



DELAWARE LABORATOR



SPRING 2009

INFLUENZA A/H1N1 (SWINE-LIKE)

Jane Getchell, DrPH, Director

The Delaware Public Health Laboratory's (DPHL) plunge into swine flu began on Monday April 27 with a late afternoon call from the University of Delaware (UD) Student Health Center. They had 2 students with flu-like symptoms with rapid flu A positive (+) results and wanted them tested for swine flu, even though the students had no travel history to Mexico. UD dispatched a courier to bring the specimens to the lab that night and then sent specimens from two additional students the next morning. By afternoon of April 28 the DPHL had results of flu A+, nonsubtypeable on all four students. DPHL alerted the Centers for Disease Control & Prevention (CDC) emergency operations center and the CDC influenza lab of these results and shipped the specimens to CDC that afternoon. A conference call was held that evening with DPH staff, the Governor's office and UD to prepare a public announcement regarding the probable cases and to develop a response plan.

Wednesday, April 29

The lab reported a total of ten nonsubtypeable specimens from UD students and sent a second group of six specimens to CDC for subtyping. None of the probable cases reported a history of travel to Mexico. The cases spurred additional public health actions:

- Delaware's Division of Public Health (DPH) set up a Neighborhood Emergency Help Center (NEHC) on the UD campus where students could be evaluated, tested and treated. Lab staff was there to perform rapid flu testing as a screen.

- DPHL couriers delivered a supply of flu specimen collection kits to all the state service centers for distribution to health care providers.
- DPHL ordered 1000 rapid flu test kits.
- A Joint Information Center was established at UD.
- DPH established a call center.
- Epidemiology actively conducted case investigations.
- State Health Operations Center (SHOC) Level III was declared and team members and team leaders all reported to SHOC headquarters in Smyrna.

Fortunately, the close proximity of DPHL and the SHOC site at the Delaware Hospital for the Chronically Ill enabled the lab team leader (the director) to attend the thrice daily meetings. At these meetings the lab provided hour-by-hour updates on test results and participated in planning and message development for the public and for health care practitioners. SHOC staff hashed out what patients should be tested, who should be treated, and how physician offices unfamiliar with submitting specimens to the public health lab could get specimens to DPHL. The meetings ensured that all public health sections provided consistent information and messages and the lab knew what to expect and other's expectations of the lab.

Thursday, April 30

The lab received both a telephone call and electronic reports from CDC that the initial 4 specimens from UD students were confirmed+



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SPECIAL POINTS OF INTEREST

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for swine-like flu A/H1. UD Student Health was notified of these results. After the Governor's approval, another press release went out with this information. Other activities on April 30 included:

- DPHL staff participated in a conference call with CDC and the Association of Public Health Laboratories to learn about transferring the technology for swine flu confirmation tests from CDC to state and some local public health labs. The lab would receive reagents over the weekend and needed to validate the test by showing comparable results on 5 specimens already confirmed by CDC. Delaware was fortunate to have already trained staff and the Food & Drug Administration approved influenza methodology running in the lab. CDC obtained an Emergency Use Authorization from FDA to use this same technology with swine flu primers and probes for confirmatory purposes. The swine influenza panel consists of a test for human seasonal influenza A, swine influenza, swine H1N1, and RNaseP (present in all human cells and used as a control). In order to test for influenza B or subtype human seasonal influenza A, additional testing is necessary.
- DPHL's Laboratory Information Management System (LIMS) specialist worked with DPH's Information Resource Management to develop queries addressing the urgent and insatiable thirst of the media and public health officials for swine flu testing lab data.
- CDC agreed to expedite shipment of 25% of the strategic national stockpile of Tamiflu for Delaware.
- NEHC at UD remained operational.
- DPHL worked with the Medical Society of Delaware, Delaware hospitals and SHOC to establish additional specimen collection kit pick up and drop off sites.
- Lab staff worked from 7 am to 10 pm to test specimens as soon as they arrived at the lab and reported results within hours.

