ARE WE THERE YET?
MOVING TOWARD INTEROPERABILITY

ALSO IN THIS ISSUE:
10 EXAMINING SEAFOOD FROM THE GULF
24 CONFERENCE RECAP
26 CHAT WITH CDC’S PHPR GURU
At The Baker Company, we not only share your passion for your work, but also the wider mission of most efficiently utilizing our limited natural resources. That’s why we are proud to introduce the SterilGARD e3, which offers a new standard in complete life protection—for you, your work and our environment. Its advanced technologies are engineered to provide the optimum balance of efficiency and performance, with extended filter life, reduced energy costs, and the most comfortable working environment in the industry. Making the world a better place just got a little bit easier.
Can You “Guess This Pathogen?”

Hints:
• Highly contagious
• Grows in the cells of the back of the throat and lungs
• During 2008, more cases of this were diagnosed than in any other year since 1997

To get the answer, visit www.aphl.org, click on “About APHL” and “Publications”

www.northropgruman.com/biodefense

▼ BIODEFENSE

When it comes to biodefense, Northrop Grumman is leading the way in biological threat detection, response technology, and services. From detection hardware such as the U.S. Postal Service’s Biohazard Detection System, to information systems that collect and analyze data for decision support, to our committed team at Northrop Grumman of more than 1,000 supporting our nation’s response to health threats, Northrop Grumman is ready to help protect the public from the largest — and tiniest — threats.
WE ARE RICH WITH INTANGIBLE BENEFITS

Pat Luedtke, MD, MPH, APHL president
director, Utah Division of Epidemiology and Lab Services

APHL’s incoming president always faces a dual reality: on one hand, there’s the symbolic blank slate of a new year, a fresh start, a reapplied focus—on the other, a full slate of ongoing projects, as well as public health or world crises that appear suddenly and routinely on our stage.

I would like to direct our focus to two issues this year: the value of APHL membership and the lab's role in health outcomes.

THE VALUE OF MEMBERSHIP

APHL is unique in its highly engaged membership. We take it for granted that it will always be that way. But as we strive to retain current members, maximize the value they receive from membership, and reach out to new members, we must do a better job communicating all that APHL offers.

We are rich with intangible benefits. Long-term members are acquainted with some of these; throughout the years, they have watched suggestions from APHL members emerge from meeting dialogues and land in the hands of dedicated member committees, where they grow into draft documents and then pilot projects and finally are put into practice at our own laboratories. Sometimes, our labs receive these improvements in hand with funding from external sources, monies that only appeared because of the strength and reputation of our association.

Our membership benefits aren’t as obvious as a discount card that we carry in our wallets—although we do offer an increasing number of travel scholarships, instrumentation and service contracts, and training supplies. Our member benefits are generally harder to categorize, but they are not slight or meager. As an organization, we need to do a better job of capturing, communicating, and making available these benefits—like the PHLIP program highlighted in this issue.

THE LAB’S ROLE IN PUBLIC HEALTH OUTCOMES

The impact of laboratory work is similar: we provide a host of intangible benefits to Americans and the world. As health reform changes our backdrop, we need to identify and clearly label the lab’s place in the health outcome continuum. (Health outcomes are simply a measure of the end result to the patient of any clinical intervention). Just as long-term APHL members understand the value membership has yielded, so do laboratorians understand that epidemiology and other programs are anchored through us. We perform tests that we know have powerful impacts on health, but we rarely translate that knowledge into clear language, nor do we trace our effect down the line to individual outcomes. We think the importance of our work is obvious. But, in reality, it isn’t; not to an outsider or to a policymaker. Our worth needs to be identified and emphasized.

Currently, the only projects in the clinical field being funded are those that are linked directly to health outcomes. Newborn screening is one easy way to illustrate a direct health outcome of our work: The faster we deliver results, the more likely an infant born with PKU can be saved from brain damage. Lab turnaround times continue to improve through technological innovation in testing and in data delivery. In Utah, we are working feverishly to receive birth data electronically from most hospitals in order to improve our data quality and turnaround times—and, consequently, the patient’s health outcome.

There is a “continuum of care” or “healthcare continuum” that begins when a patient first visits a doctor and ends when he or she is discharged from care. The lab’s role always appears somewhere in the middle of that continuum—namely, when we perform a test. We must begin looking upstream and downstream in that continuum to identify points where we can positively impact the patient’s health outcome.

This year, as our long-term initiatives progress toward completion, APHL leadership will cast a new focus on the lab’s involvement with health outcomes and on elucidating the values of membership. I have always been impressed with the quantity and quality of the association’s work, and I have no doubt that this will be another productive year.
Ongoing initiatives in the Laboratory Response Network include a pilot project to improve data transmission between reference laboratories and CDC, performance data studies to enhance response with evolving technologies, and efforts to expand relationships with first responders.

**LIMS INTEGRATION**

LRN laboratories are unable to transmit data directly from their facility’s laboratory information management systems (LIMS) to CDC, and must instead use an interim solution, the LRN Results Messenger application, to convey the information accurately and securely. To address this limitation, APHL and the LRN Program Office, in coordination with the Office of Surveillance, Epidemiology, and Laboratory Services (OSELS) at CDC, have engaged three pilot laboratories in a project to eliminate redundant data entry. This LIMS integration (LIMSi) process involves translating all of the LRN-biological assays and corresponding results into standard vocabulary and developing the codes needed to construct standard messages that can transport the data to CDC and other public health partners. The results of this pilot initiative will be presented at the 2010 LRN National Meeting.

**PERFORMANCE DATA STUDIES**

The LRN recognizes that public health threats, including biological terrorism and emerging infectious diseases, are dynamic and evolving in nature. As such, the regulatory component of the LRN-B program office engages partners, such as APHL and its member laboratories, to continually assess and characterize agents of interest, re-optimize existing assays and develop performance data for new and existing assays. These collaborations enable CDC and its partners to adapt to technology changes and ensure that a robust laboratory network is in place to respond to the next threat.

**OUTREACH TO FIRST RESPONDERS**

LRN reference laboratories, mainly public health laboratories, work with FBI and first responders to respond to unknown threats. Many federal agencies and partners are collaborating to develop standards for kits, devices and assays used in the field and to issue more comprehensive guidance on field screening. APHL and the LRN Program Office collaborated with the National Guard Bureau to issue guidance on the role of Civil Support Teams (CSTs) in support of the LRN. The 2010 LRN National Meeting will highlight this guidance and also feature model relationships with more traditional first responders across the US. The meeting will likewise address the ongoing challenges posed by a lack of standards for validation, proficiency testing and training for first responders.
LRN LEADERSHIP RELIES ON THE EXPERTISE OF NETWORK MEMBERS:
A BRIEF OVERVIEW OF KEY LEADERSHIP GROUPS

by Sikha Singh, MHS, specialist, laboratory response network

In 1999, the CDC, in partnership with the FBI and APHL, launched the Laboratory Response Network (LRN). Despite evolving resources, the LRN and its mission statement—the LRN and its partners will maintain an integrated national and international network of laboratories that can respond quickly to acts of chemical or biological terrorism, emerging infectious diseases and other public health threats and emergencies—have been put to the test successfully over the past decade.

APHL LRN OPERATIONAL WORKGROUP

First convened in 2007, the APHL LRN Operational Work Group provides member-driven feedback and recommendations to the CDC/Division of Preparedness and Emerging Infections (DPEI)/Laboratory Preparedness and Response Branch (LPBR), to improve the quality of products and services provided by the LRN program office.

To date, seven in-person meetings of the Work Group, augmented by frequent virtual communications, have addressed pertinent matters such as protocol and algorithm revisions, assessment of reagents, proficiency testing implementation, enhancements to electronic data messaging and evaluation of the network. The group has provided guidance on surge capacity assessments and models to assess capacity, improvements to LRN biological agent protocols and strengthened biosafety language for LRN laboratorians working with high-risk unknown environmental samples.

The utility of this group is measured by quantifiable quality improvement recommendations, the progress of which is tracked in real-time with frequent status updates offered by the LRN program office. This partnership of experts convening regularly to discuss opportunities, promote transparency and increase collaboration within the network exemplifies the paradigm shift that the LRN-B adopted at its inception, whereby a decentralized approach utilizes the expertise of many in working toward a unified and consistent goal.

JOINT LEADERSHIP COMMITTEE

The Joint Leadership Committee (JLC), formed to address strategic and high-level operational issues within the LRN, is comprised of founding partner representatives from APHL, CDC and the FBI and works to develop recommendations on strategic direction, growth, resources and operational policies.

LRN PARTNERS WORKING GROUP

The LRN Partners Working Group, created to discuss protocols, proficiency testing and other operational items across the multiple laboratory networks, allows key stakeholders to provide agency and organizational project updates, and to discuss all-hazards preparedness and the role of the LRN in broad public health initiatives. As a result, federal agency and private sector partners are able to network, share useful information on new preparedness initiatives, and collaborate on laboratory issues.

ABOUT THE LRN

The Laboratory Response Network (LRN) was founded in 1999 to prepare and respond to potential acts of bioterrorism. In 2003, the LRN expanded its capabilities to address chemical as well as biological threats. The chemical component of the LRN, abbreviated “LRN-C,” links 62 state and local public health laboratories throughout the US and its territories. LRN-C laboratories work together as a true network during emergencies and collaborate on multi-state exercises that simulate a chemical emergency. These exercises allow CDC and public health laboratories to test and refine their plans and preparations. Such planning and coordination will translate into lives saved. As a founding member of the LRN, APHL continues to collaborate with LRN laboratories, CDC and FBI, among other partners. APHL member state public health laboratories make up the biological and chemical laboratory components of the LRN. APHL works to maintain the LRN and facilitate communications between the laboratories and CDC.
NEW CDC GUIDELINES FOR TARGETED TB TESTING

GUIDELINE HIGHLIGHTS

The T-SPOT®.TB test may now be used in place of the tuberculin skin test (TST) in all situations in which the CDC recommends tuberculin skin testing.¹

Targeted Testing Specific Recommendations:

- “An IGRA is preferred for testing persons who have received BCG.”¹
- “An IGRA is preferred for testing persons from groups that historically have low rates of returning to have TSTs read.”¹

Are you challenged by:

- BCG vaccinated individuals?
- Two-step new hire testing?
- TST non-returners?
- TST reliability?

Eliminate these headaches with a new, SIMPLE solution.

CALL TODAY
1-877-59 TBLAB
Visit: TargetedTBtesting.com

Note: IGRA (Interferon Gamma Release Assay) is a TB blood test. | ¹MMWR 2010;59:(No. RR-5): 1-25.
T-SPOT and Oxford Diagnostic Laboratories are trademarks of Oxford Immunotec, Ltd. | © 2010 Oxford Immunotec, Inc. All rights reserved. | JACDC-ODL-US-V1
ENVIRONMENTAL DISASTER HITS THE GULF

by Erinna Kinney, MPH, specialist, environmental laboratories

On April 20, 2010, cascading events associated with a deadly explosion on the oil rig Deepwater Horizon resulted in the largest continuous oil-generated environmental disaster in US history. Leased by British Petroleum (BP), the Deepwater Horizon sank in 5,000 feet of water, triggering the collapse of the riser—a 5,000-foot pipe that connected the well at the ocean floor to the surface drilling platform—and the discharge of vast quantities of crude oil into the Gulf of Mexico. An estimated 92 to 225 million gallons of oil have entered the gulf, based on projections by the US Department of Energy, BP and a collective of scientific experts. Affected states include Louisiana, Alabama, Mississippi and Florida with approximately 129 miles of their Gulf Coast shoreline currently exhibiting moderate to heavy oil impacts, and another 527 miles demonstrating light to trace oil impacts.

