (ITB) was written, posted and awarded, allowing DPH to purchase necessary testing equipment for identification of TRECs.

June 2011 – A laboratory analyst attended a molecular training workshop, hosted and sponsored by the Newborn Screening and Molecular Biology branch of the CDC and the APHL.

Summer 2011 - The DPHL, with established history of a wide array of molecular testing including newborn screening for cystic fibrosis mutations, prepares laboratory space for the addition of SCID testing, estimated to be 15,000 tests/year. This involved the moving of several testing processes, equipment, and even an installed glove box to other areas of the laboratory. The appropriated space was designated as a Molecular Testing laboratory with dedicated clean, dirty, and amplification areas to be used by all DPHL staff involved with molecular testing.

August 2011 – Analyst Clover Carlisle traveled to the CDC to prepare the calibrators and controls . This trip to Atlanta was made possible by generous support from Dr. Francis Lee, Dr. Robert Vogt and the CDC. Staff from Connecticut, the CDC and Delaware prepared sufficient controls and standards to last at least a year. There are no commercially-produced controls or standards available for the identification of TRECs.

August 2011 – The Agilent Stratagene MX3000 real-time PCR platform was received at the DPHL and training was conducted for two staff members.

September 2011 through December 2011 – Validation of the equipment and method was completed including experiments for precision, accuracy, analytical sensitivity, analytical specificity,

SCID Testing continued

reportable range, and reference range. During this pilot phase of testing, more than 4000 babies were tested.

September 2011 through Present Delaware received a 100% performance score on four model performance evaluation survey challenges (five samples each) that were received from the CDC and tested for TRECs at the DPHL. Results of testing were compared to expected values and results from the 12 participating laboratories (in the world), including Massachusetts, New York, Wisconsin, California, Connecticut, Delaware and Michigan.

October 2011 through Present – DPHL is in the process of purchasing a specialized automated dried blood spot puncher capable of punching a 2.0 mm punch, required for Delaware's method.

December 2011 through Present The DPHL continues to work with Natus, Inc. to modify the Newborn Screening database, MSDS IV, to accommodate SCID screening including; tracking of TREC values, internal control values, interpretation algorithms, follow-up activities, and reports.

Following what we felt to be a productive year in tight economic times, the Sawyer family was invited to the DPHL on 12/29/11 to witness firsthand the progress made by DPH in bringing on a newborn screening test for SCID. The Sawyer family, who were at the start of our SCID testing journey, are uniquely interested in this disorder because of their two teenage children, Alex and Austin, both born with SCID. Their story is a compelling one, with Alex born first and being undiagnosed until 9 months of age. She celebrated her first birthday in a hospital bed, on life support, and is referred to as the million dollar baby. Austin was tested at birth and spent his first birthday enjoying birthday cake. This scenario demonstrates the difference that newborn screening can make for families with SCID -affected children.

A News Journal reporter, Kelly April Tyrrell, was present and we invite you to read her feature article on the Sawyer family, (2011, December 30) Parents' past worry will save Delaware babies' lives.

SAVE THESE DATES!

Sentinel Laboratory Workshop
May 9, 2012
or
May 10, 2012

Laboratory Preparedness Advisory Committee Meeting
May 15, 2012

PURPLE DRINKING WATER, YIKES!

MARY ANN LUSTFIELD, LABORATORY MANAGER I

Water, water, everywhere,
And all the boards did shrink;
Water, water, everywhere,
Nor any drop to drink.

By Samuel Taylor Coleridge

On September 21, 2011 the Delaware Office of Drinking Water (ODW) notified the Delaware Public Health Laboratory (DPHL) of their response to a complaint concerning purple drinking water at a church in Frankford, DE. They had collected samples from this location for total coliform, routine inorganic, trace metal and volatile organic compounds testing and were anxious to find out what was causing the water to turn purple. On September 22, 2011 the laboratory received these drinking water samples that were indeed purple in color. (See picture below).