- The newborn screening lab manager was reassigned to the virology lab and assisted with coordination of services, preparing reports, and keeping updated logs. Other staff from both newborn screening and microbiology re-familiarized themselves with the flu testing procedure and completed proficiency testing. They were on call to handle increased testing volumes.
- Staff from the chemistry lab packed and shipped specimens to CDC.

Friday, May 1

- DPHL reported a total of 21 probable cases and sent 10 more specimens to CDC for confirmation.

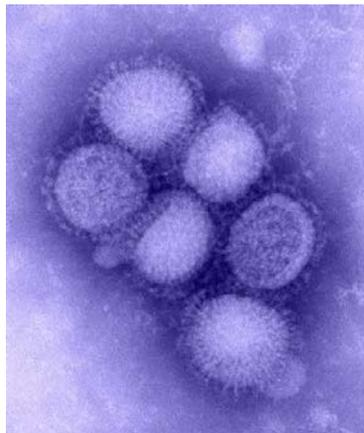


Image of the newly identified H1N1 influenza virus (CDC).

- A seven member team from CDC was dispatched to help in the investigation of UD cases.
- Lab couriers initiated late afternoon runs to pick up specimens in New Castle County.

Saturday and Sunday, May 2 and May 3

- Laboratory continued testing, finding probable positives outside the UD community.
- DPHL received swine flu PCR reagents from CDC.

Monday, May 4

- DPHL validated testing for swine Influenza and after reporting results to

CDC, received a letter from CDC attesting to the validation. Due to the sequestering of reagents for influenza testing by the CDC and the need to conserve reagents, seasonal influenza testing was placed temporarily on hold.

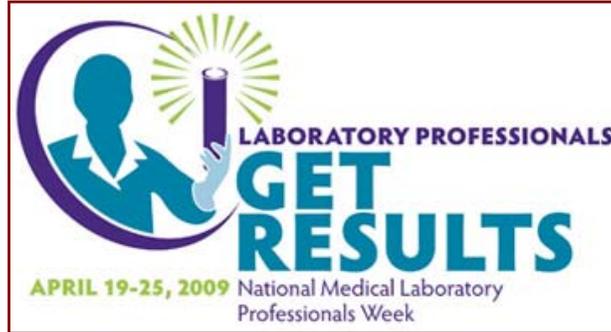
Tuesday, May 5

- DPHL developed a new test in LIMS for swine flu PCR, using CDC guidelines for result entry verbiage.
- DPH confirmed 33 cases of H1N1 influenza, up from 20 just the day before. The 13 new confirmed cases included 6, previously reported as probable, which were confirmed by the CDC lab. Those included four UD students plus two school-aged children reported as probable over the weekend.
- All of the confirmed cases reported mild symptoms and recovered after receiving medical treatment. DPH epidemiologists worked on contact investigations. At this time, there were no known hospitalizations in Delaware due to H1N1 influenza.

“What we see today with confirmations of additional cases from outside the University of Delaware is what we had been expecting, which is that H1N1 is spreading through our state, just as it is spreading throughout the country and the world, as the media and the public now know,” said Dr. Karyl Rattay, DPH director. “It is my opinion that our quick work in setting up a clinic and doing tests on the UD campus last week and our ability to now confirm our own cases are why we are showing confirmed case numbers higher than many other states. But, again, it has been and will continue to be expected that we will see new cases in Delaware, in the U.S. and in other countries.”

As of 05/26/09, the number of confirmed swine flu cases reached 108 spread among all three Delaware counties. We will continue this accounting of swine flu happenings in the next issue of LabOrator and fill in additional details for the May dates.

**NATIONAL MEDICAL LABORATORY PROFESSIONALS WEEK
OPEN HOUSE—APRIL 22, 2009**



The DPHL celebrated National Medical Laboratory Professionals Week April 19-23. This annual observance recognizes the vital contribution laboratories make to the quality of health care. We kicked off the celebration with a potluck lunch and trivia games on Monday and concluded with duck races and a barbecue on Friday. The highlight of the week, if not the year, was an Open House on Wednesday, April 22 which included tours of the laboratory, visits with laboratory partners, as well as informational displays provided by DPH programs, equipment manufacturers and providers of laboratory supplies. The displays highlighted public health and related programs and products. Outside in the parking lot, the Kent County emergency response vehicle, Kent County Society for the Prevention of Cruelty to Animals (SPCA) tent, and the 911 Mobile Response Unit were available for tours. Participants also had the opportunity to respond to a survey addressing the future of the public health laboratory system in Delaware*. Invited guests included public health officials, legislators, other state agencies and colleges and technical schools as well as the general public. Lab staff were honored to have Lt. Governor Matt Denn as the keynote speaker, highlighting the important work performed by our state public health lab. He singled out