BP spearheaded several attempts to stop oil flow at the source, including the installation of a new containment cap assembly on July 12, 2010, and completed plans to cease oil flow from the deep-water well via "static kill" on August 6, 2010, with a future option to perform a "bottom kill" to permanently seal the well by mid-September. As a primary means of addressing the oil spill in the waterways, BP has utilized dispersants (chemicals that adhere to oil and "disperse" amongst the water column). Methods to mitigate the effects of the oil spill include the deployment of “booms” (11 million feet, to date), construction of sand berms, burning the oil and even piloting Kevin Costner’s Ocean Therapy—a vacuum-device that employs high-speed centrifuge to separate the oil and heavier water.

APHL’S IMPACT ON LABORATORY RESPONSE

APHL has been working with affected states and federal partners to coordinate the response from a laboratory and scientific perspective. APHL convened an information session in May with more than 120 participants from across the country and various disciplines, including epidemiologists, occupational health experts, state health officials, food safety regulators and environmental health professionals. Federal representatives from the FDA, EPA, CDC, National Institute of Occupational Safety and Health (NIOSH) and National Oceanic and Atmospheric Administration (NOAA) were also in attendance.

At the 2010 APHL Annual Meeting and Fourth State Environmental Laboratory Conference in June, APHL orchestrated a late-breaking plenary session to provide informative situational updates and allow affected states to discuss questions and needs. A second session focused on methodologies for measuring seafood safety following an oil spill.

Other major APHL response initiatives include:

- Establishing the eoc@aphl.org email information center to provide technical assistance and address oil spill issues within the laboratory community.
- Serving as the organizational and informational hub for environmental, agricultural and public health laboratories involved in the response.
- Participating in other federal stakeholder calls and meetings (i.e., FDA, CDC, ASTHO, Association of Analytical Communities) to monitor the broader response and give updates to the laboratory community.
- Maintaining communication and engagement with federal partners (EPA, CDC, NOAA, FDA) and affected states (Louisiana, Mississippi, Alabama, Florida, Texas).
- Utilizing communication and media vehicles including regular email updates to members, the APHL website, Twitter and Facebook.
- Conducting an affected states’ laboratory needs assessment survey. Salient results emphasized the need for funding baseline testing, faster/higher throughput methods, increased workforce, instrumentation and other supplies.
- Forming two workgroups: Polycyclic Aromatic Hydrocarbon (PAH) Detection Workgroup to coordinate research and PAH method development among states and help them navigate a path to FDA/NOAA for approval of use and the Alternative Markers Workgroup to focus on alternative markers of oil contamination in seafood. These workgroups have since been merged into the Gulf Seafood Safety Response Work Group.

APHL will continue to monitor and address the laboratory needs of the affected states. APHL will work with members, federal partners and the greater laboratory community to provide the most current and accurate information on the oil spill response. For more information, contact APHL at eoc@aphl.org. To access Gulf Oil Spill-related guidance and methodologies, please visit APHL’s Environmental Health Program site at http://bit.ly/d5uFFp).
GREENING LABORATORIES AND BEYOND
by Jennifer Pierson, MPH, senior specialist, environmental health

Green chemistry, one of the latest trends in environmental responsibility, is the use of sustainable chemicals and processes that result in less waste, safer outputs and reduced pollution.

APHL joined the green movement formally with the adoption of an environmental responsibility policy in 2008 (See http://bit.ly/bXSrT9f). Through this policy, APHL is working to promote actions that take into account its environmental impact and to encourage members and staff to do the same. Internal activities include educating staff on green activities, applying green principles to office supplies and promoting the use of mass transit, both when commuting and on travel. External activities focus on providing laboratories with a forum to share green knowledge and practices with other member laboratories.

Then, in 2009, the APHL Board of Directors created a new taskforce, the Healthiest Laboratory Initiative (HLI), comprised of members interested in going green and encouraging healthy behaviors. The HLI developed a self-evaluation tool to help laboratories foster environmental responsibility and healthy personal choices in the workplace and beyond.

At the 2010 annual meeting, APHL, with the support of HDR/CUH2A (a large architectural, engineering and consulting firm) awarded the first Healthiest Laboratory award to the laboratory with the most points on the self-evaluation. First place went to the Texas Public Health Laboratory. Susan Neill, PhD, MBA, the laboratory director and APHL’s immediate past president, accepted the award and will select a green prize from a list supplied by HDR/CUH2A. This year’s runner-up was the Arkansas Public Health Laboratory. APHL will send the evaluation to member laboratories each year to encourage green practices and track progress.

Laboratories are changing physical structures to save energy, and are also changing bench level operations. Green chemistry, one of the latest trends in environmental responsibility, is the use of sustainable chemicals and processes that result in less waste, safer outputs and reduced pollution. EPA has twelve principles of green chemistry, the first of which is to prevent waste before it is created. Laboratories can do this by reducing the use of solvents and other harmful chemicals.

The American Chemical Society hosts a Green Chemistry Institute to encourage innovation and knowledge-sharing. Many other state laboratories and universities are following this trend and greening their laboratory practices. APHL is interested in helping laboratories go green, and several members submitted their green practices to the growing APHL Member Resources Center. To access or contribute information to this topic, see www.aphl.org/memberresources/.
**BRAVO, BOTSWANA!**
**LABORATORY ACCREDITATION CONTINUES APACE IN AFRICA**

by Nancy Maddox, writer

This summer, Botswana’s Bamalet Lutheran Hospital (BLH) laboratory—a district-level laboratory in this landlocked southern African nation—secured accreditation from the South African National Accreditation System (SANAS), making it the first accredited clinical lab in its health district and one of the first in the country.

This success, say laboratory experts who work in the region, is especially important for two reasons. First, since 2008, the BLH laboratory has been working with the Botswana Bureau of Standards (BOBS) to improve its quality management systems and work toward applicable International Organization for Standardization (ISO) standards.

Laboratory expert Ebi Bile, BSc, MA, who oversees laboratory support activities in CDC’s Botswana office (CDC/BOTUSA), said the accreditation is “great news” because it was achieved with the “technical support of a local structure, BOBS,” in line with the in-country capacity building goals stressed in the latest targets for the US President’s Emergency Plan for AIDS Relief (PEPFAR), a US aid program begun in 2003.

Second, the attainment of ISO standards by a medical laboratory in this developing nation bodes well for a nascent World Health Organization (WHO) effort to provide African laboratories with stepwise recognition of their evolving fulfillment of ISO standards, rather than pass/fail grading. John Nkengasong, PhD, chief of the international laboratory branch of CDC’s Global AIDS Program and co-chair of the PEPFAR Laboratory Technical Working Group, celebrated the success in an e-mail. “Bravo! Bravo!” he wrote. “This [milestone] clearly shows that the WHO AFRO laboratory accreditation program...will be scalable, affordable and practical at all levels of the health system...What an achievement!”

In addition to the assistance provided by BOBS and BOTUSA, APHL provided significant support to the Botswana National Quality Assurance Program by developing a five-year strategic plan (2002-2007) to coordinate the development and implementation of the Quality Management System for all health laboratories in the country. APHL also linked the BLH laboratory with SANAS and assisted with instrument calibration and maintenance. APHL’s Botswana-based consultant is working with five additional laboratories that are working toward accreditation by SANAS—the preeminent accreditation body in the 14-nation Southern African Development Community.

---

**We Stand Behind Your Lab Testing.**

Our expertly engineered laboratory glassware washers are designed and tested to outlast the competition. We also ensure our results so you can successfully deliver yours.

Call for a free quote and ask about our cleaning guarantee.

☎ 800.991.9380
✉ proinfo@mieleusa.com
🔗 labwasher.com

---

---
DETECTING PAH IN SEAFOOD FROM THE GULF OF MEXICO
BUILDING COMPREHENSIVE SEAFOOD SAFETY TESTING PROGRAMS
by Kirsten Larson, senior specialist, food safety

Following the Deepwater Horizon oil spill in the Gulf of Mexico, APHL reached out to affected member laboratories to assess immediate and upcoming needs and provide assistance. Seafood safety and testing were an early concern among laboratories. Affected member states anticipated the submission of hundreds of seafood samples for testing in the coming weeks and months, both for re-opening of closed fishing waters and enhanced surveillance.

In collaboration with the National Oceanic and Atmospheric Administration (NOAA), the FDA responded very quickly to concerns about seafood safety in part by developing a protocol for re-opening oil-impacted areas closed to seafood harvesting. A key piece of the re-opening protocol involves the chemical analysis of seafood for polycyclic aromatic hydrocarbons (PAHs).

A NOAA-developed PAH method is the current gold standard for PAH detection in seafood. The NOAA method was used to test seafood following the Exxon Valdez oil spill in 1989, as well as several subsequent spills; it has withstood scrutiny in both the scientific and legal communities. However, this method is complex, time-consuming, and best suited for small sample sizes. Due to its complexity and resource requirements, the NOAA method is challenging, if not impossible, for many labs to bring up. Several laboratories have expressed concern with regard to testing availability and sample sizes.

APHL PAH DETECTION WORKGROUP

Based on discussions with federal partners, members and key stakeholders at two late-breaking sessions during the 2010 APHL Annual Meeting, APHL convened a PAH Detection Workgroup to discuss state and local activities related to PAH detection in seafood samples. The workgroup's main goal is to provide a communication venue to discuss response initiatives, help coordinate individual laboratory’s research activities and then facilitate FDA/NOAA approval of those methods.

The PAH Detection Workgroup has held regular calls, which have already provided benefits to members and federal participants. Participants have discussed seafood testing needs, especially among the affected Gulf States; identified current and perceived challenges; and have proposed solutions to issues such as funding and laboratory capacity. Through the workgroup venue, participants have discussed validation requirements for alternate PAH methods, and members have interacted with federal partners with the authority to approve such methods. Workgroup members are aware of current, ongoing research efforts by federal partners and other participating laboratories and are notified of funding opportunities, inter-laboratory comparison exercises, upcoming meetings and webinars, and other items of interest.

NEXT STEPS

Due to ongoing concerns from the public and scientific communities regarding seafood safety, the PAH Detection Workgroup will merge with APHL’s Alternative Markers Workgroup and continue exploring the need to develop methods to detect alternate markers of seafood contamination. APHL will continue bringing members and federal partners together to build a comprehensive response to seafood safety testing.
If you’re looking for clearly better MS results, Agilent has the answers. With a 37-year track record of innovation and the industry’s largest installed base, Agilent’s best-in-class portfolio of MS technologies delivers what you expect from a mass spectrometry leader. Superior analytical performance, and 24/7 Agilent reliability to maximize your lab’s uptime and productivity. Intelligent, easy-to-use software to help you get excellent results. And end-to-end MS workflow solutions to help you generate better results, faster than ever.

© Agilent Technologies, Inc. 2009

LC/MS, GC/MS, ICP-MS and MassHunter Software
Agilent’s full spectrum of MS solutions can match your lab’s analytical needs and budget.

www.agilent.com/chem

Our measure is your success.
SAVE MONEY WITH CDC HEPATITIS C SCREENING RECOMMENDATIONS

by Kelly Wroblewski, MPH, MT(ASCP), manager, HIV, viral hepatitis, STD and TB programs

A recent APHL survey indicated that several public health laboratories may be unaware of existing CDC guidelines for hepatitis C virus (HCV) antibody testing. Guidelines for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus, released in 2003, stresses the importance of performing supplemental testing on specimens that test positive by anti-HCV Enzyme Immunoassay (EIA)³.

Supplemental testing is particularly important in low-prevalence settings to exclude false positive screening results. Available supplemental tests include the recombinant immunoblot assay (RIBA) and nucleic acid amplification tests (NAAT) for HCV RNA. The RIBA can be performed on the same specimen that was collected for the anti-HCV test and is the more cost-effective option. While NAATs are more expensive and require a different specimen, positive NAAT results indicate the presence of active HCV infection while a positive RIBA only indicates the presence of HCV antibodies. However, a positive anti-HCV screening test and negative HCV NAAT require follow-up with a RIBA1. Detailed information on acceptable HCV screening algorithms is available on the CDC’s Division of Viral Hepatitis web page at www.cdc.gov/hepatitis.