On their initial visit, ODW personnel saw the well, the pump and the storage tank but did not see a treatment system. They were originally informed by the church that there was no treatment system associated with this water system. Because there was no treatment system in place, ODW eliminated the possibility of a potassium permanganate canister malfunction or a treatment system issue. Potassium permanganate is purple and is sometimes used in water treatment. Office of Drinking Water staff had seen many potassium permanganate overfeeds in the past which had only given the slightest pink tinge to the water; this water was a deep purple.

On September 23,2011, DPHL asked one of their partners, the 31st Civil Support Team (CST), Delaware National Guard for assistance in analyzing the sample . The CST has analytical resources available that the DPHL does not have and they were able to perform supplemental testing. After initial discussions with Lt. Robert Annis, Science Officer, and testing the laboratory made the following observations.

- The samples were a deep dark purple color.
- pH=5.2
- The solution turned purple → yellowish → clear with a black precipitate with the addition of sodium thiosulfate .
- The solution was reduced by hydroxylamine HCl; solution became colorless.
- ICP MS showed a considerable amount of manganese, i.e., greater than 600,000 mg/L manganese.
- The Volatile Organic Compound screen was clean.
- Ion Chromatography analysis for anions showed modest amounts of chloride and sulfate however nothing alarming.
- The solution probably did not contain detecting dyes used in plumbing because dyes tend to fluoresce and are not normally visible.
- So far the sample results were consistent with the presence of potassium permanganate.

Purple Drinking Water continued

Lt. Annis had initially surmised that the sample was of an inorganic nature. He also thought that the problem might be caused by potassium permanganate but, he thought, like ODW, that the lack of a treatment system almost negated this possibility. However, he did contact a geologist to determine if potassium permanganate could exist in natural deposits.

Meanwhile, while waiting for identification and confirmation of tests results, ODW had to contemplate serious questions regarding how the water system became contaminated and why the water system was contaminated. There existed a possibility that this contaminant was intentionally introduced. If so then who introduced it and why? What are the health consequences of this yet unknown substance?

On September 26, 2011, using Polarized Light Microscopy Lt. Annis' analysis supported the presence of potassium permanganate.

The results of the DPHL and the CST presented a conundrum to both laboratories and ODW. How to explain these laboratory results? The answer came the next day.

On September 27th the issue was settled. A representative from ODW and a plumbing inspector visited the property to inspect the water system. They observed that there ***was*** indeed a water treatment system that had a ***vat of potassium permanganate feeding directly into a greensand filter treatment system!*** Adding to the confusion, the water treatment system was located separately in the basement, separate from the well, the pump and the storage tank.

The problem was discovered and the puzzle was solved. Although this situation did produce a lot of anxiety there were positive outcomes. No one was injured by drinking the water. The problem was the result of a simple accident or oversight. It was not the result of ill will, a prank, criminal mischief or political machinations.

This experience was an opportunity for DPHL to exercise the recently signed Memorandum of Understanding (MOU) with the CST and, in doing so, to work closely and effectively with some of our partners both inside and outside the State system. It was, in essence, an exercise or practice run for a real emergency for the laboratory and its partners. The MOU with the CST was shown to be successful and invaluable. With the potential of a more ominous or widespread future incident, this partnership greatly increases DPHL's analytical capacity and capability, allowing a structured, unified, and rapid response to potential and unusual public health threats.

SAVE THIS DATE!!

LABORATORY PROFESSIONALS
GET RESULTS
NATIONAL MEDICAL LABORATORY PROFESSIONALS WEEK APRIL 22-28, 2012

Delaware Public Health Laboratory

Open House

April 25, 2012

9:00 a.m. - 1:00 p.m.

Agents of Bioterrorism: Sentinel Laboratory Workshop

May 9, 2012
or
May 10, 2012

Sponsored by the Delaware Public Health Laboratory

Description

This hands-on laboratory workshop begins with an overview of laboratory safety and a review of the Laboratory Response Network (LRN) structure to include discussion on select agents. The afternoon will include hands-on exercises based on case studies using "mimic" and attenuated or vaccine strains of select agents. These exercises are designed to enhance the microbiologist's capability to recognize the cultural and microscopic characteristics of potential agents of bioterrorism.

Audience

This one-day, intermediate-level workshop is designed for clinical microbiologists with bench-level experience from designated "sentinel" laboratories within the Delaware Laboratory Response Network.

