

Bureau of Laboratories – July 2009

- **Public Health Lab – Jacksonville**
- **Public Health Lab – Pensacola**
- **Public Health Lab – Lantana**
- **Public Health Lab – Miami**
- **Public Health Lab – Tampa**

ACCOMPLISHMENTS

LabCorp contract – substantial savings for DOH

A panel comprised of representatives from the Bureau of Laboratories, Headquarters Purchasing and representatives from various county health departments, under the leadership of Cheryl Robinson, negotiated a renewal of the DOH agency term contract with LabCorp for laboratory services provided to the county health departments. It is anticipated that DOH statewide will save more than \$1 million per year.

Electronic Laboratory Ordering (ELO) roll-out

The purpose of LabWare Laboratory Information Management System (LIMS) Electronic Laboratory Order (ELO) is to enhance the functionality of LabWare LIMS to include the ability to receive and process electronic laboratory orders from the Department's Health Management System (HMS). The original intent of the ELO project was to replace the paper barcode requisition form used by HMS to order laboratory tests from the state's five public health laboratories. Furthermore, LabWare LIMS integrates with laboratory instruments, which eliminates manual data transcription for improved data quality. LabWare LIMS includes automated electronic ordering and reporting capabilities that result in improved accuracy, timeliness, and quality of data to BOL customers. - An average of almost 5,000 samples per day are processed through LabWare LIMS — 1.3 million samples each year.

Discontinuation of paper copies

All laboratory results generated in LabWare, the Bureau of Laboratories' Laboratory Information Management System are reported electronically through the Department of Health Cloverleaf Integration Broker within 1 hour of completion. The Cloverleaf Integration Broker then forwards the results to the Health Management System (HMS). In HMS, the laboratory results are 'posted' in the patient's record within hours of when the laboratory issues them.

The completion of the transition to LabWare and the roll-out of Electronic Laboratory Ordering (ELO) has created an exciting opportunity for the County Health Departments and the Bureau of Laboratories to save both personnel and monetary resources during these difficult financial times through the discontinuation of paper reporting of results for tests ordered through the HMS system.

Discontinuation of paper reporting for tests ordered at the Bureau of Laboratories through HMS means that:

- Laboratory results are directly posted into patient record and available within hours of reporting
- Clerical errors are less likely to occur
- Costs associated with printing and mailing the paper result will be eliminated
- Clinic staff will no longer have to open and sort the mail and file the results in the patient charts
- We will be using less paper - becoming a greener operation

CDC Influenza Electronic Data Exchange Interoperability Partnership Project

The Bureau of Laboratories received \$729,970 for the Influenza Electronic Data Exchange Interoperability Partnership Project, in cooperation with the Texas Department of State Health Services (TDSHS) to: I) Demonstrate an ability to share influenza surveillance laboratory test results from the Bureau of Laboratories to local, state, and cross-border international public health partners, as well as with CDC. II) Demonstrate an ability to share influenza surveillance laboratory test results from TDSHS to local, state, and cross-border international public health partners, as well as with CDC. III) Develop the ability to accept electronic orders for influenza reference tests and sharing electronic reference test results between partners and CDC. IV) Demonstrate a capacity for inter-state and international cross-border laboratory test result and test order exchange that supports surge capacity among laboratories by partnering with the state of Texas. And V) Develop a model multi-state cooperative data exchange strategy between Texas and Florida that incorporates national standards and best business practices.

New 3rd party billing contract

In late May, the Bureau of Laboratories reviewed vendor responses to its Request For Proposals for third party billing services; specifically for the processing of non-Medicaid claims for services provided by the Bureau's Newborn Screening Program. There were four proposals received, and subsequent to review of each, and scoring of each by a five member evaluation team, award was made to Public Consulting Group of Boston Massachusetts. A contract with the vendor was executed in mid-June 2009. Close working relationships have been established with the vendor's project manager, and their information and billing systems staff, and live claim data has been successfully transmitted to them for analysis and initial configuration of their processing systems. This is a contingency fee based contract in which the vendor receives 14% of the amount recovered for the first \$500,000 of reimbursements, 6% for the next \$500,000, and 3% of recovery amounts in excess of \$1,000,000. The previous supplier of these services had been receiving a fixed 13% fee, and in their response to the procurement request had proposed a new fixed fee of 14.25%. It is estimated that the tiered fee structure will save \$50,000 annually as compared to the previous contract, and \$65,000 when compared to the previous vendor's new proposal.