More specific recommendations advise laboratories to perform supplemental anti-HCV testing only on specimens with anti-HCV EIA signal-to-cut-off (s/co) ratios greater than a predetermined value. The report cited data that indicated that positive anti-HCV EIA results for specimens with s/co ratios greater than or equal to that predetermined threshold are highly predictive of true anti-HCV status, signifying that supplemental testing is not necessary. Implementing this practice would reduce the need for anti-HCV supplemental tests, thereby reducing costs. Table 1 lists the recommended s/co thresholds for all FDA-licensed HCV screening test kits.

According to the 2009 APHL Viral Hepatitis Testing Survey, some public health laboratories were not following these recommendations. Only 13 of 29 laboratories reported performing supplemental HCV testing as recommended in CDC guidelines. Six laboratories report only providing supplemental testing upon physician request, leading to a potential greater likelihood of false positive results. Three laboratories reported performing supplemental testing on all anti-HCV positive specimens, missing an opportunity to conserve laboratory resources². To view the full APHL Viral Hepatitis Testing 2009 Survey Report, visit www.aphl.org/hepsurvey.

Table 1: FDA-licensed anti-HCV kits with recommended s/co thresholds for determining supplemental testing requirements.

<table>
<thead>
<tr>
<th>Screening Test Kit Name</th>
<th>Manufacturer</th>
<th>Assay Format</th>
<th>Signal-to-cut–off ratio predictive of a true positive ≥ 95% of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ortho HCV Version 3.0 ELISA Test System</td>
<td>Ortho</td>
<td>EIA (Enzyme Immunoassay)</td>
<td>≥ 3.8</td>
</tr>
<tr>
<td>Abbott HCV EIA 2.0</td>
<td>Abbott</td>
<td>EIA (Enzyme Immunoassay)</td>
<td>≥ 3.8</td>
</tr>
<tr>
<td>VITROS Anti-HCV</td>
<td>Ortho</td>
<td>CIA (Chemiluminescent Immunoassay)</td>
<td>≥ 8.0</td>
</tr>
<tr>
<td>AxSYM Anti-HCV</td>
<td>Abbott</td>
<td>MEIA (Microparticle Immunoassay)</td>
<td>≥ 10.0</td>
</tr>
<tr>
<td>Architect Anti-HCV</td>
<td>Abbott</td>
<td>CMIA (Chemiluminescent Microparticle Immunoassay)</td>
<td>≥ 5.0</td>
</tr>
<tr>
<td>Advia Centaur HCV</td>
<td>Bayer</td>
<td>CIA (Chemiluminescent Immunoassay)</td>
<td>≥ 11.0</td>
</tr>
</tbody>
</table>

References:
RECAP OF THE NORTH AMERICAN LABORATORY SUMMIT FOR INFLUENZA:
CROSS-BORDER COLLABORATION CRITICAL TO INFLUENZA RESPONSE
by Lab Matters staff reports

APHL, in collaboration with the Canadian Public Health Laboratory Network (CPHLN) and the Mexican Institute of Diagnostic and Epidemiological Reference (InDRE), held the 2010 North American Laboratory Summit for Influenza in Vancouver, British Columbia, August 10-11. APHL and CPHLN held the first bi-national summit in 2008. Dedicated to public health lab partnerships and exchange of scientific information, the North American Laboratory Summit was a tri-national event centered on improving border relationships and enhancing collaboration among North American countries and their respective laboratory systems.

The summit provided participants with information about public health threats and ongoing preparedness activities such as biosafety training, updates on technical activities for influenza testing, modeling and surge capacity, and the vast support provided by CDC to the international community for testing. Speakers emphasized not only the value of network-building to exchange laboratory information, but also the importance of communications between countries across the border during outbreaks.

CHALLENGES AND SOLUTIONS

Communication was among the most challenging issues noted, including ongoing/routine communication at the local, state and provincial levels; technical support for laboratory issues; and standard operating procedures across jurisdictions. The need for a single forum for lab communications and exchange of information as well as ensuring that laboratories are represented in national planning efforts (such as the Canadian-US-Pan-Border Public Health Council) were noted as key opportunities towards improving cross-border collaboration. APHL will continue to work with CPHLN, InDRE and other partners to address these challenges.

KUDOS FOR LABORATORY RESPONSE

Speakers highlighted the success of Mexico’s public health laboratory, InDRE, in achieving a system-oriented response to flu and other infectious diseases (via a network of 31 public health laboratories), and the strong cross-border collaboration between British Columbia and the Washington State Public Health Laboratory during the 2010 Winter Olympics.

A report from the summit will be issued soon and distributed to participants directly and to partners via APHL’s weekly newsletter, e-Update. For questions about the summit, contact Tricia Aden, manager of influenza programs at tricia.aden@aphl.org.
SUSTAINING PHL SURVEILLANCE FOR HIV-2 INFECTIONS
by Kenneth Landgraf, MS, specialist, HIV programs

Two years after the identification of the Human Immunodeficiency Virus Type 1 (HIV-1), a distinct but related type of HIV was isolated from a West African AIDS patient. Although endemic in many African countries, HIV-2 infections remain rare in the United States. However, continued surveillance is critical to monitor its spread and provide the highest quality laboratory testing.¹

In March, APHL and CDC convened the 2010 HIV Diagnostics Conference to review available evidence and discuss potential updates to the HIV diagnostic testing algorithm. Though HIV-2 infection remains relatively rare in the United States, data indicate that cases are likely to exist in every state. As such, it remains important for the US to test for HIV-2 and have assays capable of differentiating HIV-1 from HIV-2.²

Several attendees at the HIV Diagnostics Conference questioned the necessity of such testing, especially in areas of the country where HIV-2 has not been reported frequently, such as the Midwest. However, recent findings have shown that testing for HIV-2 is important in all areas of the country. Dr. Michael Pentella, associate director of the University of Iowa Hygienic Laboratory, states, “We have identified two HIV-2 infections in recent years that may have been missed if thorough laboratory testing was not conducted. Public health laboratories, through their ability to identify difficult infections like HIV-2 and acute HIV-1 infections, make a significant contribution to HIV prevention efforts.”

The most recent APHL HIV Diagnostics Survey found that the most common approach to identifying HIV-2 infection is use of an HIV-1/2 differentiating assay to resolve indeterminate or discordant western blot results.³ Confirmatory testing at CDC is recommended for specimens that test positive for HIV-2 by HIV-1/2 differentiation assays or are from patients at risk of HIV-2 infection.

Public health laboratories will continue to play an important role in the surveillance of HIV-1 and HIV-2. As new diagnostic algorithms are proposed and studied, APHL and CDC will promote strategies to reduce costs and increase surveillance capacity for difficult HIV infections.

¹ CDC. Factsheet: Human Immunodeficiency Virus Type 2. October, 1998.
² The conference presentations are available online at www.hivtestingconference.org
LAOS SHOWS DRAMATIC GAINS
THE LATEST IN THE INTERNATIONAL INFLUENZA LABORATORY CAPACITY ASSESSMENT PROJECT
by Erik Reisdorf, CLS (M) NCA, team leader, Virology Laboratory, Wisconsin State Laboratory of Hygiene

In 2009 and 2010, I participated in the international influenza laboratory capacity review project supported through APHL by the CDC Influenza Division Cooperative Agreement. APHL members and CDC have assessed influenza laboratory diagnostic capacities in approximately 28 countries, throughout Africa, Eastern Europe, South America and Southeast Asia. CDC and APHL developed a capacity review tool that helps resource-limited countries build laboratory capacity for influenza diagnostic testing, as well as to identify strengths and opportunities to improve laboratory practice. These efforts will improve global influenza surveillance, and guide international policy and resource decisions.

The project involves on-site visits to administer the influenza laboratory capacity review tool, which collects in-depth information on all aspects of a lab’s diagnostic capacity including virus culture, genetic sequencing and molecular diagnostics. The assessment documents laboratory equipment, laboratory procedures, surveillance systems and testing algorithms. In addition, the tool helps identify areas of need including the procurement of critical equipment and reagents, training needs and technical assistance.

One of the international laboratories I had the opportunity to visit has shown dramatic improvements in its influenza diagnostic capacity during the past several years. In March 2010, I visited the National Center for Laboratory and Epidemiology (NCLE) in Vientiane, Laos. Established in 2006, the influenza laboratory initially performed only conventional RT-PCR for the detection and sub-typing of influenza viruses. APHL member Dr. Rick Alexander, director of California’s Contra Costa public health laboratory, provided technical support for this initial testing. Since Alexander’s visit three years ago, the laboratory has undergone amazing progress, which I was able to witness firsthand. The NCLE has acquired the capacity for cell culture and influenza virus isolation in its new BSL-2 laboratory. It now has a lab-based surveillance system in place and routinely performs Real-Time PCR for the detection and sub-typing of influenza viruses along with conventional PCR for other respiratory viruses.

Due to limited resources, some international public health laboratories are faced with many challenges, including the procuring and sustaining of equipment, supplies and reagents. With no in-country distributors, it is not uncommon for it to take more than a month to obtain critical reagents from neighboring countries. The NCLE has overcome this challenge by developing an electronic inventory database, which helps staff track the inventory and ensure that reagents are available.

Laos’ NCLE is now applying to the World Health Organization for recognition as a National Influenza Center (NIC). Most countries in Southeast Asia have at least one laboratory that has obtained NIC status. The March 2010 capacity review produced the necessary documentation to support the lab’s NIC application. This status is a remarkable achievement considering the lab’s day-to-day challenges.

These assessment experiences have been a unique and mutually beneficial experience. I have been able to provide technical assistance and recommendations for improvement while gaining useful insight on developing influenza surveillance and laboratory diagnostic systems. I look forward to continued participation, providing support to the international community through technical assistance that encourages global influenza surveillance activities.
ARE WE THERE YET?
MOVING TOWARD INTEROPERABILITY

by Nancy Maddox, writer
As perhaps only an emergency of this magnitude could, 2009 H1N1 spotlighted the gaping hole in US emergency preparedness: the general absence of interoperable electronic messaging systems to transport disease data from PHLs to health authorities through a secure channel in near real-time.

April 24, 2009, was the first day of the 2009 Influenza A H1N1 crisis in the San Antonio Metro Health District (SAMHD) Laboratory. In the days and weeks that followed, the laboratory, which serves the 2.4 million residents of Texas’s south central health region, implemented a brand new CDC protocol to confirm H1N1 infection and ramped up its flu testing by more than seven-fold.

Patricia Blevins, MPH, the lab’s bioterrorism coordinator, recounted those harried days. There was insufficient refrigerator space to store specimens; not enough testing reagents. The laboratory director pulled staff from rabies testing, water testing and bacteriology to help with everything from prepping nasal swabs to answering the door. Phones rang “off the hooks.”

Despite all these challenges, however, one problem was paramount.

“Reporting,” said Blevins, “was the jugular of our process. It was the absolute killer.”

And so it was in many public health laboratories across the country.

While information technology (IT) innovations have streamlined communications in many business sectors, public health laboratories (PHLs) today still rely on a hodgepodge of processes—some old, some new—to send critical disease surveillance data to local partners and to state and federal health authorities.

According to APHL survey data, during the 2009 H1N1 pandemic, six state public health laboratories sent test data to the CDC via facsimile and nine labs aggregated data in Excel spreadsheets, which they forwarded via email. At least one state laboratory was unable to send data to the agency during the event at all, citing “insufficient staff to handle this [task] at this time.”

Even among the subset of state public health laboratories that sent surveillance data via dedicated, internet-based mechanisms—such as the CDC’s Public Health Laboratory Information System—some were still doing manual data entry.

As perhaps only an emergency of this magnitude could, 2009 H1N1 spotlighted the gaping hole in US emergency preparedness: the general absence of interoperable electronic messaging systems to transport disease data from PHLs to health authorities through a secure channel in near real-time.

“The role of the PHL is to provide data that can be utilized from a surveillance and epidemiology standpoint,” said Glen Baker, MD, director of the Arkansas Public Health Laboratory. “As long as that data remains in the laboratory, it’s of no use to anyone. It absolutely must be distributed to those agencies or entities that have the responsibility for public health decision-making.”

