Section 9

Laboratory Status Report

The Bureau of Laboratories (BOL)

The Bureau of Laboratories (BOL) – a network of five laboratories located in Jacksonville, Lantana, Miami, Pensacola, and Tampa – provides population-based, diagnostic, screening, monitoring, reference, emergency, and research laboratory services, as well as collects epidemiologic (demographic) information to support the core public health functions of the Florida Department of Health (FDOH). Technical services, based on evolving community requirements, include screening and confirmation tests for biological and chemical threats and disease outbreak investigations. Agents tested for include a wide variety of viral, bacterial, and parasitic pathogens, such as mosquito- and arthropod-borne viruses, animal rabies, intestinal parasites, sexually transmitted diseases, tuberculosis, and human immunodeficiency virus (HIV). The Bureau also provides training to healthcare providers and laboratory scientists; tests samples from potable, environmental, and recreational water sources, pollution spills, and suspected contaminated foods; and certifies environmental and water-testing laboratories. The BOL provides laboratory screening of all newborns in the state for 34 genetic disorders, which, without detection and early treatment, can lead to death or severe physical and/or mental disabilities.

The BOL supports all 67 county health departments (CHD), other FDOH programs, physicians, hospitals, and numerous state and federal agencies by providing public health diagnostic, screening, and reference laboratory services.

Electronic Laboratory Ordering (ELO) Roll-Out

The BOL has been using Electronic Laboratory Ordering (ELO) from CHDs in the LabWare laboratory information management system since August 2008. With ELO, the BOL has the ability to receive and process electronic laboratory orders from the internal FDOH health management system (HMS). ELO eliminates the need for CHDs to use paper laboratory requisitions to order laboratory tests from the BOL five-laboratory system. Benefits to the state include:

- improved data quality. Data re-entry is not required for electronic orders as all patient data, provider data, and test request data delivered from HMS is automatically entered into the specimen record in LabWare;
- faster turn-around time by eliminating data entry, a primary source of delay in reporting results;
- lower cost of operation, as BOL resources used for data entry could be eliminated or used elsewhere.

ELO was rolled out to all CHD HMS sites in phases and was completed at the end of October 2008.

Electronic Laboratory Reporting (ELR)

All laboratory results generated in LabWare, the BOL's laboratory information management system, are reported electronically through the FDOH Cloverleaf Integration Broker within one hour of completion for use by CHDs and FDOH surveillance systems. The Cloverleaf Integration Broker forwards the results to the CHDs' HMS, and places the results in a central database where they are accessed by the Bureau of Epidemiology's reportable disease management system (Merlin), the Bureau of Sexually Transmitted Diseases' client management system (PRISM), and HIV/AIDS state surveillance staff. In the HMS, the laboratory results are "posted" in the patient's record within hours of the time the laboratory issues them, significantly reducing turn-around times. Additionally, this electronic data transfer, through the Integration Broker, makes all laboratory results for reportable (and non-reportable) diseases available to the Bureau of Epidemiology in Merlin. This eliminates the need for manual entry of these laboratory data into the Merlin system where they can be reviewed by epidemiologists for public health action, outside of the clinical management setting. Likewise, results for sexually-transmitted diseases are electronically transferred to the PRISM system. With ELR, epidemiologists and disease intervention specialists have access to the results within hours of reporting and no longer have to wait for paper reports. ELR also improves the disease reporting process by eliminating the reliance on laboratory staff to manually sort through paper results and make decisions regarding which results should be copied and forwarded to the appropriate Bureau for follow-up.

The completion of the transition to LabWare and the roll out of ELO have created an exciting opportunity for the CHDs and the BOL 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. The BOL no longer prints, sorts and mails hard copies of these lab results via the U.S. Postal Service to CHD and FDOH surveillance programs, although this process still occurs for non-FDOH ordering partners such as hospitals. This reduces the costs of paper, mailing supplies, postage, and staff time, which is a significant savings to the FDOH. In addition, the CHDs can avoid costs by eliminating the need to sort and file the incoming paper reports and the Bureaus of Epidemiology and Sexually Transmitted Diseases can avoid time and labor costs associated with manually entering data into their respective systems.

CDC Influenza Electronic Data Exchange Interoperability Partnership Project

BOL received $729,970 for the Centers for Disease Control and Prevention (CDC) Influenza Electronic Data Exchange Interoperability Partnership Project, in cooperation with the Texas Department of State Health Services (TDSHS), to do the following:

- demonstrate an ability to share influenza surveillance laboratory test results from Florida's BOL to local, state, and cross-border international public health partners, as well as with the CDC;
- 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 the CDC;
- develop the ability to accept electronic orders for influenza reference tests and sharing electronic reference test results between partners and the CDC;
- 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
- develop a model multi-state cooperative data exchange strategy between Texas and Florida that incorporates national standards and best business practices.

2009 Influenza A H1N1 Virus

The 2009 influenza pandemic began at the end of April and by June 19, 2009, BOL had tested 4,784 specimens for the 2009 influenza A H1N1 of swine origin; 869 were positive. This was an overall positivity rate of 18%. In the beginning, the CDC was the only testing laboratory able to confirm the novel influenza virus nationwide, leading to diagnostic delays. Within a week, the CDC provided the state public health laboratories with novel test kits under an Emergency Use Authorization from the Food and Drug Administration (FDA), requiring that the testing be performed only with a brand new platform, the ABI 7500FAST DX real-time PCR instrument. Additional staff were quickly trained in the use of this instrument by CDC-trained personnel in Tampa and Jacksonville in order to use these kits according to requirements of the federal Clinical Laboratory Improvement Act. In addition, staff at the BOL in Tampa trained scientists from the BOL in Miami and the BOL in Pensacola on this new test platform, while also simultaneously testing specimens. In the beginning, the BOL was tasked with providing diagnostic testing for healthcare providers in the state as testing was not available in the commercial setting. The BOL also conducted all influenza surveillance testing for the Bureau of Epidemiology. For the previous two years, the CDC Cooperative Agreement funding supported 1.5 FTEs at all five BOL locations, as part of Florida's pandemic influenza readiness plan. In 2009, the funding had been eliminated. Not having these additional FTEs during the initial H1N1 response significantly reduced the BOL's testing capacity. However, the Lantana and Pensacola laboratories were able to take on additional testing for rabies, which is usually performed by the same staff as influenza testing, thus freeing up portions of their time for additional influenza tests.