National Laboratory Response Network For Chemical Terrorism Meeting

The Bureau of Laboratories-Jacksonville hosted the 2009 National Laboratory Response Network For Chemical Terrorism (LRN-C) Laboratory Surge Meeting April 22-23, 2009, sponsored by Centers for Disease Control and Prevention (CDC). Staff from all 10 LRN-C Laboratories (California, Florida, Massachusetts, Michigan, Minnesota, New Mexico, New York, South Carolina, Virginia, and Wisconsin) were in attendance, in addition to representatives from the CDC, Federal Bureau of Investigation, US Food and Drug Administration, Florida Department of Environmental Protection, and Jacksonville Fire and Rescue Department.

GOALS FOR THE UPCOMING YEAR

- Attract staff into leadership and technical positions in order to maintain the level of readiness to fulfill the mission of the DOH Bureau of Laboratories, specifically addressing the Bureau of Laboratories-Miami Director vacancy.
- To continue seeking improvements in the business aspects of the Bureau of Laboratories.
- To increase the level of sophistication in laboratory testing in order to keep pace with changing technology.

- To update the physical structure of the laboratory facilities to assure that the five laboratory locations are in a constant state of readiness in order to provide a timely response to any situation requiring public health laboratory services; especially to ensure all 5 Bureau of Laboratories facilities are prepared with redundancy for the event of a power outage at the same level as a hospital facility.
- Implementation of After Action Report for Novel Influenza H1N1
- To continue seeking improvements in the business aspects of the Bureau of Laboratories
- Update Business Plan for 2009-2010 Fiscal Year. Fiscal Year 2008-2009, the Bureau of Laboratories developed a Business Plan, which should be updated for the 2009-2010 fiscal year.
- Linking Newborn Screening (NBS) specimen information with Vital Statistics records: The Bureau of Laboratories is evaluating the possibility to access Office of Vital Statistics' Live Birth data. This data exchange would reduce re-keying demographic data from the newborn screening card and would enhance the quality not only of the newborn screening program but the reporting of live births as well. This project includes electronic linkage of the state's more than 220,000 birth records and 300,000 NBS records in the future leading to future elimination of NBS data entry and reduction in turnaround time for result reporting. This linkage of NBS/Vital Statistics data and development of NBS electronic registration module is being piloted at the hospital level, with a hospital identified in Jacksonville, FL.
- 3rd party insurance – NBS - The Department of Health, through its Bureau of Laboratories, is the sole provider of Newborn Screening (NBS) testing services in Florida, as set forth in F.S. 383.14(1)(b). In section (3)(h) of that statute the Department is authorized to bill third-party payors for these services; however, there is no mandate that insurers or HMO's pay claims submitted by the Department for testing associated with the provision of these services. Because of this lack of mandate, payors are denying claims stating that the screening tests are not covered or medically required services, or that the Department of Health Bureau of Laboratories (the sole provider of NBS screening under FS 383.14) is not their contracted laboratory services provider. These payment claim denials create fiscal viability and stability issues within the NBS program. The Bureau of Laboratories estimates losing about \$2 to \$5 million per year.
- Performance Contracting - An initiative from the Great Ideas/Saving Money initiative of the Bureau of Laboratories produced a myriad of suggestions from rank and file Bureau of Laboratories staff. One major initiative is to conserve electricity. Dr. Jack Perman, Assistant Laboratory Director of the Bureau of Laboratories-Tampa has investigated this avenue, and will be leading the implementation. It is estimated that savings based on the current use could be as high as \$300,000 per year.
- Environmental Chemistry-Water Testing - State Statute (403.862) specifies that budget for the DOH water laboratory (Bureau of Laboratories-Jacksonville) shall come from DOH and DEP in a coordinated effort. In reality however, like other governmental chemistry laboratories in the state (specifically the DEP laboratory), the budget for the Environmental Chemistry Laboratory in the Bureau of Laboratories-Jacksonville came from two main sources of revenue: 1) Salaries in the laboratory were primarily supported by General Revenue (GR) monies; 2) Equipment service contracts and consumables were supported by recovery fees charged for the testing that was performed. It is

understood that future GR would most likely be reduced and that the laboratories needed to re-structure to support salaries from other sources.