PHLIP: THE ROAD TO INTEROPERABILITY

As the nation’s primary advocate for PHLs, APHL has long been a proponent of standards-based electronic messaging systems to move laboratory data faster and with less human effort and error. In 2005, the association joined with the CDC Coordinating Center for Infectious Disease and the CDC National Center for Public Health Informatics to begin the Public Health Laboratory Interoperability Project (PHLIP).

PHLIP aims to improve the quality, accessibility and timeliness of data of public health significance by:

- Achieving bi-directional electronic data exchange among state PHLs, CDC and other partners, including state and local health agencies and clinical laboratories;
- Mapping test procedures and outcomes to a vocabulary of specific SNOMED® terms for clinical data and LOINC® codes for laboratory procedures, so data are consistent and unambiguous across laboratories;
- Establishing electronic test ordering and result reporting among PHLs and partners.

At the time of the 2009 H1N1 pandemic, state public health laboratories in Colorado, Iowa, Nebraska and Virginia had already implemented the PHLIP protocol for uni-directional influenza messaging to the CDC. Once they plugged in the unique LOINC® identifier for the new virus, it was a minor matter to deliver H1N1 test data to federal authorities electronically, in near real-time.

Lynette Brammer, an epidemiologist in the CDC Influenza Division, said, “For those laboratories [using the PHLIP protocol], it really almost took away the burden of reporting to CDC during the pandemic. It was something that was happening behind the scenes that they didn’t have to worry about.”

PHLs using alternative messaging systems took days or weeks to deliver pandemic test data to the agency, compared to as little as 24 hours after specimen collection for the four “live” PHLIP laboratories.

(continued, next page)
Importantly, the PHLIP protocol employs a Health Level 7 (HL7) message format, which is fast becoming the international standard for the exchange and management of electronic healthcare information.

The CDC’s Public Health Information Network (PHIN)—an initiative providing standards, services and tools to move the nation toward interoperable public health information systems—specifies the use of an HL7 format, albeit a more recent version than that currently specified by PHLIP (version 2.5 versus 2.3.1). The Nationwide Health Information Network (NHIN)—a similar effort overseen by the Office of the National Coordinator for Health IT and involving a much broader array of public and private sector stakeholders—also relies on HL7.

With HL7 as the common denominator, PHLIP is a public health gateway into the NHIN, which is often described as a network of networks. Although PHLIP’s major focus has been influenza, its promoters envision a day when virtually all PHL disease data is routed to local, state and federal partners simultaneously, in near real-time using the project’s harmonized coding vocabulary and messaging protocols.

“What it really comes back to is—what PHLIP is—interoperability,” said Steve Hinrichs, MD, director of the Nebraska PHL and chair of the PHLIP steering committee. “The NHIN has provided the so-called conceptual framework, but the operational framework needs to be realistic. Meaning: How do you create secure data-exchange hubs for health results? How do you pay for it? How do you manage it? These are the details PHLIP works on.”

Because of funding fluctuations, the five-year-old project has progressed in fits and starts. But the ever-present threat of bioterrorism, foodborne disease outbreaks and emerging infectious diseases—which have been identified at the rate of at least one per year since the 1970s—make PHLIP a much higher national priority than is reflected by its base annual budget of about $900,000.

In fact, many PHL officials view the electronic interoperability that PHLIP promises as a matter of survival, enabling them to respond effectively during public health crises and to continue to serve the myriad of fee-for-service customers that provide a portion of their revenue.

APHL President Pat Luedtke, MD, head of the Utah Division of Epidemiology & Laboratory Services, averred that HL7 messaging will soon no longer be optional.

He said, “I firmly believe PHLIP is the future. We need to work on HL7 message test results for all our work. Some of our customers are demanding it. Planned Parenthood is one of them. I can understand it. It’s good quality [data], it’s very fast, and, once the system is up and running, it’s low cost. The writing is on the wall that we need to go in this direction.”

Dan Jernigan, MD, MPH, deputy director of CDC’s Influenza Division, was one of several public health officials who echoed that thought.

"A necessary component of providing laboratory services is having electronic interoperability, and without that, you cannot compete,” he said. “With health reform, there's an enormous focus on interoperability and electronic messaging, and if the PHLs and the state health departments are not able to participate in that, they risk becoming irrelevant in an increasingly interconnected world.”

**CHANGING THE DYNAMICS**

Last summer, 22 additional state PHLs joined PHLIP, but with fiscal constraints all around and the continuing distraction of 2009 H1N1, there was scant project activity.

The pandemic, however, did perform a useful service by drawing attention to the widespread variability in PHLs’ electronic messaging capabilities and its impact on emergency response.

In January, the CDC Influenza Division awarded APHL $2.5 million in supplemental funding, specifically for PHLIP. Patina Zarcone, MPH, who oversees APHL’s informatics program, said the new resources are “laser-focused on rolling out the PHLIP flu message across the country” to speed the flow of surveillance data to the CDC.

To accelerate the process, APHL completely revamped its technical assistance strategy. The new approach uses two teams of contractors to guide laboratories through the implementation process. While the teams are prepared to provide as much or as little support as needed, more often than not, they have
For the past 20 years, the Wisconsin State Laboratory of Hygiene (WSLH) has been building a statewide laboratory network that now encompasses more than 130 hospital and clinic labs. These facilities route virtually all of their state notifiable disease reporting through the WSLH’s electronic information system.

gone onsite to help laboratory stakeholders develop an implementation plan and to provide the tools, technical expertise and other resources needed to implement the PHILIP electronic laboratory surveillance message for influenza. The use of the teams, said Zarcone, “completely changed the dynamics.”

Since March, state PHLs in Arizona, Arkansas, California, Florida, Hawaii, Idaho, Indiana, Massachusetts, Missouri, Utah and Wisconsin have been approved for production with the PHILIP flu message. State PHLs in Maine and Maryland are in the final stages of validating the message, and those in Alabama, Alaska, Montana, New Hampshire, North Dakota, Rhode Island, South Carolina and Texas are in the queue.

“Projects of this complexity and magnitude tend to evolve and change,” said Zarcone. “We as an association don’t want to have a programmer for PHILIP on staff. Using the contractor model makes us much more flexible to meet emerging needs.” And, she said, “States love it.”

The Arkansas Public Health Laboratory was one of the first to receive a PHILIP technical assistance visit early this year. Erin Qualls, the lab’s applications and systems manager, said the assistance team “gave us a one-stop shop for content. If we didn’t have that resource, I think we’d still be working on the PHILIP messaging protocol now.”

Qualls said, “We put everything else aside, and we just did that for a week.” Such an intense effort, he said, is possible only with the support of the lab director. “Oftentimes with [IT],” he said, “the executives don’t know what the priorities are. That wasn’t the case here.”

By the time an assistance team visited the Missouri State Public Health Laboratory in May, the lab had already had experience with HL7 messaging, having set up a process to send STD and HIV test results to one of its larger customers, the St. Louis County Health Department.

Nonetheless, Shondra Johnson, the PHL’s information management system administrator, said the visit “if anything, improved our way of sending messages.”

Without a vocabulary specialist, Johnson said, “We struggled to pick the appropriate LOINC® and SNOMED® codes for our tests when we created the message for St. Louis County. It was much smoother having people [available] with the right expertise.”

The laboratory is now sending influenza data to the CDC electronically and is setting up an electronic messaging protocol with the Kansas City Health Department using PHILIP processes.

"WE SET OURSELVES UP AS AN INFORMATION HUB.”

Hinrichs said the next challenge for PHLs is to think broadly: "How does the IT strategy for public health reflect [federal] health reform? What planning has taken place in the state or region with IT planning, and has the laboratory been at the table?" PHLs, said Hinrichs, “have to be at the table.”

“In fact,” he said, “we know more about laboratory IT and data exchange than anyone, and we need to offer that expertise to the community.”

The Wisconsin State Laboratory of Hygiene (WSLH) has taken that message to heart. For the past 20 years, it has been building a statewide laboratory network that now encompasses more than 130 hospital and clinic labs. These facilities route virtually all of their state notifiable disease reporting through the WSLH’s electronic information system.

Garrett Peterson, who manages the WSLH's information systems section, figures he captures 70-80% of all the state's notifiable disease reporting.

He said, “We set ourselves up as an information hub. That's what I think is really worthwhile. We take their information, do [any necessary] data transformation and send the data to the public health department in a way that they can utilize it.”

The process is completely paper-free and employs the same technical infrastructure the laboratory uses to send the PHILIP surveillance message for influenza.

Once surveillance data are transmitted to the state health agency, they are immediately available to patients’ local health departments.

Mary Wedig, who coordinates electronic laboratory reporting (ELR) for the WSLH communicable disease (continued, next page)
feature

PHLIP itself will be piloting ETOR within the next year or so, and expects eventually to achieve capability for ETOR between CDC and state PHLs, between state PHLs and clinical labs, and among state PHLs.

CHALLENGES AHEAD

Bolstered by $2 million of federal stimulus money, which the CDC awarded to APHL in June, the association is preparing to expand PHLIP considerably. In addition to rolling out the ETOR message, the plan is to offer the services of the PHLIP technical assistance teams to additional state PHLs, as well as state health agencies and select hospital labs.

In effect, PHLIP hopes to create nationwide what is happening now in Wisconsin—with electronic notifiable disease reports sent to state health agencies, rather than directly to CDC—and to eventually eliminate the need for the data transformations.

Engaging new stakeholders will inevitably require accommodations. APHL’s Zarone said, “The vocabulary harmonization we created for PHLIP was created for PHLs to share with CDC epidemiologists. Most of that work will suffice [for other messaging partners]. But when you’re doing projects like this, you cannot be prescriptive. We haven’t worked with these other stakeholder audiences before, and we may need to capture additional data elements.”

This ambitious undertaking is just beginning. In the meantime, PHLIP has several other balls in the air.

With the experience of the electronic laboratory surveillance message for influenza behind them, the project’s technical experts are working on an electronic message for Salmonella.

“We picked Salmonella just because it’s one of the most complex challenges,” said Hinrichs.

Because Salmonella is not just one disease, the diagnostic work that takes place goes far beyond the identification of a single isolate; there is a whole host of follow-on analyses, called reflex tests, that are automatically performed if the results of the initial screening fall within certain criteria ranges. Therefore, the electronic message needs to accommodate supplemental testing that is almost certainly omitted from the original test order.

In addition, the message must accommodate information of interest to public health officials, but not necessarily of interest to ordering physicians.

Said Hinrichs, “The original test order only asked one question. It did not ask the public health questions. If it is Salmonella, what is the serotype? Is it related to other serotypes? Is it associated with an outbreak? And who gets to share this information? And how much of that goes back into the original report, which the physician and the computer system are only anticipating a yes-no answer to?”

Hinrichs expects these issues to be resolved within the next year or two, at which point the project

division, said the process is “fast, very fast.” Notifiable disease test data can be available to appropriate local authorities anywhere from 30 minutes to several hours after a lab releases the result to a reporting queue, depending on the frequency with which the lab forwards its data to the WSLH. State and local health officials, said Peterson, “often have the information at least as fast as the ordering physician.”

The WSLH is already planning its next advance into the Information Age: automating test orders and reports to specimen submitters.

Other states are also making messaging strides. At least one state PHL, the Rhode Island Department of Health Laboratories, is piloting the transfer of test data to the state’s health information exchange, and the Utah Division of Epidemiology & Laboratory Services expects to do so within the next two years, assuming funding holds out.

Using pandemic influenza preparedness funds, two sets of state PHLs are piloting the transfer of electronic laboratory flu messages amongst themselves. One project involves the University of Iowa Hygienic Laboratory, Minnesota Public Health Laboratory and Nebraska Public Health Laboratory; the other involves the Florida Bureau of Laboratories and the Laboratory Services Section of the Texas Department of State Health Services.

