

THE APHL MINUTE

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FDA Closure of Neonatal Test-Kit Plant Has Lasting Effect

Planning Underway to Revamp Nation's Newborn Screening Systems

In the first weeks of 2004, if anyone had asked APHL Executive Director Scott Becker to name potential challenges to the nation's public health laboratories (PHLs) his likely response would have been "CT (chemical terrorism), BT (bioterrorism), or avian influenza." Instead, when the first laboratory crisis of the year arrived on February 4, it came from an entirely unanticipated quarter: a FDA seizure of nearly \$1 million worth of newborn screening products from the PerkinElmer Life Sciences, Inc., facility in Norton, OH.

State public health laboratories screen nearly all of the 4 million children born annually in the United States for inherited genetic conditions. A stoppage in the flow of test kits and reagents "was a potential disaster that was off our radar screen," said Becker. He noted, "It was the first regulatory emergency that I know of."

FDA Deems Kits "Adulterated"

According to a FDA press release, the newborn screening kits were "adulterated" under federal law, since they were not produced in accordance with FDA's good manufacturing practice quality system regulation. The press release goes on to say that "these violations do not necessarily mean that PerkinElmer's diagnostic products will harm patients, but the firm's failure to follow the quality system regulation decreases the level of assurance the devices are safe and effective."

While PerkinElmer officials declined to detail specific violations, the company's general counsel, Ken Horton, said in a telephone interview that the company had been working with the FDA over a period of some months to correct problems cited in earlier agency audits. However, he said, "The FDA was very clear when they took this action to say 'we're not saying there are problems with this product.' . . . We believe very strongly that the products are safe to use for their intended use, and they perform the required functions without creating any health hazard."

Reverberations of the Seizure

In practice, the seizure itself precipitated a public health crisis of national proportions and highlighted vulnerabilities in the newborn screening system. According to data collected by APHL, as of February 9 more than a dozen states were set to run out of supplies for one or more neonatal tests within



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PRESIDENT'S THOUGHTS

Be Engaged in Transformation

The ongoing CDC Futures Initiative is a bold effort to enhance the agency's ability to protect and improve health in the 21st century. To bring about this enhancement, CDC has conducted a comprehensive internal and external examination of its leadership role, operational functions, organizational structure and communication capabilities. This effort is driven by CDC's desire to improve and measure its impact on protecting health.

As CDC's strategic transformation moves forward, I am optimistic about its effect on our public health laboratories. While perhaps not everyone shares this point of view, I believe change is usually beneficial. It is always inevitable. The key is for us to be engaged in the transformation process, to be part of the new way of thinking, to help drive its success rather than cause its derailment.

Apart from my penchant to be a cheerleader for public health laboratories, I am optimistic about the Futures Initiative for several reasons. First, our laboratories exist as an integral part of the nation's governmental public health system, a unique tripartite partnership of local, state, and federal entities directly accountable to the public, for the public. Though at times it may seem that CDC leadership fails to recognize the significance of our essential, state-based laboratory perspective, I am confident overall that CDC leadership understands and supports the key role our laboratories play in achieving our mutual goal of protecting the public's health.

I am also optimistic about the Initiative because of our recent accomplishments in partnership with CDC. While it appears that over the 50 plus years of our organization's existence there has been a persistent diminution in the visibility, role, and voice of laboratories at CDC, I think we are beginning to reverse that trend. APHL continues to have a long-standing cooperative agreement with the Division of Laboratory Systems that is a model umbrella agreement for all of CDC. In addition, we continue to develop the remarkable joint (CDC/APHL) training program known as the National Laboratory Training Network, and recently, with CDC support, we established the new, future-focused National Center for Public Health Laboratory Leadership. Also, we have experienced an influx of

critical funding to build infrastructure in our laboratories to address emerging health threats that include chemical and biological terrorism, as well as epidemic infectious diseases.

Finally, I believe CDC leadership is beginning to understand that desired outcomes of the Futures Initiative will depend on continued strong partnership with our public health laboratories. For example, while considered to be separate laboratory efforts at CDC, programs such as the Laboratory Response Network, the National Laboratory System, and the National Molecular Subtyping Network (PulseNet) are viewed at our state level as being closely interconnected, synergistic, and the force that drives development of essential new partnerships with the health care community, academia, and many other state and local entities, both public and private.