- Improvements in the LIMS Sample Manager. In Environmental Chemistry, Bureau of Laboratories-Jacksonville, the Sample Manager was upgraded to the newest version, to have the ability to pull demographic data from the DOH. Bureau of Water Programs Database in Tallahassee, reducing the number of demographic data that required manual entry at Jacksonville. The new software version will also allow for the move to paperless reporting. Work is being done to produce all laboratory reports in a secure PDF format backed up by digital signatures. This effort will allow the counties to retrieve data directly online and eliminate the need to issue paper reports. In addition, to these efforts, the option of changing the Sample Manager LIMS system to Labware LIMS is being investigated.
- Changes for the Newborn Screening Dried Blood Spot (DBS) card: A working group is charged with revising the DBS card. The information collected on the card was not sufficient for efficient follow-up and/or was not accurate or complete for proper testing and billing.
- To increase the level of sophistication in laboratory testing in order to keep pace with changing technology - Rapid detection of multidrug resistance in tuberculosis patients - Tuberculosis (TB) continues to incur significant social, public health, and economic costs in the U.S. Costly TB outbreaks occur and multidrug-resistant and extensively drug resistant TB continues to spread. Altogether, TB related costs approach \$1 billion each year in the U.S. Florida identifies about 1,000 new TB cases each year out of almost 14,000 nationwide. In addition, Florida serves as a gateway to Latin America where multi-drug resistant TB cases are rising. In November 2007, the Bureau of Laboratories implemented on a limited basis as the first laboratory in the nation, a molecular-based line-probe assay to detect drug-resistant TB within 1-2 days instead of the traditionally 3 to 6 weeks in highly infectious patients. In July 2009, the Bureau of Laboratories will automatically perform this assay on newly diagnosed highly infectious acid-fast bacilli smear positive TB patients. This will provide the Department of Health with test results much faster which will enable caregivers to interrupt transmission of drug-resistant TB much earlier in the entire state. This enhanced capability will foster more appropriate treatment regimens avoiding the mistake of initiating treatment with ineffective first-line drugs. It is estimated that the average TB patient spreads the disease to 20 to 30 other individuals (or 2 per month) and the cost to treat one multi-drug resistant TB patient is more than \$350,000.
- To update the physical structure of the laboratory facilities to assure that the five laboratory locations are in a constant state of readiness in order to provide a timely response to any situation requiring public health laboratory services; especially to ensure all 5 Bureau of Laboratories facilities are prepared with redundancy for the event of a power outage at the same level as a hospital facility. For the past eight years the Bureau of Laboratories has been making incremental improvements to the infrastructure (facilities and instrumentation). However, there is still much more that needs to be accomplished to assure that the five laboratory locations are in a constant state of readiness in order to provide a timely response to any situation requiring public health laboratory services.
- Implementation of After Action Report for Novel Influenza H1N1 - From April 24-May 28, 2009, the FDOH BOL tested a total of 3,616 specimens. Of the specimens analyzed during that period: 72.3% (2,614) tested negative for Influenza, 19.9% (719) tested positive for Influenza A, and 4.7% (171) tested positive for Swine-Origin Influenza A (H1N1). Throughout this period, the BOL facilities in Jacksonville, Miami, Pensacola, and

Tampa collectively resourced the State of Florida's need to conduct public health surveillance and provided the only source of diagnostic testing.

- **Capability Summary:** The Laboratory Testing capability included the rapid detection, confirmatory testing, data reporting, investigative support, and laboratory networking to support ongoing public health surveillance for Swine-Origin Influenza A (H1N1). Major activities performed as it pertains to this capability include, but are not limited to: procedures used to test for H1N1; communications to and from the laboratory regarding H1N1 testing; maintenance of laboratory continuity of operations, and; human resources necessary to conduct laboratory surge. Human resources necessary to conduct laboratory surge. As noted in previous sections, laboratory surge requires that the BOL pull staff from other program areas to help test samples. BOL staff adapted well to this rapidly evolving public health emergency. They were able to quickly step in, receive training, and begin working on various roles in the laboratory testing process. Although staff adapted well early in the event and developed an efficient process to test H1N1 specimens, the ability to continue at this rate diminished. The various stages of testing were assigned to specific staff. These staff would repeat these procedures for many hours each day. This routine became monotonous and stressful and could have resulted in mistakes and possible compromises in safety. Each laboratory lost 1.5 employees through reductions in pandemic influenza grant funding. These positions would have significantly mitigated the personnel shortage. Most staff worked 10-12 hour shifts, six days per week. The long hours conducting this type of stressful work in the laboratory environment could not have been sustained for more than the two week peak testing period. Also, there are not enough people who are licensed/CLIA certified to conduct PCR testing on clinical specimens. There are unlicensed testing personnel who are able to perform PCR testing but this does not help. Due to the overall lack of personnel, laboratory technicians needed to perform non-technical tasks such as data entry, building of sampling kits, shipping of supplies, taking out trash, etc. Performance of these tasks detracted from the work of processing and analyzing specimens.