State-to-state messaging capability is a crucial element of emergency response to assure continuation of operations after a laboratory is shut down and forced to distribute some of its workload out of state—which happened to the Louisiana Public Health Laboratory after hurricane Katrina—and to facilitate interstate surge capacity testing during a large-scale event when all the laboratories in one state or region are overwhelmed—which happened during the 2009 H1N1 pandemic. In each of these crises, data exchange constraints hindered important public health activities.

Both pilot efforts are based on PHLIP guidelines for electronic test ordering and result reporting (ETOR).
can expedite the creation of electronic surveillance messages for other pathogens.

Yet another challenge pertains to the use of data sharing agreements to legally sanction the exchange of health information among PHLs in different political jurisdictions. The issue came up at the peak of the H1N1 pandemic, when the Virginia Division of Consolidated Laboratory Services (DCLS) agreed to perform surge testing for one of the most overburdened state PHLs. There was no difficulty sending patient specimens to Virginia, but the DCLS was unable to transfer the test results back, having no data sharing agreement in place.

Zarone said, “They eventually worked it out, but it took lawyers getting involved.” APHL would like to work with relevant partners, probably including state attorneys general, to develop a Data Use and Reciprocal Support Agreement (DURSA) template that PHLs can customize. “It’s a huge undertaking,” said Zarone, “but it needs to be done.”

APHL, through PHLIP, is also developing a white paper exploring the advantages and disadvantages of different models of IT support for PHLs.

“The need for a skilled PH informatics workforce is always a huge issue,” said Zarone. “We want to find out which IT support models work best for PHLs from a fiscal standpoint and from a practical standpoint.”

In Utah, for example, IT staff are centralized within a state department of technology services, which bills the PHL for its services. In both Arkansas and Wisconsin, the state PHLs have dedicated, in-house IT support.

Finally, together with the US Food and Drug Administration (FDA), PHLIP is beginning a novel project to institute procedures for designating standard coding elements for new laboratory tests at the same time the tests receive FDA approval. The idea is to include the harmonized coding vocabulary in the test package insert so the information is immediately available to laboratorians using the test.

Despite the project’s current momentum, the speed with which PHLs achieve electronic interoperability is still very much dependent on funding.

Establishing and maintaining a modern IT infrastructure, said Zarone, is “not just a one-time cost deal. States need to spend money on this for perpetuity. Systems need to be updated at the rate technology changes. It’s something that is never going to go away. It’s like electricity. It needs to be viewed as a core PHL function. And right now, it’s not viewed that way.”

At least for the next year or so, there is reason to be hopeful for meaningful progress. In addition to APHL’s supplemental federal funding for PHLIP, the CDC will soon be awarding $5 million to a select group of its Epidemiology and Laboratory Capacity grantees for “infrastructure and interoperability support”—with individual awards falling somewhere between $100,000 and $600,000.

The funding, authorized through The Health Information Technology for Economic and Clinical Health Act of 2009—a subsection of The American Recovery and Reinvestment Act of 2009, is specifically intended to promote electronic messaging between public health and clinical laboratories. Moreover, required program activities include implementing the PHLIP influenza message.

Reflecting on the hectic days of the 2009 H1N1 crisis, CDC’s Jernigan said in those labs using the PHLIP influenza message, “the reporting kept up with the surge.” He said, “I think having gone through the pandemic, people probably have a different view of the whole process. It was an opportunity to see how this could make a difference.”

---

**IS YOUR LAB READY FOR A PHLIP TA VISIT?**

A two- to four-day PHLIP technical assistance site visit can help your laboratory institute an automated process to extract, transform and transport influenza surveillance data from an in-house laboratory information management system (LIMS) to the CDC Influenza Division.

The two- to three-person technical assistance teams, funded by CDC through APHL, provide support to:

- **Translate in-house messaging vocabulary to the PHLIP vocabulary of standardized LOINC® and SNOMED® codes**
- **Translate patient demographic information into the standard PHLIP message and build out the HL7 message using the data currently captured in the LIMS**
- **Configure the PHIN messaging system (PHINMS) sender and receiver to encrypt the data**
- **Make an electronic connection to CDC using the PHLIP route-not-read hubs**
- **Assist with related tasks, such as working with an outside vendor to reconfigure the LIMS to meet the data exchange standard**

**Minimum site visit requirements are:**

- Commitment of laboratory leadership to make the project a high priority, to sign off on the PHLIP charter and to engage all relevant stakeholders internal and external to the PHL (e.g., IT staff and influenza specialists)
- An IT infrastructure that includes a LIMS, PHINMS and, if necessary, an HL7 translator, such as the Rhapsody Integration Engine
- Participation in a pre-visit discussion to review capabilities, needs and expectations and to walk through the process
STAYING VIGILANT AGAINST VACCINE-PREVENTABLE DISEASES
by Travis Jobe, senior specialist, laboratory systems & standards

WHAT’S ALL THE WHOOP ABOUT?
Whooping cough, also known as pertussis infection, has affected California with its largest outbreak in 50 years. By mid-July, California had more than 1,500 cases of pertussis, including six infant deaths.

Because the incidence of pertussis disease is normally low, pertussis testing is often halted when budget-strapped public health laboratories are forced to shrink testing services. The recent discontinuation of a widely-used commercial PCR kit for pertussis detection has also enlarged the gap in testing capacity for the disease.

Fortunately for Californians, the state’s Microbial Diseases Laboratory (MDL) has helped many county public health laboratories implement a multi-target PCR assay, partly in response to a smaller outbreak five years ago. According to MDL’s Dr. Will Probert, performing the multi-target PCR helps eliminate false positive test results; especially in the absence of confirmatory culture testing, which CDC still considers the gold standard test. Due to this advance preparation, California’s county laboratories have played a critical role in the overall outbreak response this year.

The CDC has also developed a multi-target real time PCR assay for pertussis identification and will help with its implementation at other public health laboratories.

IT COULD STILL BE MUMPS
In 2006, a mumps outbreak in the Midwest, with about 6,000 reported cases, surprised public health authorities. Public health laboratories performed surge testing to confirm patients’ diagnoses. However, the interpretation of serological test results can be complicated for vaccinated individuals. The CDC identified a need for new diagnostic tests and developed an ELISpot assay to detect mumps-specific antibody secreting B-cells. This assay is more specific than standard ELISAs and can resolve complications resulting from patients’ pre-existing antibodies.

In mid-2009, mumps cases appeared in New York and New Jersey—one year later, there have been more than 2,000 cases. CDC is using the B-cell assay to assist with the testing response. Now, several state public health laboratories have had staff trained at the CDC and are in the process of obtaining IRB approval to use this assay in their laboratories.

MEASLES ARE TOO COSTLY TO IGNORE
Measles cases among returning travelers continue to occur in the US, and response costs are estimated at more than $140,000 per case. Laboratory diagnosis of infection is usually confirmed by serological testing, yet false negative results can occur if specimens are collected within three days of the appearance of rash. Jennifer Rota, from the CDC’s measles laboratory, recommends that “laboratories have the capacity to test viral samples by real-time RT-PCR since early collection increases the sensitivity for viral samples, and can provide confirmation when an IgM negative result is inconclusive due to early collection.”

LABORATORIES TRAIN AND PREPARE FOR VPDS
How can public health laboratories prepare for a surge in testing requests for vaccine-preventable diseases? For PCR testing of pertussis and measles, the CDC can share protocols, as well as validation and proficiency specimens for measles; however, laboratories need to obtain reagents independently. One-on-one trainings at CDC are also possible, including training for the ELISpot B-cell assay for mumps. APHL’s website also carries notices of NLTN-sponsored hands-on training workshops at CDC.

How can laboratories maintain proficiency without frequency? Most laboratories find it difficult to obtain specimens for measles IgM serology or pertussis PCR, so later this year, APHL and CDC will send specimen panels to interested laboratories. The test-specific panels will help a laboratory evaluate the performance of its current assays. This proficiency-like exercise will help laboratories maintain competence.

For more information on trainings and other quality improvement activities for vaccine-preventable diseases testing, contact senior specialist Travis Jobe at Travis.Jobe@aphl.org or 240.485.2764.
LABS TEAM WITH STATE PARTNERS TO IMPROVE LABORATORY SYSTEMS
23 STATES HAVE COMPLETED THE L-SIP ASSESSMENT
by Tina Su, MPH, specialist, laboratory systems & standards

In recent months, laboratories in South Dakota, Minnesota and Oregon participated in APHL’s Laboratory System Improvement Program (L-SIP), bringing the number of states with a completed assessment to 23. Partners from epidemiology, environmental health, law enforcement and health departments participated in the one-day meeting to improve public health laboratory activities at the state and local levels. Guided by the L-SIP assessment tool, which is based on the 10 Essential Public Health Services1 and APHL’s Core Functions and Capabilities of State Public Health Laboratories2, participants focused on identifying the strengths and weaknesses of the state system, as well as possible steps for improvement.

The assessment is a good opportunity to strengthen existing partnerships and create new ones. Miki Van Houten, Oregon Public Health Laboratory’s quality management and safety officer, observed that participants “had really good discussions, met people whom the laboratory had worked with in the past or who we should have been connecting with, and gained some insights into working across cultures, particularly with Native American health.” Van Houten noticed that many participants in the Oregon assessment referred to “working in silos” across the state and would like to “do a better job of coordinating our efforts and capitalizing on each others’ strengths.” Similar observations were made in South Dakota, and one immediate outcome of the dialogue among partners was a dramatic increase in awareness of the quantity of work done within the system, as well as the role and importance of system partners.

Communicating more effectively among partners and promoting the system concept were identified as areas for improvement at the end of all three of the assessments; making these changes will require a collective team effort with committed partners. Gail Gray, from the South Dakota Department of Health, pointed out that “...it will be up to those who called the meeting to take the next step. We just all have to contribute.” Laboratory staff from each state are summarizing meeting results and determining next steps for system improvement.

The states reported that APHL’s support—provided through technical assistance calls, printed materials, the L-SIP website and mini-grants—was instrumental. Maureen Sullivan, Minnesota’s Bioterrorism Preparedness laboratory coordinator, stated that “the tools APHL provided for the L-SIP planning process were helpful. The conference calls allowed us to ask questions to those that had already been through the process.” Paula Snipes Vagnone, Minnesota’s laboratory program advisor, added, “Having APHL send us all of the printed material was incredibly helpful. It was all very professional looking, which may not have been in our budget to do, so it was very helpful in a monetary way.”

Recruitment for the fall 2010 cohort will begin in late summer/early fall. The technical assistance call schedule and mini-grant application information will be distributed when available.

Contact Tina Su (bertina.su@aphl.org) to schedule an L-SIP assessment. Setting an assessment date is not a prerequisite for participating in the technical assistance calls. All interested states are encouraged to join these calls. For more information about L-SIP, visit www.aphl.org/lsip.

1 www.cdc.gov/od/ocphp/nphpsp/essentialphservices.htm
2 www.aphl.org/aphlprograms/lss/publications/Documents/Core_Functions_PHLs.pdf
EMERGING ISSUES EXPLORED AT APHL’S ANNUAL MEETING
by Rachel Zetts, communications intern

APHL hosted its 2010 Annual Meeting and Fourth State Environmental Laboratory Conference, “Public Health Laboratories: A Climate of Change,” in Cincinnati, OH, in June. This year’s meeting drew more than 300 participants from more than 50 public health and environmental laboratories in the United States and abroad. The seven plenary sessions focused on key issues in the public health laboratory field, including electronic data exchange, pandemic influenza (H1N1), EPA partnerships with laboratories, SCID newborn screening programs, developments in food safety and CDC priorities in the laboratory field. Breakout sessions explored other emerging issues within public health and environmental laboratory practice, such as APHL’s oil spill response efforts, antimicrobial resistance, global health and climate change. Participants had access to industry technologies, with 37 exhibitors displaying everything from the latest laboratory equipment to architectural ideas.

One participant, Paul Kimsey, PhD, director, California Department of Public Health, listened in on the electronic data exchange plenary session and noted, “It is becoming more and more clear that there is a big future for public health laboratories brokering electronic laboratory data with the private sector and public health. California is excited about continuing and expanding its role with PHLIP (public health laboratory interoperability project) nationally,” he stated. For more info and conference presentations, visit http://bit.ly/cgJTWa.