Location

Delaware Public Health Laboratory (DPHL)
30 Sunnyside Road
Smyrna, DE 19977

Faculty

William W. Ward, PhD, MT (ASCP) SSB, Director
Debbie Rutledge, MBA, MT (ASCP),
Lab Manager II, BT Coordinator
Marion Fowler, BS, MT (ASCP), BT, Microbiologist II
Diane Hindman, BS, MT (ASCP), SM, Microbiologist II
Bela Patel, BS Microbiology, Microbiologist II
Donna Colatrella, MLT (ASCP), Microbiologist II
Nancy Valeski, BS, MT (ASCP), Microbiologist II

Objectives

At the conclusion of this program the participant will be able to:

- Discuss the proper usage of available safety equipment and the safety implications of handling suspected agents of bioterrorism in clinical specimens and isolates.
- Recognize culture, staining, and biochemical characteristics of suspected agents of bioterrorism.
- Discuss the role of the clinical laboratorian to "rule out or refer" suspicious isolates according to ASM guidelines to DPHL
- Outline the process for contacting appropriate personnel and transporting suspected organisms to DPHL.

Registration required. *Seating is limited so register early!*
Fee: NO CHARGE!
Registration Deadline: April 25, 2012
To register email Pat Selg at pat.selg@state.de.us

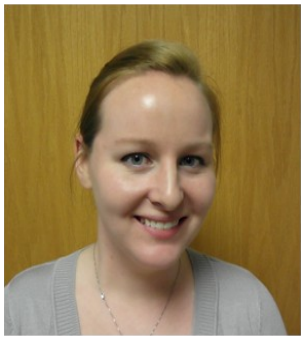
For Program Content and Information: Contact Marion Fowler at the DPHL by email at marion.fowler@state.de.us. Agenda, directions and further instructions will be emailed after workshop registration is complete.

EMPLOYEE NEWS

WELCOME TO THE LAB!

DPHL is pleased to introduce our new laboratory director, Dr. William W. Ward. Dr. Ward brings a wealth of administrative, scientific and technical expertise having lead broad service and specialty clinical laboratories in military and private medical centers, a commercial reference lab and, most recently, a lab supporting pharmaceutical clinical trials. He holds a Ph.D. in Pathology specializing in clinical immunology and virology, and master's degrees in medical technology and business management. His areas of expertise include bacterial and viral diseases, sexually-transmitted diseases, biothreat agents, autoimmune and immunodeficiency disorders, immunopathology, transplant immunology, molecular pathology, laboratory management, quality management, and regulatory compliance. While serving in the U.S. Air Force as a biomedical laboratory officer, Dr. Ward received training in medical readiness, field laboratory deployment, and operations in biological and chemical threat environments. In his spare time, Dr. Ward enjoys reading, sailing, and playing the 'cello. Please join us in welcoming Dr. Ward to the DPHL team.

DPHL welcomed Kylie Lewis as our new operations support specialist on November 7, 2011. Prior to DPHL, Kylie worked at the Department of Corrections in the financial area. Kylie also works part time at the JK Tangles salon in Camden. Kylie is currently performing data entry for Newborn Screening, Drinking Water, STD, and Virology, and greeting visitors to DPHL. She will soon begin processing documents in the First State Financial (FSF) system and providing assistance to DPHL's Senior Accountant.



Tori Johnson joins the chemical terrorism section as our new and first contract chemist. She is already hard at work learning multiple techniques and instruments to support the Laboratory Response Network Chemical. Tori grew up in New Jersey and graduated from Richard Stockton College of New Jersey with a BS in chemistry. With a concentration in environmental chemistry, she researched terpenes in Atlantic Cedar trees using GC/MS and has previous experience with QC Labs performing water microbiology testing. Her strong environmental interests extend outdoors to camping, fishing, and traveling. She also keeps busy bowling in a league with her sisters.

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
- Epidemiology
- Newborn Screening
- STD prevention
- TB Elimination
- Drinking water
- Preparedness

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

William W. Ward, PhD, Director, DPH Lab, Delaware Public Health Laboratory

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

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