As I near the end of my term as APHL president, I look forward to a future in which the historic partnership between CDC and our public health laboratories continues to develop and mature. These are indeed interesting, challenging times packed with opportunity and need for innovative new approaches at the local, state and federal level.

Sincerely,



Norman A. Crouch, PhD



EXECUTIVE DIRECTOR'S NOTE

Shaping Our Own Future



As many of you know from frequent emails from me, our CDC partners, or your own agency, CDC has embarked upon a strategic organizational planning effort, aptly named the Futures Initiative. It is my understanding that this is the first time in over a decade that CDC has reconsidered its strategic directions.

CDC dedicated the first phases of this effort to listening to its customers. Comments were received from thousands of interested persons, including some from public health laboratory leaders. A few comments that resonated with me were: "If CDC is serious about its commitment to the customer, it shouldn't take six months for a lab result to be sent back," or "CDC is stove-piped and operates like an academic institution," or "The grants management process is broken, please fix it." Not all the comments were negative, "We value the relationship with CDC and hope that the laboratory community will gain greater prominence," or "The CDC scientists are top notch, and I hope they can continue to attract the best and the brightest."

The Futures Initiative has recently turned its focus to CDC's organizational structure. From my perspective, this is much more than figuring out "where the boxes go." It is an opportunity for CDC to fine-tune its business practices, relationships (both internal and external), and set a new course. I've been told that this restructuring will demonstrate that government can be nimble—just think of the presidential transition team approach. That's the speed at which this is moving. By the time this issue of *The Minute* reaches your desk, I hope that you will have taken advantage of the many opportunities to contribute your thoughts on restructuring to CDC.

During the last quarter of 2003, APHL conducted its own listening sessions. We hired Bob Kingon, an Atlanta-based consultant with strong ties to the public health field, to talk with our CDC colleagues to identify their views and recommendation on our relationship, work products, and areas of focus for the next five-year agreement.

One comment from these sessions that struck a chord with me was the notion of accreditation. As you probably know, for several years there has been movement within the field of public health to consider accrediting public health agencies as a means to assess the quality of their work. Objective IV of the APHL Strategic Plan (See www.aphl.org/About_APHL/newstrategicplan.pdf.) calls for promoting the development and use of quality laboratory practices in public health at the national and international level. Advocating for accreditation of laboratories that perform public health testing is one component of this objective.

APHL members already work with a variety of licensure and accreditation bodies in the laboratory world, but no formal accreditation program focuses on the public health aspects of public health laboratories. Accreditation could be one way to differentiate us from other laboratories, especially from a quality standpoint. APHL's leadership has asked that we begin *exploring* accreditation for public health laboratories in the coming months. As a first step, we will conduct an environmental scan of the factors that might impact the feasibility of this concept.

I want to reiterate that this work is exploratory but potentially of great import to the field. We must distinguish public health laboratories from the plethora of other labs if we wish to shape our own future. If we do not, I fear it will be decided for us.

Sincerely,

A handwritten signature in black ink that reads "Scott J. Becker" with a stylized flourish at the end.

Scott J. Becker, MS

30 days. At least four states would exhaust certain critical supplies within seven days.

Texas, the largest consumer of PerkinElmer neonatal testing products, was hardest hit by the crisis. Eldridge Hutcheson, who oversees newborn screening at the Texas Department of Health, explained that the state laboratory handles roughly 3,200 neonatal specimens each day and reports out more than 3.5 million test results per year. "It has to go like clockwork," he said. "We can't have too many disruptions or it slows—or could even stop—our work flow."

In a February 10 letter to PerkinElmer executives, Hutcheson outlined the severity of the problem. As early as February 17, the state would deplete its supply of materials to test infants for phenylketonuria and galactosemia—illnesses that, if not detected and treated soon after birth, lead to mental retardation or even death. "We were going to do whatever we could to continue testing," said Hutcheson, "but limiting screening was not out of the realm of possibilities."

In fact, by February 10 Hutcheson was assessing the feasibility of sending Texas laboratorians to the public health laboratory in Oklahoma City to do testing on its equipment after normal business hours. He was also exploring the possibility of securing alternate test kits from Natus Medical, Inc., and ICN Pharmaceuticals.

Collective Response

Fortunately, the worst of the crisis was resolved before Hutcheson or any of his colleagues in other states were forced to execute alternate plans for newborn screening. Immediately upon learning of the product seizure, APHL and CDC representatives took steps to document the public health implications of the supply shortage and to communicate this information to the FDA.