CONFERENCE AwarDEES

- **Committee Service**: Michael Wichman, PhD, associate director, State Hygienic Laboratory at the University of Iowa, Environmental Health Committee, 2004-2007
- **2010 Presidential Award**: CDC Influenza Division, Daniel Jernigan, MD, MPH; Joseph Miller, PhD; Stephen Lindstrom, PhD; Roy Johnson
- **2010 Thomas Maxson Education, Training and Workforce Development Award**: Judy Delany, MS, MPH, liaison to Office of State Tribal, Local and Territorial Support and Office of Surveillance, Epidemiology, and Laboratory Services
- **2010 Gold Standard in Public Health Laboratory Excellence Award**: Sammie Malone, MS, bureau director, Environmental Services, Mississippi Public Health Laboratory
- **2010 Emerging Leader Award**: Robyn Atkinson, PhD, director, Knoxville Regional Laboratory, Tennessee Department of Health
- **2010 On the Front Line Award**: Robert Maxfield, MS, associate director, USEPA Region 1 – New England Regional Laboratory
- **2010 Lifetime Achievement Award**: Ronald Laessig, PhD (Joan Laessig accepting)
DrRichardBesser: On my way to Cinci to talk to Public Health Labs on communications. @ APHL. Lab science is cool! The key is to make it so to non-scientists!
5:26 PM June 8th

BecomingADoc: Just finished my opening address @ the #APHL Conference in Cincinnati! What a great audience – their work promoting health is truly inspiring!
9:37 AM June 6th

phlcom: Labs are one of the real treasures of CDC, public health system #aphl
10:18 AM June 9th

APHLNews: BREAKING NEWS: FIRST TRUE #SCID BABY IDENTIFIED BY NEWBORN SCREENING IN WISCONSIN! ANNOUNCED BY DR. BROKOPP #APHL
11:05 AM June 8th

PubHealthLabs: This is my first tweet – thanks #APHL for having sessions at mtg You CAN teach an old dog new tricks!
5:06 AM June 7th

phlcom: Monroe – must be flexible, think creatively to move public health forward. #aphl is example of flexibility, forward-thinking.
10:52 AM June 9th

scottjbecker: State pub health #labs accept chllnge to dev new methods fr seafood testing frm gulf wtrs. Leading way again! #aphl #oil
10:00 AM June 7th
Ali Khan joined the Office of Public Health Preparedness and Response as director on August 2, 2010. Previously, he served as assistant surgeon general and the deputy director of the National Center for Emerging and Zoonotic Infectious Diseases at CDC. Dr. Khan was one of the main architects of CDC’s public health bioterrorism preparedness program and designed the joint global field epidemiology and lab training program.

Q1: What are you most looking forward to in your new role as director of OPHPR at CDC?

A: The opportunity to reconsider how we deploy the significant national resources for public health preparedness in best support of state, tribal and local health entities for broad-based preparedness that extends to their daily activities. A chance to shift the focus of preparedness from federal actions to community preparedness and better integration of public health, healthcare and emergency management at the local level for whatever threatens good health.

Q2: What are your key priorities for OPHPR over the next 12-24 months? What direction do you see OPHPR going in the next couple years, and how do laboratories fit into this vision?

A: Laboratories are a critical component of our public health system and the keystone for detection activities and subsequent pathogen/toxin characterization activities. My priorities include:

-Working to expand the definition of public health lab to clinical labs doing select tests, and consider a financing scheme so the tests of public health significance are not held hostage to whether a patient has the ability to pay.
-Improving diagnostic development as an integral component of the Medical Countermeasure enterprise.

Q3: What is the biggest emergency preparedness challenge (or challenges) facing PHLs in the next several years, and how should PHLs prepare for it?

A: Public health laboratories will face many challenges, but it’s hard to imagine anything more serious than trying to maintain, improve and provide enhanced laboratory services with the pressure of decreasing laboratory budgets. Without sufficient funding, these frontline laboratories cannot sustain core preparedness and response activities, retain a dedicated workforce or even maintain existing instrumentation. Diminished laboratory funding in an era of increasing responsibilities represents a significant threat to the health of Americans.

Public health laboratories are at the vanguard of public health preparedness and response, and, thus, the integrity of the services they provide cannot be compromised. In this challenging fiscal environment, public health laboratories will need to increase the visibility of their impact on everyday life in the US and abroad, improve communication and sharing of best practices to continually build on success, enhance the efficiency of both information and fund utilization and explore innovative partnership models that leverage the strengths and resources of other organizations in the public, nonprofit and private sectors.
Q4: What would happen to the nation’s preparedness and response capability if PHL capacity were to be lost or reduced?

A: Public health laboratories are a critical component, if not the most critical component, of the nation’s preparedness infrastructure. Public health laboratories are where the rubber hits the road. These laboratories are essential for surveillance and the rapid identification and characterization of disease agents, both natural and man-made. Without them, our public health system would not be able to implement appropriate control measures, leading to increased disease burden and higher fatality rates.

Take the H1N1 influenza outbreak for example. The first US case was laboratory-confirmed in mid-April 2009. By May 1, two weeks later, the first diagnostic kits were being distributed to the US and international public health laboratories. Laboratory testing allowed the virus to be characterized throughout the US and the world, providing critical data for formulating the vaccine and allowing enhanced surveillance of the virus.

Q5: What can APHL and PHLs do to more effectively demonstrate their role in preparedness to policymakers and funders?

A: One essential approach is to more effectively utilize community organizations and advocacy groups to influence policymakers and funding agencies on the fundamental role of public health laboratories in our health system. This national laboratory system is an essential platform that integrates across federal, state and local organizations to provide comprehensive emergency preparedness and response services for emerging infectious diseases and biological, chemical and radiological terrorism. These core services safeguard communities, and community leaders can help demonstrate this value to drive policy change and secure reliable funding.

Q6: Is there anything else that you would like our readers to know? For example, what are the real risks to the US in the event of a bioterrorism attack?

A: Infectious disease risks that include, but are not limited to, anthrax, pandemic influenza, novel pathogens like SARS are real concerns, as are continued threats from improvised explosive/nuclear devises. We can’t say we are finished preparing. While we can mark and measurably improve our preparedness, we can’t ever declare it complete or check the block – rather it’s a process. One only has to look back over the course of the last year or two and note that our agency has responded to pandemic flu, an earthquake in Haiti, and anthrax transmitted via a goat skin on a drum to know that we must expect the unexpected. In closing, I would note that global health is a priority for this agency, and that we must ensure global health security in conjunction with ensuring our national health security. If infectious disease and public health threats have shown us anything, it’s that we really do live in a global neighborhood.
FELLOWS PUBLISH AND ADVANCE RESEARCH

by Heather Roney, manager, fellowship programs

Many of APHL's EID Fellows attended the International Conference on Emerging Infectious Diseases (ICEID) conference in Atlanta in July, and presented posters:


Mark Gallivan: “Pooling the Flood: A Novel Approach to Meet Surge Capacity in the Public Health Lab,” co-authored by former fellow Tam Van

Rachael Lask: “Multiplex Microsphere-Based Immunooassay (MIA) for Detection of Sentinel Chicken Serum Antibodies for Surveillance of Arboviruses in the State of Florida”

Jeni Vuong: “Correlation between Adherence and Genotype in Non-typeable Haemophilus influenza (NTHi) Clinical Isolates”

Fellows presented posters at the American Society for Microbiology’s (ASM) annual meeting in May:

Amber Schmidtke: “Comparison of three molecular methods for typing Bordetella pertussis isolates”

Abel Wu and Sean Buono: “Neisseria gonorrhoeae isolates with extreme resistance to azithromycin possess mutations in both the 23S rRNA and mtrR genes”

Sean Buono: “Using the Neisseria gonorrhoeae multiantigen sequence typing (NG-MAST) to assess strain diversity and predict drug resistance in San Francisco, CA”


Alicia Zimbeck: “Mutations in Candida glabrata FKS Genes Related to Elevated Echinocandin MICs in Isolates from a Population-based Surveillance in the United States”

Maureen Diaz: “Ultra-rapid Detection of Mycoplasma pneumoniae and Chlamydia pneumoniae from Respiratory Clinical Samples Using a Fast Cycling Real-time PCR Assay”

Magdia De Jesus: “Assessment of methods to determine Legionella pneumophila viability in water samples using real-time RT-PCR”

De Jesus was awarded the ASM postdoctoral minority travel award.

In June, Infection Control Hospital Epidemiology published Kristen Kreisell’s work, “Assessment of the 48-hour Rule for Identifying Community-Associated Methicillin-Resistant Staphylococcus aureus Infections Complicated by Bacteremia.”

The May issue of Free Radical Biology & Medicine included Patrick Bryant’s article, “Accumulation of oxidized proteins in Herpevirus infected cells.”

EID Fellows Kara Levinson, Anna Van Stelten, Jeremi Mullins and Brock Neil presented the poster “Growth and isolation of Pandemic (H1N1) 2009 virus from 19 difference states/territories at the University of Iowa Hygienic Laboratory for Antigenic, Genetic, and Antiviral Resistance Screening by the Centers for Disease Control and Prevention” at the 2010 Iowa Governor’s Conference on Public Health in Ames, IA.


Former fellow Samantha Rudd co-authored “Improving molecular detection of fundal DNA in FFPE tissues: comparison of five tissue DNA extraction methods using panfungal PCR,” in the June 2010 issue of Journal of Clinical Microbiology.

Jing-Wen Tan presented the poster, “Laboratory Surveillance for West Nile Virus and St. Louis Encephalitis Virus in Maryland From 2008-2009,” at the 7th Annual Planet xMAP USA Multiplexing Symposium in May.

NOMINATION FOR PUBLIC HEALTH AWARD

Due October 1

American Society for Microbiology recognizes outstanding work. Apply to the Abbott Award in Clinical and Diagnostics Immunology and the Gen-Probe Joseph Public Health Award at http://bit.ly/9Wgsf8

fellows

APHL Selects 16th Class of EID Laboratory Fellows
by Heather Roney, manager, fellowship programs
Following two days of candidate interviews in June, APHL and CDC staff selected the 2010-11 class of Emerging Infectious Diseases (EID) laboratory fellows. Twenty fellows were chosen from a pool of more than 200 candidates. The fellows will be placed in local, state and CDC laboratories in California, Florida, Georgia, Hawaii, Iowa, Massachusetts, New York and Virginia.

The work of the EID and Environmental Health Fellows contributes to progress made in laboratory science research through

hands-on activities at the bench; analysis of collected data; participation in training events, science club gatherings and sharing of training resources; presentations at local and regional conferences; participation in outbreak investigations; publications in journals; and activities that address workforce shortages at all levels within the laboratory community through the building of career awareness.
MEMBER SERVES AS PUBLIC HEALTH OFFICER FOR SCOUTS
CELEBRATING 100 YEARS OF SCOUTING IN THE US, SAFELY
by Kim Ross, editor, Lab Matters

Dr. David Carpenter attended this year’s Centennial Boy Scouts of America Jamboree July 26 – August 2 in Fort AP Hill, VA, as one of its first Public Health Officers. Held every four years to help build confidence and character in young people, the event is a staple of the organization and has become increasingly focused on public health concerns at the Jamboree. Nearly 50,000 attendees are bused in from all over the country to spend 10 days in the wilderness—a setting that has numerous environmental and public health implications. Carpenter and roughly 20 other public health professionals were recruited to advise on public health issues and to help control the potential for an outbreak. Working closely with medical staff, Carpenter helped to ensure safe food preparation and temperature control, proper waste disposal, and informed surveillance on communicable diseases and environmental health issues. He made decisions on how to treat symptomatic kids and recommended appropriate antibiotic therapy for various illnesses, like gastroenteritis. The organization now offers a public health merit badge for the first time, recognizing scouts who demonstrate exceptional knowledge of public health issues.

To learn how to become a volunteer public health officer, visit http://www.scouting.org/.