It was not until mid-summer that a commercial test became available, enabling non-public health laboratories to perform diagnostic testing for 2009 influenza A H1N1. Although some diagnostic

specimens continue to be submitted to the BOL, they were mostly from influenza-associated deaths, those with severe life threatening illness, outbreaks submitted by CHDs and from ILINet, the Florida influenza-like illness network of sentinel physicians. ILINet, in collaboration with the Bureau of Epidemiology, is designed to detect influenza virus strain changes.

Between April 25, 2009 and December 31, 2009, the BOL received 13,873 clinical samples for testing in response to the 2009 influenza pandemic. Of those specimens, 5,076 were positive for 2009 influenza A H1N1 influenza virus, 757 for seasonal influenza A, and 36 for influenza B. The Tampa and Jacksonville Laboratories continue to participate as collaborating laboratories for the World Health Organization Influenza Surveillance Network, accepting specimens from over 100 sentinel physicians in the state of Florida.

Revised Florida Guidelines for the Use of Nucleic Acid Amplification Testing for Tuberculosis (TB)

In January 2009, the CDC updated the guidelines for the use of nucleic acid amplification testing (NAAT) for TB. Since 1996, this test has been standard practice at the BOL, and now the CDC recommends the use of NAAT to become standard practice throughout the U.S. to ensure TB elimination. In collaboration with the Bureau of TB and Refugee Health and as a first in the Nation, the BOL recently rolled out the HAIN Genotype® MTBDR*plus*, a commercially available line probe assay that detects mutations associated with the majority of cases of rifampin (*rpoB*) and isoniazid (*KatG* and *inhA*) resistance, which is integral to the diagnosis and early detection of drug-resistant cases within our state. The HAIN test allows detection of multi-drug-resistant TB within one to two days instead of the traditional three to six weeks in highly infectious patients. This provides the FDOH with test results much faster, which enables caregivers to interrupt transmission of drug-resistant TB much earlier. This enhanced capability fosters more appropriate treatment regimens avoiding the mistake of initiating treatment with ineffective first-line drugs.

The increasing threat of multi-drug-resistant (MDR) and extensively drug-resistant (XDR) TB not only has a human price (more patients are dying of drug-resistant tuberculosis compared to patients with drug-susceptible TB), but also has an economic impact on healthcare. It is estimated that preventing a single case of MDR TB would save the U.S. healthcare system more than $250,000 and the average estimated hospitalization cost for treating a patient with XDR TB is $600,000, not including costs of outpatient care and related health interventions.

New 96-well Plate Method Development

A new 96-well plate method was developed for a Metabolic Toxins Panel (MTP) in urine by Liquid Chromatography/Tandem Mass Spectrometry. Staff scientists from the Chemical Terrorism Laboratory Response Network Level 1 Laboratory in Jacksonville (one of only ten laboratories nationwide designated for surge capacity by the CDC) converted the testing of MTP from a single-test analysis to a high-throughput method with results sent to the CDC Chemical Laboratory Response Network. This will greatly improve analysis response time for monofluroroacetate and monochloroacetate samples from a five-day to a two-day turn-around time.

Discontinuation of Clinical Chemistry and Hematology for A.G. Holley State Hospital

As of October 7, 2009, the BOL in Lantana discontinued clinical chemistry and hematology testing for A.G. Holley State Hospital. These specimens are now sent to LabCorp, the laboratory contracted by FDOH for these tests. Because of this, there is a slight delay in the turn-around times of the laboratory results, which was approved by A.G. Holley senior medical staff. However, staff from the BOL in Lantana continue to draw blood from patients. Staff will be shifted to other functions within the laboratory, including the send-outs of these specimens to LabCorp as a service to A.G. Holley State Hospital, and will record the results received into patient charts. This testing was discontinued at the BOL in Jacksonville and in Pensacola for the CHDs in the spring of 2008.

2009 Newborn Screening Morbidity Data

BOL in collaboration with FDOH Children's Medical Services manages the newborn screening program for Florida. The program screens for all disorders recommended by the March of Dimes and the American College of Medical Genetics as well as some with additional disorders, including cystic fibrosis, totaling 35 diseases and conditions.

Table 1. Newborn Screening Morbidity Counts, Florida 2009

Conditions	Count
Live Births	221,632
Confirmed Diagnosis by Florida Referral Centers	
Biotinidase Deficiency	0
Partial	6
Congenital Adrenal Hyperplasia	5
Congenital Hypothyroidism	68
Cystic Fibrosis	
2 mutations	23
1 mutation	10
Ultra-High IRT/No mutations	1
Galactosemia (G/G)	1
Variant	1
Sickle Cell	
Sickle Cell Anemia (SS)	130
Hemoglobin SC Disease (SC)	74
Sickle Beta Thalassemia (SA)	8
Disorders detected by Tandem Mass Spectronomy	32
Hearing Loss recognized through NBS Follow-Up Program	197