Harry Hannon, chief of CDC's Newborn Screening Branch, worked from his home where he is convalescing from a broken leg. Hannon said in a telephone interview that he was "concerned that the FDA didn't realize the magnitude of the problem that was being created. We were all a little embarrassed that PerkinElmer allowed

this to occur. But if there was a miss (in identifying an infant with a neonatal disease), it didn't matter who was responsible for the miss—the FDA, PerkinElmer, or the public health laboratory—a child would be suffering and we would all be publicly embarrassed."

APHL wrote to the FDA on February 10 and participated in a number of emergency conference calls with Hannon and FDA officials to craft a remedy based on medical need. Jelili Ojodu, APHL's newborn screening and genetics program manager, explained that state public health laboratories generally had no viable

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—Scott Becker, APHL executive director

short-term alternative to PerkinElmer products given the specifications of their testing equipment, the time needed to optimize a new test, issues with reduced throughput with alternative reagents and other factors. Hutcheson, for example, noted that one

manufacturer required a six-month financial commitment before it would have been willing to supply the equipment needed to run its tests. Even then, there would have been a seven- to ten-day delay before the equipment could be delivered and the manufacturer could ramp up its production to meet Texas's high-volume needs.

The final solution led to the release of seized materials and the resumption of product manufacturing on February 13, but with special package inserts requiring state laboratories to compensate for possible product defects. The inserts read, in part:

Use of this device may result in unexpected failure, which should be captured by including augmented quality control measures. Therefore, you should include additional quality control samples in your assay so that four different control values (or markers in a qualitative test) are performed and results monitored for each day's run.

Hannon said the FDA "did a remarkable job in responding as quickly as possible."

Subsequent Communication

On February 20, Becker, APHL President Norman Crouch, APHL staff, and several members—Ken Pass (NY), Eldridge Hutcheson (TX), Bill Becker (OH), Susan

Neill (TX), Ming Chan (FL), Paul Kimsey (CA) and John Sherwin (CA)—met with PerkinElmer President Peter Coggins and other company officials to discuss long-term issues. At that meeting and in a subsequent telephone interview, Coggins explained that the product seizure took place within the backdrop of the company's transfer of product manufacturing from Ohio to its "center of excellence" in Turku, Finland, where more than 90 percent of the firm's neonatal products are currently made.

In response to complaints about inconsistent customer service, failure to forewarn laboratories about possible FDA actions, and what some perceived as a lackluster response to a public health emergency, Coggins said the company considers genetic screening to be a "very critical and very necessary service." "Our primary concern was how to deal with this from a customer standpoint," he said. Coggins noted that the firm has no set timetable for its move to Finland and is focused on "fixing those systems that the FDA wants us to fix."

Before a final transfer of manufacturing, Coggins said the firm would establish a forward stocking location in the US to assure a steady supply of products to the American market. (No location for this facility had been decided upon as of April 2, although several sites were under consideration.) Since February 20, Coggins has also visited about a dozen public health laboratories and established a dedicated group of customer care representatives to deal with genetic screening products. The company may also establish a product users' group.

For public health laboratories, the incident continues to reverberate. On March 30, Hutcheson said that in his laboratory "the crisis is not over; we cannot get the inventory that we wish." Although PerkinElmer has resumed product manufacturing under a FDA reconditioning plan, Coggins noted separately that "demand is outstripping the speed with which we can ramp production back up."

A Long-term Perspective

In the long-term, the crisis has prompted a rethinking of basic newborn screening systems. Response to an informal inquiry from APHL indicates that many state laboratories have no contingency plans for newborn screening in the event of an emergency.

Hutcheson said the supply disruption highlighted his lab's dependency on one company to deliver genetic screening products. "We're going to look at the cost of maintaining a back-up system," he said, noting that high-volume customers are especially vulnerable since manufacturers do not generally stock large quantities of reagents for emergency situations.

Ojodu said the experience "emphasizes the need for state public health laboratories to think about the national impact of events and the APHL role in the national impact. States have to trust APHL's leadership role when something like this happens." In addition to gathering data and bringing together the parties who could resolve the immediate problem, APHL worked throughout the crisis to help states identify options that would enable them to continue neonatal testing if the shutdown persisted. [New York's Wadsworth Center and California's state public health laboratory offered to take on part of the workload for laboratories that were contemplating limiting or stopping screening. And both Bio-Rad Laboratories and Pediatrix Medical Group stepped up their production of newborn screening products to assist laboratories.]