David Carpenter, PhD, is a research associate professor at the Southern Illinois University School of Medicine, Department of Medical Microbiology & Immunology. An emeritus member of APHL, he served eight years on the Food Safety Committee and currently serves on a Workforce Development Subcommittee and the L-SIP Committee.

MEMBERS ON THE MOVE

BOARD MEMBER RETIRES
Sally Liska retired in August as director of the San Francisco Public Health Laboratory. We appreciate her service on the APHL Board as local public health lab representative and wish her well!

Hawaii’s State Laboratories Division received the Department of Health’s 2010 Team of the Year Award on July 15 for its remarkable response to the 2009 influenza A H1N1 pandemic. Impressive contributions from staff plus effective use of their incident management system and Continuity of Operations Plan enabled the lab to maintain all other environmental and public health services during the pandemic. The laboratory team will compete with other state agency teams for the Governor’s Award in October.

Grace Lin, a microbiologist with the California Department of Public Health Laboratory, recently became the first recipient of the Ed Desmond Award for Excellent Service by a TB laboratorian. Ed Desmond, PhD, is the chief of the Mycobacteriology and Mycology Section at the California Department of Public Health Laboratory. The award was presented at the 2010 National TB Conference in Atlanta, GA.

Kim Lindsey, PhD, has been appointed as deputy director of the Laboratory Science, Policy & Practice Program Office within the Office of Surveillance, Epidemiology and Laboratory Services. Lindsey previously held the position of associate director with the Office of Public Health Preparedness and Response, where she provided oversight for the $1.5 billion terrorism preparedness budget.
MISSOURI DEPARTMENT OF NATURAL RESOURCES: MAINTAINING A REPUTATION OF EXCELLENCE

by Nancy Maddox, writer

Laboratory staff, Missouri Department of Natural Resources

LOCATION

Outsiders can be forgiven if they are a little confused about the state of Missouri. Acquired as part of the Louisiana Purchase, the Show-Me State has gone from a Western territory to “Little Dixie” to part of the Midwest. Even today, St. Louis is sometimes called the “westernmost Eastern city” in the US and Kansas City the “easternmost Western city.” The state’s Department of Natural Resources (DNR) is located roughly halfway between these two population centers, about 30 miles south of Interstate 70 in Jefferson City, the state capital. Chris Boldt, manager of the department and its environmental services laboratory, calls Missouri “a beautiful state with lots of trees and streams” and, of course, the beautiful Ozark Mountains (actually a plateau). Jefferson City itself is a river town, and the famed Lewis and Clark expedition traversed the Missouri River within a mile of the laboratory’s current home.

FACILITY

The 8,400-square-foot environmental services laboratory occupies about a third of a state-owned building constructed in 1991 specifically for the DNR Environmental Services Program. It sits next to a cemetery and a business enclave and is, said Boldt, a substantial upgrade from the converted furniture showroom that previously housed the laboratory. “When this building was built,” he said, “a lot of effort was put into making it efficient, user-friendly and state-of-the-art.” Volatile and organic analyses are separated to prevent cross-contamination and the interior layout facilitates sample throughput. Although the building has “worn well” over the years—with an addition added in 1998—it is now near capacity in terms of staff and instrumentation, but continues to meet agency needs.

DIRECTOR

Boldt is a Missourian through and through. Although he was born across the border in Illinois (just 50 miles from St. Louis), he grew up in Jefferson City and studied math and chemistry at local Lincoln University. After graduation, Boldt went to work as a public health laboratory scientist at the Missouri Department of Health, concentrating on volatile organic analyses and blood lead chemistry. He followed a friend to the DNR, where he worked as a senior chemist and inorganic chemistry unit chief before becoming laboratory manager in August 2008.

STAFF

The laboratory employs 20 full-time staff members, including Boldt, 14 chemists and five technical support staff who prepare test kits, enter data into the laboratory information management system (LIMS) and otherwise “support the entire laboratory.” After recently filling two of the technical support positions after a retirement and a job change, the laboratory has no vacancies. “Over the years, we’ve run a pretty tight ship in terms of staff,” said Boldt. After going for a couple months with the two support staff vacancies, he said, “You realize it is very difficult to perform all the work we do as a whole without every piece being filled. It was a gentle reminder that we need everyone in the laboratory to perform our function.” Because of the addition of autosamplers and other high-efficiency instruments, Boldt said, “We actually have three-four fewer chemists than we did ten years ago, and we’re doing the same or more work.”

REVENUE

The laboratory has an annual operating budget of about $1.4 million. About $750,000 per year—enough to cover staff salaries—comes from dedicated drinking water fees and environmental fees for wastewater discharge, landfill use, hazardous and solid waste control, etc. “If a particular state program provides 10% of our samples,” said Boldt, “that program pays 10% of staff salaries.” The remainder of the budget—used for
Missouri has one of the country’s largest programs to monitor lead in air, and the laboratory analyzes about 125 air filter samples each month.

equipment and other expenses—comes from a unique revolving services fund. Boldt explained, “We bill state programs on a cost-per-test basis. This saves us a lot of time because we don’t have to quote prices.” Expedited testing is provided at no extra charge.

TESTING

Nearly all of the laboratory’s work is performed in support of the DNR, with many samples coming from staff who share the laboratory’s building: state employees who conduct environmental emergency responses, water quality stream sampling and monitoring, wastewater treatment plant inspections, air quality monitoring, hazardous water sampling and related environmental services. About 70% of laboratory samples are drinking water samples, coming from the roughly 2,800 public water supplies that serve the state’s five million residents. Missouri has one of the country’s largest programs to monitor lead in air, and the laboratory analyzes about 125 air filter samples each month. As the state’s primary laboratory for chemical analysis, it also performs occasional work for the state parks system, health agency, transportation department and a few other customers. During fiscal year 2009, the lab performed more than 67,500 chemical analyses on more than 24,000 samples.

SUCCESSES/BEST PRACTICES

• About 12 years ago, the laboratory began leasing all of its major equipment, with a purchasing option—an innovative arrangement that has enabled the laboratory to remain on the cutting edge of technology and to “do what we do very well.” Said Boldt, “We can reevaluate the technology every five years... We don’t feel like we’re stuck with an older instrument that doesn’t perform well or doesn’t accommodate emerging analytes.” Moreover, the leasing contract requires manufacturers to fix or replace malfunctioning instruments. “This gives us a little extra leverage.”

• With the help of a new LIMS, installed last July, the laboratory now posts most test results on the DNR website within two business days after completing all quality assurance protocols—a proactive practice that increases the laboratory’s transparency and enhances public awareness. “Public citizens can see our results almost immediately after they are validated.”

• Increased automation, also attributable to the LIMS, has made the laboratory more efficient and better able to meet the challenges of a changing laboratory environment.

• For nearly 20 years, the laboratory has run a certification program for drinking water labs. In this capacity, laboratory certification officers conduct on-site audits of Missouri drinking water labs and provide reciprocal certification for non-Missouri labs.

• The laboratory is part of the EPA Region 7 Regional Laboratory Response Plan, developed to coordinate the laboratory response to drinking water contamination events.

CHALLENGES & GOALS

The Missouri environmental services laboratory, said Boldt, is “not unique among laboratories” in terms of its challenges and goals: “We face some of the same challenges in terms of retaining qualified staff and working within a budget that sometimes changes.” Despite having “to do a little bit more with a little bit less,” he said the laboratory “is in pretty good shape... We’ve been able to maintain our current staff and current workload and even pick up some new workload over the year and still maintain high-quality, defensible data and deliver it in a timely manner so [state officials] can make good decisions for the environment and for the public health of the state.”

Looking ahead, Boldt said his primary goal is to continue to meet customer needs and expectations in a dynamic laboratory environment. Part of this challenge will involve keeping abreast of emerging analytes, such as pharmaceutical agents, and assuring the technological capacity to test for them. So far, he said, “We’ve been fairly lucky that we can do what we’ve been asked to do.”
VIRGINIA DCLS: “THE MOST DIVERSE PUBLIC LAB IN THE UNITED STATES”

by Nancy Maddox, writer

The Virginia Division of Consolidated Laboratory Services. Jim Pearson, director for the DCLS lab in Richmond, Virginia, calls his laboratory the "most diverse public lab in the United States.”

The Commonwealth of Virginia has a long history of "firsts." In 1607, the first English-speaking settlement in the United States was established here in Jamestown. In 1789, Virginia, nicknamed “Mother of Presidents,” gave the newly independent nation its first chief executive, George Washington, who was succeeded by seven other Virginians, among them Thomas Jefferson, James Madison and Woodrow Wilson.

Less well-known, the commonwealth is home to the nation’s first—perhaps only—truly consolidated state laboratory, with environmental, clinical, agricultural and consumer protection functions all handled under one roof and one director, James Pearson, DrPH.

Pearson, who is also a clinical consultant under the auspices of the Clinical Laboratory Improvement Amendments, calls his laboratory the “most diverse public lab in the United States.” In addition to human specimens, it tests animals, animal milk and animal feeds; water, soil and air; fertilizers and commercial foodstuffs; industrial and weapons-grade chemicals; gasoline; and consumer commodities ranging from floor wax to lottery tickets to condoms.

The Virginia Division of Consolidated Laboratory Services (DCLS) occupies almost 200,000 square feet in a seven-year-old, state-of-the-art building situated in a biotechnology park in the state capital, Richmond. Its current organizational structure, however, dates to 1972, when virtually all state testing services were integrated to enhance efficiency and cost-effectiveness. In this, said Pearson, the lab has succeeded immensely.

“Having everything together means you can have economics of scale. You don’t have to have separate pieces of equipment for each of the different program areas. You can have highly trained staff who are doing multiple tasks... All the samples come into one place and one LIMS application is used for all samples.”

The DCLS performs testing for more than two dozen state agencies, and a huge part of its value, said Pearson, as is a vast data repository.

In addition to an unusually expansive mission, the DCLS is unique in one other regard: its location within the hierarchy of state government. While most other state public health laboratories are part of a health agency or university system, the DCLS is located within the Virginia Department of General Services (DGS).

Said Pearson, “None of our customers are within the agency, so we don’t report to any of them. That gives us a clear advantage in my view, because the [other state] agencies don’t see us as a subordinate and they don’t have direct control over our budget.”

Volume-wise, the laboratory’s #1 service is newborn screening, which it performs for the roughly 95,000 infants born in the commonwealth each year. Other high-volume work includes sexually transmitted disease (STD) testing, drinking water analysis for about 300 water systems across the state, routine agricultural testing and analysis of motor fuels to verify octane ratings and other quality parameters.

Virginia has always been a politically important state—playing key roles in colonial and Confederate America—and the business of government is big business here today. A slew of federal offices and agencies, including the Department of Defense and Central Intelligence Agency, are sited in Northern Virginia. And the commonwealth is home to more than a dozen military installations, including the Norfolk Naval Station—the largest in the world—Quantico Marine Base, Langley Air Force Base, Dahlgren Naval Surface Warfare Center and seven army posts.

“Virginia has a huge military presence, so you have troops being moved into and out of bases all the time,” said Pearson. “That’s always a concern—the vulnerability to biological, chemical, radiation threats.”

The DCLS was one of the first four state labs in the nation to test clinical specimens for evidence of exposure to chemical weapons and is a Level 1 chemical terrorism laboratory. It is also a chemical weapons prototype lab for the Department of Homeland Security and Environmental Protection Agency and is a member of the Laboratory Response Network, the Environmental Response Laboratory Network and the Food Emergency Response Network.

In addition to its work on behalf of the commonwealth’s eight million residents, the DCLS, said Pearson, is “very quick to say ‘yes’ when others
ask for help.” Just within the past two or three years, the laboratory has performed anthrax testing for a New England state, melamine testing on animal feed and urine samples from East Coast pigs, Q fever testing for soldiers returning from the Iraqi War and dengue testing for Haitian relief workers. The DCLS was one of six states that helped to validate the CDC’s PCR influenza assay in the months before the 2009 H1N1 pandemic and is a regional testing center for the PulseNet food safety network.