Dr. Jane Getchell welcomes Lt. Governor Matt Denn



Participants listen to Lt. Governor Denn discuss the importance of public health laboratories



The Newborn Screening program sets up their display



Dr. Jane Getchell and Lt. Governor Matt Denn

The Delaware Public Health System Survey! Your input is essential as we move forward. Click on the link below to visit our website and take the survey:

<http://www.dhss.delaware.gov/dhss/dph/lab/labs.html>

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MORE PHOTOS FROM THE DPHL OPEN HOUSE

Below (left to right), microbiologist Jennifer Cascarino conducts a tour; the Newborn Screening program display; microbiologist Amanda Bundeck wears a different hat for the open house as a volunteer firewoman manning the Hazmat mobile unit; microbiologist Carrie Paquette Straub explains virology testing to Lt. Governor Matt Denn and Acting Director Henry Smith; the Food Safety program display; and the Department of Public Safety Incident Command mobile unit.



THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) WHY IS IT IMPORTANT FOR LABORATORIES?

Fred Franze, Quality Assurance Lab Manager and Donna Phillips-DiMaria, CLIA Inspector

The purpose of CLIA is to set minimum standards for all laboratories and to determine if laboratories are achieving those standards. The acronym "CLIA" stands for the Clinical Laboratory Improvement Amendments. Congress passed these amendments in 1988 establishing quality standards for all clinical laboratory testing to ensure the accuracy, reliability and timeliness of patient test results.

CLIA began in the late 1960's when problems arose in the cytology laboratories that read PAP smears. The personnel in these laboratories were overworked and had a very high error rate. Many women suffered or died because the cytologists had missed the early stages of cancer on the PAP smears. In 1967, the Clinical Laboratory Improvement Act was passed and the first laboratory regulations were born. The amendments to this Act, though passed in 1988, did not go into effect until February 28, 1992 when the new regulations were approved and published in the Federal Register.

The CLIA requirements are based on the complexity of the tests performed and not on the type of laboratory where the testing is performed. CLIA Brochure #5, "How to Obtain a CLIA Certificate", states that CLIA requires all facilities that perform even one test, including waived tests (see Certificate of Waiver, below), on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed. The Centers for Medicare and Medicaid Services (CMS) is responsible for ensuring CLIA compliance and administering the program. There are different types of certificates, all of which are effective for two years:

Certificate of Waiver (COW) is issued to a laboratory that performs only waived tests. A waived test is categorized as simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. The FDA determines if the test meets the criteria for waived status. An example of a waived test would be a urine pregnancy test.

Certificate for Provider Performed Microscopy (PPM) Procedures is issued to a laboratory in which a physician or midlevel practitioner performs specific microscopy procedures during the course of a patient's visit. The primary instrument used to conduct these tests is the microscope, and the procedures authorized are categorized as moderately complex.

Certificate of Compliance is issued to a laboratory that is conducting moderate and highly complex testing. This certificate is only issued after the laboratory has passed an on-site inspection that is conducted to ensure that the lab is compliant with all applicable CLIA requirements. Moderate and highly complex tests require a high degree of skill, training and education for accuracy. This type of testing is now referred to as "Nonwaived".

The Delaware Division of Public Health Laboratory (DPHL) holds two Certificates of Compliance. One certificate covers the main laboratory to perform testing in the following specialties: virology, molecular microbiology, bacteriology, parasitology, TB testing, newborn screening and blood lead analysis. The second certificate covers the 11 satellite labs located in the various Division of Public Health clinic facilities located throughout the state. Testing at these sites includes tests for sexually transmitted diseases (std) and std and pregnancy testing for family planning. The Director of the Public Health Laboratory is listed as the responsible individual for both of these certificates.