We're going to look at the cost of maintaining a back-up system.

—Eldridge Hutcheson, PhD, on lessons learned

Ken Pass, chair of APHL's Newborn Screening and Genetics Committee, outlined a number of measures that the committee is

considering to avert similar crises in the future:

- ◆ Establishing a listserv to improve communication between newborn screening laboratories and APHL and among laboratorians themselves.
- ◆ Conducting a series of surveys to document the instrumentation, normal reagent inventory, estimated surge capacity, quality control procedures, and contingency plans in place at each newborn screening laboratory.
- ◆ Developing boilerplate language that newborn screening laboratories can use to establish cooperative agreements with other laboratories for surge capacity.
- ◆ Establishing a national stockpile of newborn screening reagents.
- ◆ Establishing a laboratory that would be able to take on the full newborn screening load of any US laboratory "on a moment's notice," conduct quality assurance/quality control activities, provide training

and proficiency testing, and develop and monitor genetic screening protocols. Such a facility could be funded through an insurance fee paid by each state lab and/or with funds from vendors that supply the newborn screening market.

APHL's Newborn Screening Quality Assurance Subcommittee will also be working with the CDC's Newborn Screening Quality Assurance Program to review the package inserts for all newborn-screening reagents to determine the extent of interchangeability among them.

From an organizational perspective, Becker noted that the APHL board of directors is studying the association's procedures for handling regulatory crises. Currently, no single committee has jurisdiction over regulatory affairs, and the association lacks the resources to establish a staff function for regulatory oversight. Absent a new staff position, the board will be "looking at other means to reach the same end," said Becker.

Overall, the APHL members interviewed agreed that the association was "instrumental" in resolving the crisis. "APHL took the lead on this," said Hutcheson. "Scott (Becker) was able to speak for the whole newborn screening community."

Said Becker, "We pulled out all the stops. As an organization, having the right technical expertise and the right contacts at the national level made all the difference." ■

HIV TESTING UPDATE

HIV Rapid Test Confirmatory Guidelines

Rapid HIV testing technology implemented and carried out properly provides an important tool for HIV prevention and for getting infected persons more quickly into care. These tests are screening tests, similar to enzyme immunoassays (EIA), in which reactive or preliminary positive rapid test results must be confirmed by supplemental testing using either a Western blot (WB) or Indirect Immunofluorescence Assay (IFA). Currently, the FDA has approved three rapid HIV tests: two are categorized as moderate complexity and one is waived under the regulations for the Clinical Laboratory Improvement Amendments (CLIA). Table 1 summarizes the HIV rapid tests currently on the market with manufacturer's Web sites for further information.

Interim CDC Guidelines for Confirmatory Testing

Soon after the OraQuick test was approved, the CDC, in conjunction with a workgroup of external experts, including representatives from APHL, developed a document, "Quality Assurance Guidelines for Testing Using the OraQuick Rapid HIV-1 Antibody Test." These guidelines for confirmatory testing for reactive/preliminary positive OraQuick test results can be viewed at www.cdc.gov/hiv/rapid_testing/materials/QA_Guidelines_OraQuick.pdf. These confirmatory testing guidelines apply not only to OraQuick, but to all rapid HIV testing.

Briefly, the CDC recommends that all reactive/preliminary positive rapid test results be followed up with either a WB or an IFA. If EIA testing is performed, confirmatory testing is to be done regardless of the EIA results. Data recently collected indicates that some specimens from individuals with reactive rapid test results test negative by EIA, but positive by WB. Although the manufacturers' instructions for the WB and IFA kits are not yet consistent with this practice, the FDA has approved some labeling changes that are in the process of development. These changes will provide an intended use statement that includes use as a more specific test for confirmation of rapid testing results in addition to confirmation of repeatedly reactive EIA results. Additionally, if the WB or IFA is negative or indeterminate, confirmatory testing should be repeated with a follow-up blood specimen to rule out specimen mix-up or early seroconversion. Because of the current inconsistency in the product labeling and the need for more testing data, these recommendations are provided on an interim basis.