Pearson is especially proud of the laboratory’s training programs, which are sought out by laboratorians worldwide. The lab’s molecular quality assurance program is extraordinarily strong, notes Pearson. Employees who perform any biosafety Level 3 (BSL-3) testing go through a structured 40-hour program before they are even allowed to enter the BSL-3 suite. Then they undergo escorted training before being granted limited solo access to the suite.

Last year, the DCLS trained more than 3,000 people, including employees, laboratory workers from the US and other countries, FBI agents, first responders and local sentinel laboratory staff. High-demand training topics range from shipping and handling of high-risk samples to quality systems to specialty courses for people who collect STD specimens.

Altogether, Pearson employs about 230 people. At the time of the interview for this article, he had vacancies for 13 positions, including one for a much-needed PhD chemist. “Our salaries just cannot compete,” he said.

The laboratory’s $25.5 million budget comes from general state funds (42%), fees and other non-general funds (36%) and federal grants, cooperative agreements and contracts (22%). Despite a $1.5 million budget cut, and despite having to stop most work for one furlough day earlier this year—the first in the lab’s history—Pearson said he has no complaints about the laboratory’s fiscal situation. “There are states that have been harder hit, so I’m not gonna whine,” he said.

The commonwealth is planning to close a handful of local public health laboratories—which report to the Virginia Department of Health—and Pearson expects the DCLS may be called upon to pick up some of the workload (excluding routine clinical chemistries, which the laboratory does not perform).

But future uncertainties do not unsettle the DCLS director, whose constant mantra is When you’re planning, plan for change. “We don’t have challenges. We have opportunities,” he said.

This philosophy has guided Pearson his entire life. Born in Minnesota and raised in North Dakota, Pearson has had an unusual share of opportunity. He “fell into” microbiology as an undergraduate at North Dakota State University in Fargo.

“Just days before I graduated,” he said, “I got a call out of the blue from A.A. Gustafson, the director of the branch [public health] laboratory in Grand Forks. ‘Do you want a job?’ he said. I had a young family and didn’t know where we were going to get the next nickel. So I went to work for the lab, physically located at the University of North Dakota (UND).”

Pearson ended up as UND faculty, teaching microbiology to medical technology students who rotated through the various laboratory units. After three years, Gustafson walked by, said Pearson, “and put a brochure on my desk.” It was a flyer for the laboratory directors’ training program then in place at the University of North Carolina at Chapel Hill.

“I applied to that program and—surprise, surprise—I was accepted,” said Pearson. “I was really surprised.”

He and his wife sold all of their belongings— “everything we had in Grand Forks, everything”—and “packed up the kids and moved to Chapel Hill.”

It was there that he responded to a research proposal from Bruce Evatt, MD, who was running the CDC hematology branch at the time. Pearson did his graduate research in Evatt’s laboratory, studying one of the components of the clotting cascade.

“It was something I knew almost nothing about,” said Pearson. “It was really new, really different, intriguing.” Evatt became a mentor and introduced Pearson to CDC’s Epidemiology Intelligence Service (EIS) and its then-director, Lyle Conrad, MD, MPH, a North Dakota native and fellow goose hunter who became a lifelong friend.

After graduation, Pearson returned to North Dakota, this time working at the main branch of the state PHL in Bismarck. About two years later, the state health officer petitioned him to fill a vacancy for state epidemiologist, going so far as to arrange for Pearson to go back to CDC and complete the EIS training program, which he did.

Pearson served as director of the North Dakota Division of Disease Control for five years, and became the DCLS director in October 1992.

Today, the self-described “recovering epidemiologist” spends much of his time looking ahead. In Virginia, he said, “We’re seeing more TB, influenza.” State officials are already bracing for the arrival of oil from the massive spill in the Gulf of Mexico. “What happens if we start seeing tar balls in shellfish beds or rolling up on the beach? What do we do?”

But change is a given at the DCLS. “There are never two days the same,” said Pearson. “The challenges keep me going. Life is good.”

Last year, the DCLS trained more than 3,000 people, including employees, laboratory workers from the US and other countries, FBI agents, first responders and local sentinel laboratory staff.
MEMBER RESOURCES CENTER: SHARING BEST PRACTICES WITH COLLEAGUES

by Emé Martin, MPH, associate specialist, public health programs

“We should all be aware that, in public health laboratories, we shouldn’t have any secrets, and to share resources and ideas is a noble deed so that we all don’t need to reinvent the wheel in every jurisdiction,” said Dr. Max Salfinger, chief of the Bureau of Laboratories in the Florida Department of Health, in reference to APHL’s online Member Resources Center.

Public health laboratories face routine operational challenges, from the bench level to administration. Although facilities vary in size, staffing and capabilities, all share the common interest of protecting the public from disease in the most efficient manner possible; consequently, many processes are interchangeable among laboratories.

In response to member requests, in 2009, APHL’s Knowledge Management Committee developed the Member Resources Center (MRC), an online repository for helpful laboratory practices and initiatives. Currently, the MRC contains more than 60 practices submitted by association members and staff. Topics range from public health preparedness and response to “greening” laboratories to laboratory marketing strategies. Content is searchable by keywords, publication year and submitting state. The MRC is an efficient way to share concepts that might translate successfully to other labs.

“The potential of a knowledge repository such as the MRC is enormous, but it all depends on us to share our knowledge and experience with each other,” said Bonnie Rubin, assistant director of the State Hygienic Laboratory of the University of Iowa and chair of the Knowledge Management Committee.

Due to the many practices, protocols and procedures in use, members may be unsure what to share publicly with colleagues. The purpose of the MRC is to provide members with quality practices or information to address gaps in the laboratory in both analytical and non-analytical operations. If a document or procedure has contributed noticeably to laboratory operations, it may be helpful to others. Some examples of submissions include:

• Marketing tips or contributions, such as newsletters
• Procedural algorithms
• Diagrams
• Presentations

To make a submission, email memberresources@aphl.org or an APHL staff member, or upload the item directly to the MRC via the SharePoint platform. Visit www.aphl.org/memberresources to view and add to current holdings.

Congratulation MRC Winners
APHL awarded its first Member Resources Center Prize at the 2010 annual meeting in June. The award recognized the laboratory that submitted the most entries into the MRC. Award winners shared materials such as examples of model communications (fact sheets, etc.) and ways to go about "greening" laboratories.

First Place: Florida Bureau of Laboratories
Runner-up: Arizona Bureau of Laboratory Services
PERKINELMER GENETICS OFFERS NOVEL “LAB-IN-A-LAB” APPROACH FOR SCID SCREENING

by Dr. Zhili Lin, director of research, PerkinElmer Genetics, and Dr. John E. Sherwin, director of laboratory operations, PerkinElmer Genetics

Following a recent recommendation by the US Secretary of Health and Human Services, the core panel for universal screening of all newborns in the US should now include Severe Combined Immune Deficiency (SCID), commonly known as “bubble boy disease,” and related conditions.

SCID is a primary immunodeficiency. Babies with SCID generally appear healthy at birth but have absent or very few T-cells, leaving them susceptible to recurrent and opportunistic infections. It is estimated that one in 50,000 to one in 100,000 infants suffer from SCID, though researchers say that no adequate prospective study has been undertaken to determine incidence. Some infants with SCID go unrecognized until they develop infectious complications.

As states adopt the new screening recommendation, PerkinElmer Genetics, a state-of-the-art newborn screening laboratory, is offering a novel services laboratory solution that embeds a “lab-in-a-lab” into public testing facilities, so that they can conduct onsite SCID screening within 72 hours.

PerkinElmer Genetics will embed its technology, equipment, software, supplies and employees in the state’s public health laboratory. The PerkinElmer "pod" is a service laboratory federally regulated by the Clinical Laboratory Improvement Amendments (CLIA), designed to ensure quality laboratory testing.

Rapid adoption of the new SCID screening test is challenging, since no commercial screening kits exist. One option would be for state labs to create their own procedure. Then, they would need to develop the assay and validate it clinically and operationally. However, the turnkey SCID solution offered by PerkinElmer Genetics overcomes the hurdle of time and resources with a fast, cost-effective and validated method.

This assay is a modification of a concept originally published by Dr. Jennifer M. Puck, a professor at the University of California, San Francisco, in the Department of Pediatrics and Institute for Human Genetics. It is similar to those in use by newborn screening programs in Wisconsin and Massachusetts.

The assay is based on detection of T-cell Receptor Excision Circles (TRECs), circular DNA fragments generated during T-cell receptor rearrangement. In healthy neonates, TRECs are made in large numbers, while in infants with SCID they are absent or barely detectable. PerkinElmer Genetics uses a real-time quantitative PCR assay to determine the TREC copy number in blood, used to distinguish T-cell lymphopenic SCID infants from healthy babies. For more information, email Fred Meindl at fred.meindl@perkinelmer.com.
STEP IT UP
by Scott Becker, MS, executive director

Creating a national focus on public health has always required a galvanizing event. It is time—in light of the vast health reforms sweeping the nation—for our laboratories and the varied special interests of public health to step it up to exert leadership over the change.

Recently, I have been involved with an APHA planning committee for a day-long Health Reform Implementation meeting that will precede the APHA Annual Meeting. The overall meeting theme this year is promoting the importance of the public’s health. (Not public health; the public’s health. The theme was chosen very specifically in response to the health reform initiative.) The pre-meeting on implementation will address some of our specific concerns, including some of the smaller, below-the-radar issues that can have a dramatic impact on day-to-day operations. Billing is a good example: some of our labs have absolutely no experience with it. This meeting will provide a forum to identify pending changes and discuss shared solutions that will ease the transition. I am going to urge many of you to attend.

CDC and its director, Tom Frieden, place a priority on connecting labs to Health Information Exchanges. For years, we have talked about the need to transmit data securely, quickly and accurately to CDC. It is very important to note that the goal has suddenly expanded exponentially. Yes, we still need to connect with CDC. But now it is vital to understand that, eventually, your lab must be connected electronically to the entire healthcare network. This is one of the ways that health reform is changing everything.

The feature article in this issue is about the PHLIP program. I encourage you to read it, and if you haven’t already, start working with APHL staff to get your lab onboard. Projects like this one take a lot of effort, but the payoff is enormous.

We should all feel a sense of urgency in the current climate. Our labs, our association, need to be at the intersection of science, practice and policy. Typically, our members are found at the intersection of science and practice, but health reform is pure policy. We need to understand the frame of the health reform conversation so that we can participate. We need to chart that new path, and though APHL is working as hard as it can to clear the way, you cannot stand to the side and wait. We all need to be figuring this out together.

Right now, the best advice I can offer is to get more deeply involved with your agency and your partners. Keep your eyes and ears open for news and opportunities. When you can, give information: at the moment there is a lot of talk about accreditation in the health field and public health labs know more about that than practically anyone. Public health laboratorians have a long history of adaptability and have diverse expertise. These qualities lend themselves to leadership during upheaval: don’t hesitate to step up if you can. Be open to what comes, and together, we will work to make sure our doors stay open throughout this process.
One punch. Multiple results.

An evolution in newborn screening, from the worldwide leader in multiplexing solutions.

- Multiplexed immunoassay* for CH/CAH/CF
- Simplified laboratory workflow
- Expand testing capabilities without the need for additional sample
- T4/TSH combined
- Built on the proven, flexible xMAP® Technology platform

For more information call Luminex at 888.219.8020

*Assay in development, T4/TSH, 17-OHP, IRT

From a single punch, your lab can achieve multiple benefits such as workflow improvements, increased throughput, test consolidation and sample preservation.
APHL SUSTAINING MEMBER PROGRAM

The following corporations partner with APHL to support the nation’s public health laboratory system.

**DIAMOND PARTNERS**

Abbott

Applied Biosystems

**PLATINUM PARTNERS**

Labware Lims Solutions

Luminex

Meridian Bioscience, Inc.

**GOLD PARTNERS**

BD

BIO-RAD

DiaSorin

ApolloLIMS

**APHL PARTNER**

LABS VITAL