The following DPHL employees play an integral role with regards to CLIA compli-

ance of laboratories located in Delaware:

► The **quality assurance manager (QA)** is responsible for monitoring the quality assessment functions utilized by the various DPHL specialties to ensure compliance with CLIA requirements. Some of these functions include proficiency testing, identification and resolution of testing errors, personnel qualifications and training as well as quality control procedures. Additionally, the QA manager is responsible for providing technical oversight to the 11 satellite sites throughout the state.

► The **CLIA compliance officer** is responsible for inspecting all laboratories in the state that hold a Certificate of Compliance, and a certain percentage of labs that hold a Certificate of Waiver or Certificate for PPM Procedures. Additionally, this office will investigate any complaints received about any CLIA certified lab throughout the state. The compliance officer is required to pass an annual audit conducted by CMS to ensure that inspections, documentations and follow-ups are done correctly and in a timely fashion.

Some states have additional regulations for clinical laboratory testing and personnel requirements; however, the state of Delaware only follows CLIA guidelines. There are no additional requirements unique to Delaware.

To apply for a CLIA certificate in Delaware, download the CMS-116 CLIA application form from the CMS CLIA website and follow the directions to fill it out: <http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf>

Mail completed application to:

State of Delaware CLIA Program
DHSS DPH Laboratory
30 Sunnyside Road,
Smyrna, DE 19977

For further information about CLIA see the DPHL web site <http://www.dhss.delaware.gov/dhss/dph/lab/clia.html>

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the work done in the newborn screening program to keep our children healthy and help assure a bright future for our state. In his previous position as insurance commissioner, Lt. Governor Denn worked with the screening program and the PKU support group to help get legislation passed which provides for insurance coverage for special food and formula for children diagnosed with PKU & other inherited metabolic diseases. It was because of this shared commitment to infant and child health in Delaware that we invited him to help us celebrate Lab Week.

It was a great day for DPHL with 85 people coming through the laboratory. The entire week was full of fun and fellowship and served to lift the spirits of all the staff in spite of the specter of an 8% pay cut.

LIMS UPDATE

Kathy Gray, LIMS Administrator

The Laboratory Information Management System (LIMS) has been steadily growing since completion of the initial installation in June 2006. Currently, 430 users from over 250 agencies throughout Delaware have access to their client/patient/sample data in a secure online environment. The latest additions to LIMS are Christiana

Care Medical Center, both Kent and Milford campuses of Bayhealth Medical Center, Beebe Medical Center, Nanticoke Memorial Hospital, and La Red Healthcare Center. One local pediatric practice was extremely interested in having access, so it was added to the LIMS family as well. Other users include high school-based wellness centers, the University of Delaware, Delaware State University, the Office of Drinking Water, the Department of Natural Resources and Environmental Control (DNREC), the Department of Corrections (DOC), Westside Health, and Planned Parenthood Delaware. These users have the ability to input patient/sample data at the time of collection, thus providing more accurate information in a timely, efficient manner. They then access their reports directly online without waiting for them to arrive via regular mail. Many healthcare facilities are moving to electronic medical records. LIMS results can be sent to these electronic records, thus eliminating the need for a paper report. As we move forward, it is our hope to make LIMS accessible to any agency who desires to have their patient/sample laboratory data at the touch of their fingers.

EMPLOYEE NEWS

Welcome Greg Hovan! Gregory Hovan joined the microbiology section on February 18, 2009 as a microbiologist II. Greg graduated from Bridgewater State College in Bridgewater, MA with a BS in Biochemistry. He worked as a substitute teacher in the Sussex County school district and as a college tutor before joining the DPHL. Greg plays guitar in his spare time. We're delighted to have him here.



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



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

Jane P. Getchell, DrPH Director, Delaware Public Health Laboratory

Christina Pleasanton, MS Deputy Director, Delaware Public Health Laboratory

If you have questions regarding these articles or would like to receive a hard copy of this newsletter, contact the Delaware Public Health Laboratory at 302.223.1520.

To receive this newsletter by email, contact liz.moore@state.de.us.

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

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