Now that OraQuick has been approved for HIV-1/HIV-2 testing, the CDC is considering revising confirmatory testing guidelines to accommodate the potential increase in screening for HIV-2. The current CDC recommendations for confirmatory testing after a reactive HIV-1/HIV-2 combo test is to first confirm for HIV-1 (MMWR vol 41, No RR12, July 17, 1992). A positive HIV-1 WB or IFA confirms the presence of HIV. Additional testing for HIV-2 is indicated only if there is suspicion of HIV-2 based on epidemiologic risk factors. In these cases, if the HIV-1 WB is negative or indeterminate, the licensed HIV-2 EIA should be performed. If the HIV-1 WB is negative and the HIV-2 EIA is not repeatedly reactive, the specimen should be considered negative. If the HIV-1 WB is

indeterminate and the HIV-2 EIA is not repeatedly reactive, the specimen should be considered indeterminate, and a follow-up specimen should be requested. IFA results should be interpreted in the same manner as similar results from WB testing, however an indeterminate IFA should first be tested by an HIV-1 WB. If the HIV-2 EIA is repeatedly reactive, an HIV-2 supplemental test should be performed. Specimens can be referred to CDC for this testing. For the full MMWR Report and Recommendation see www.cdc.gov/mmwr/preview/mmwrhtml/00038078.htm.

Ensuring Appropriate Follow-up Testing

Public health laboratories should develop a system to ensure that specimens from individuals with a reactive rapid test result are tested by either WB or IFA. To avoid callbacks from the referring site if only an EIA test is performed and reported as negative, laboratories should develop a mechanism to identify and flag specimens that have already been tested and found to be reactive using a rapid test. This mechanism should include revising test requisition forms to obtain information on whether a rapid test was done and its result, as well as educating state counseling and testing sites (CTS) program staff so they can notify and train the CTS sites on the confirmatory testing process and how to indicate the appropriate information when they send in specimens. In addition, when reporting an indeterminate WB or IFA result, a recommendation for follow-up testing with a blood specimen collected in four weeks will remind the provider to recall the person for this additional testing.

What Can Laboratories Do To Assure Reliable Testing?

Public health laboratories have a critical role in assuring that the testing infrastructure is working properly. The laboratories are an invaluable resource for answering questions and clarifying how to setup and carry out a quality assurance program. Moreover, several laboratories have already played a pivotal role in developing and delivering training. The CDC, in conjunction with many state public health laboratories, has already conducted a first round of HIV rapid test training at 20 different sites around the country. A second round of training is currently underway and the CDC estimates that about 16 sites will participate. Up-to-date information on quality assurance and training is posted on the CDC’s Web site, www.cdc.gov/hiv/rapid_testing.

What is APHL’s Role?

The recently formed APHL/CDC HIV Steering Committee is dedicated to working together to assure that rapid HIV testing meets the needs of clients and public health. Numerous state public health laboratories have already assisted with the CDC training by facilitating the delivery of the first round of training courses. More on the role of the state public health laboratory in rapid HIV test training will follow.

Any questions or comments, contact Anthony Tran, program manager for HIV, STD, TB, atran@aphl.org or 202.822.5227 x229. ■

Table 1. HIV Tests Currently Available.

Test Kit	Manufacturer	Specimen Type	CLIA Category
OraQuick Rapid HIV-1 Antibody Test	Orasure Technologies, Inc. www.orasure.com/	Whole Blood (fingerstick and EDTA whole blood)*	Waived
Reveal Rapid HIV-1 Antibody Test	MedMira, Inc. www.medmira.com/	Serum, plasma	Moderate Complexity
Uni-Gold Recombigen HIV Test	Trinity BioTech, plc www.trinitybiotech.com/EN/index.asp	Whole blood, serum, plasma	Moderate Complexity

*Note: The OraQuick test was recently FDA-approved for use with plasma and oral fluid specimens; however kits incorporating these additional specimen types are not yet available. They will be categorized as moderate complexity under CLIA unless the manufacturer obtains FDA approval for CLIA waiver. In addition, OraQuick also has recently been cleared by the FDA for HIV-2 antibody detection in addition to HIV-1 antibody.

INFORMATICS

LIMS Design Project Progresses

Beginning on November 13, 2003, APHL, a subset of member states, and the Public Health Informatics Institute (Institute) initiated a collaborative project that takes the *Requirements for Public Health Laboratory Information Management Systems* document to the next level of detail—the design of a public health laboratory information management system (LIMS).

Major Accomplishments

The major accomplishments of the LIMS design project were highlighted during a well-attended 50-state conference call with state public health laboratory directors on April 12, 2004. A six-month status update included the following events:

- ◆ Formed six state public health laboratory member workgroups and conducted project kickoff with 27 state and local public health laboratories on November 13, 2003
- ◆ Conducted three face-to-face workgroup meetings and six project conference calls
- ◆ Identified the business processes in scope for Phase I of the project
- ◆ Created documentation of:
 - definitions of the business processes not included in Phase I
 - LIMS workflows for the detailed business processes in the Phase I product
 - definitions of proposed LIMS support of workflows, including logical screen layouts
 - definitions of screen content and structure model
- ◆ Visited the Kansas State University animal diagnostic laboratory to identify which aspects of their requirements are related to the LIMS design structure
- ◆ Developed agenda and approach for the May 17-18, 2004 design project participants meeting in Washington, DC
- ◆ Continued to refine communication and reporting requirements for multiple public health laboratory partners

The May meeting in Washington, DC, will wrap-up the LIMS design project; the participants will review and refine the draft design specifications. The final design specifications will become the property of APHL in June 2004.

Benefits, Existing and Future

Also during the 50-state conference call, the APHL and Institute leadership shared their vision for the future of the LIMS. State representatives detailed the benefits of the LIMS design project and suggested ways for laboratory directors to continue their involvement and support. The project continues to create open communication between laboratories on similarities and differences and has created a cooperative atmosphere for sharing LIMS best practices. The project has also uncovered the potential for expanding the data sharing and integration to other public health disciplines, such as epidemiology and veterinary laboratories.

The creation of the *Requirements for Public Health Laboratory Information Management Systems* document has allowed public health laboratories to speak with a single voice to the vendor community. Dr. Bernd Jilly, chief of the Alaska State Public Health Laboratory, shared the lab's recent experience creating and submitting an RFP based on the requirements document. "We were able to weed out the chaff from the different bidders pretty easily," he said. One vendor responded to the Alaska laboratory, "When going through the ASPHL RFP, we were astonished at the clarity on the front end. This was music to our ears, and quite honestly the only reason we are responding to this proposal. Because of the detailed list of 'deliverables' we now know on the front 'exactly' what custom work we have to do."

Advancing Further

Laboratory directors have shown great support for the collaborative effort by providing resources for the workgroup sessions, encouraging participation of project partners for documentation review, and by allowing their staff to sit in on conference calls to discuss the design work done to date. Directors are also in a unique position to network with other state and federal public officials. Meeting participants requested that laboratory directors use opportunities as they arise to include this project in their discussions with public officials; the final objective is to locate financial support for the continuation of a design and implementation of a true public health laboratory LIMS.

The 50-state conference call highlighted the need for continued support. Ed Shaw, assistant bureau director, Analytic Services, Virginia Division of Consolidated Laboratory Services, contends, "If you agree that the fundamental business operations of a public health laboratory require a strong, flexible information

management system over and above what most of us are using today, then the next step with the remaining design piece and implementation of a core LIMS is very important and will need continued commitment from the public health laboratory directors.”

For more information, contact Patina Zarcone, Informatics and LIM Systems Manager, 202.822.5227 x243, pzarcone@aphl.org. ■

ENVIRONMENTAL HEALTH

APHL Negotiates Vendor Discount for Members

Last fall the CDC's National Center for Environmental Health (NCEH) funded the implementation of chemical terrorism preparedness measures in state public health laboratories. States are funded at three levels, based upon the assessment of need. Most states are in the medium and high levels of need, which qualifies the labs for funding to hire dedicated personnel and purchase major chromatography equipment. Although CDC arranged for “direct assistance” with federal purchasing and discounts on chemical terrorism equipment, it could not arrange for federal funding for the supplies to be used with the devices. APHL has assisted state laboratories in identifying personnel, and now announces it has arranged a discount for state laboratories to purchase chemical terrorism consumables.

APHL brokered a discount on chemical terrorism consumables, such as chromatography columns and supplies, with two major manufacturers, Agilent Technologies and PerkinElmer Life Sciences. The discount ranges from 8-11% based on manufacturer and mode of order: for example, ordering online is most cost-effective. Shipping and handling discounts will be determined by the size of the order. The current ordering process will remain unchanged to avoid disruptions. If this discount proves beneficial to APHL members, it may be expanded to other supplies and programs.

States will receive letters from the vendors outlining details, and may contact the Agilent Customer Contact Center Information, 800.227.9770, option 1, then 1. For more information, or for the contact information of your Regional Product Specialists, contact Jennifer Liebreich, director of environmental health programs, 202.822.5227 x236, jllebreich@aphl.org. ■

EMERGENCY PREPAREDNESS

Emergency Preparedness & Response Committee Meeting

The Emergency Preparedness & Response (EPR) Committee met on March 22-23 in Washington, DC. The committee spent the first day of the meeting in a strategic planning session facilitated by invited guest Bob Kingon. The group identified and then prioritized main issues affecting terrorism preparedness and response in the public health laboratory.

Main priorities for the EPR Committee:

- ◆ Federal agency coordination for terrorism preparedness
- ◆ All-hazards preparedness and safety in the lab
- ◆ LRN expansion and surge capacity
- ◆ Resources for a sustained workforce and laboratory materials

After establishing these focal points, the committee discussed how the association should respond to these issues. Ultimately workgroups were established to tackle these priorities and provide information to APHL's Board of Directors and members.

On the second day of the meeting, numerous topics were discussed, including APHL's policy development process and the Laboratory Response Network expansion policy. The EPA representative, Latisha Parker, gave an overview of the EPA's responsibility in the water security arena and the Homeland Security Presidential Directive 9 (HSPD 9). HSPD 9 establishes a national policy for defense of the nation's agriculture and food system against terrorist attacks and other emergencies. Specifically, HSPD 9 mandates that the EPA Administrator must develop robust, comprehensive, and fully coordinated surveillance and monitoring systems for water quality that provide early detection and awareness of disease or poisonous agents; HSPD 9 also mandates the development of nationwide laboratory networks for water quality that integrate existing federal and state laboratory resources. The EPA has developed a response to HSPD 9 and will work with other federal agencies to implement this directive.

The EPR Committee also discussed the upcoming bioterrorism survey and assigned members to work with staff in finalizing this instrument. Committee Chair Jim Pearson provided an update on coordination and

EPR Committee continued on page 10

integration efforts with the Food Emergency Response Network (FERN) and the Department of Homeland Security.

Meeting Participants

Committee members and invited guests: Jim Pearson (Chair), Sally Beatrice, Rich Harris, Mike Kimberly, Bruce Kleger, Maurice Knuckles, Susan Neill, Tony Sambol, Chuck Trimarchi, Bonnie Rubin, Latisha Parker (represented EPA Liaison, Grace Robiou), Jasmine Chaitram (CDC/BPRP representative), Bob Kingon (Strategic Planner). APHL staff: Chris Mangal, Rosemary Humes, Peter Kyriacopoulos, and Doug Drabkowski.

For more information on the EPR Committee and APHL's emergency preparedness program, contact Ms. Chris Mangal at cmangal@aphl.org.

Laboratory Response Network Meetings Held at ICEID

The Laboratory Response Network (LRN) was a topic of discussion at the International Conference on Emerging Infectious Diseases (ICEID) in March. At the "Meet the Networks" open session, Michael J. Miller, chief of the Bioterrorism Preparedness and Response Program, Laboratory Response Branch (BPRP/LRB), Rich Meyer, director of the Bioterrorism Rapid Response and Advanced Technology Laboratory, and Richard Kellogg, coordinator, LRN, provided an overview of the network and discussed it as a model for preparedness. In 1999, the CDC and APHL established this network of laboratories, which can respond to biological and chemical terrorism events. Currently, the LRN includes state and local public health, veterinary, food, military and international laboratories.

The LRN also conducted a meeting for public health laboratories involved with the network. The CDC/LRN staff provided an update on the BioWatch Program, proficiency testing, advancing technologies, regulatory issues, the chemical component of the LRN and training opportunities. In the ensuing discussion, laboratorians emphasized the need for a technical and cooperative agreement guidance meeting. In response, staff at the BPRP/LRB and the National Center for Environmental Health is working with APHL and other organizations to plan a 50-state meeting for late fall 2004.

For more information on the Laboratory Response Network, contact APHL staff Ms. Chris Mangal at cmangal@aphl.org. ■

INFECTIOUS DISEASE

International Conference of Emerging Infectious Diseases 2004

The 2004 International Conference of Emerging Infectious Diseases was held in Atlanta, GA on February 29-March 3. The conference brought together public health professionals to build relationships and plan the next steps in response, research and prevention strategies for emerging diseases. Plenary and slide presentations addressed an array of topics such as zoonotic and vector-borne disease, foodborne and waterborne disease, surveillance, the global and local impact of emerging infectious diseases, public health law and policy.

In his opening remarks, Dr. James Hughes, director of CDC's National Center for Infectious Diseases, discussed lessons learned from recent outbreaks and highlighted the need for increased collaborations among the clinical laboratory, veterinary and public health communities. Hughes accorded special recognition to individuals with veterinary backgrounds and urged attendees to develop a working relationship with their state veterinarians. Several sessions during the conference confirmed the need for this collaboration:

- ◆ New and Emerging Zoonoses: The Human-Animal Interface
- ◆ Wildlife as a Source of Zoonotic Infections
- ◆ Emerging Zoonoses

Dr. Julie Gerberding, CDC director, identified challenges that need to be addressed to handle the emerging infectious diseases faced in public health. These challenges consisted of cognition (threat detection), containment, countermeasure capabilities, communication, and complacency. Gerberding also acknowledged the current public health situation in which global threats have local impact and local threats have global impact. The conference sessions that targeted these issues included:

- ◆ International Surveillance and Travelers' Health
- ◆ When Germs Travel: Epidemics and Anxiety in Modern America
- ◆ SARS: The First pandemic of the 21st Century

Dr. Patricia Somsel, director for the Division of Infectious Diseases, Michigan Department of Community Health, represented APHL on the program planning committee. Somsel helped convene a panel

session that dealt with emerging issues for the public health laboratory. The diverse group of speakers gave presentations on topics ranging from clinical and commercial laboratory interactions to biosecurity, including:

Roberta Carey, Loyola University, Maywood, IL. *The Declining Health of Clinical Microbiology: Issues and Answers*

Reynolds Salerno, Sandia National Laboratories, Albuquerque, NM. *Biosecurity: Balancing Risk and Research in Biomedical Laboratories*

Bruce Budowie, FBI, Quantico, VA. *Tracking Microbial Biocrime: The Evolving Role of Clinical and Public Health Laboratories*

Nancy Warren, Pennsylvania Department of Health, Lionville, PA. *Emerging Infectious Diseases, Improving the Interface between Commercial and Clinical Microbiology Laboratories and Public Health*

Other important sessions addressed epidemiology and laboratory detection of influenza, SARS, and monkeypox.

A CD-ROM of all the presentations can be ordered through Conference Archives, Inc., at www.conferencearchives.com/iceid/. However, APHL is pleased to be able to provide each state laboratory with one complimentary copy of the CD-ROM containing audio and slides from each presentation at the conference.

Infectious Disease Committee Meets

The APHL Infectious Diseases Committee, chaired by Dr. Jane Getchell (DE), met February 27-28 preceding the ICEID Conference in Atlanta. Strategic planning was the initial focus of the meeting. Invited guest Bob Kingon facilitated the discussion as the committee defined the critical infectious disease issues faced by public health laboratories. Four issues were pinpointed as the highest priorities:

- ◆ Developing a framework to assist public health laboratories in planning and responding to emerging disease outbreaks.
- ◆ Developing and enhancing relationships with commercial, private, and hospital laboratories
- ◆ Implementing a process for systematic surveillance of new technologies

- ◆ Providing expertise to assure the quality of infectious disease testing performed in public health laboratories and within their jurisdictions.

The group also reviewed and discussed member comments on the committee's technology transfer policy statement. The policy will be sent to the Board of Directors for approval, and then to the general membership for adoption.

Members had the opportunity to discuss HIV testing issues with Drs. Bernie Branson, Dale Hu, Steve McDougal, Mark Rayfield, and Ida Onorato, from the CDC National Center for HIV, STD and TB Prevention.

Drs. Nancy Cox and Alexander Klimov provided an update on avian influenza activities. Cox informed the members that the highly pathogenic avian flu co-circulating with human influenza in settings with high risk of exposure (such as bird markets) is an unprecedented situation and presents significant risk for a flu pandemic. Since 1997 it is recognized that high path avian flu can jump directly to humans. In order to enhance influenza detection, state public health laboratories are strongly encouraged to validate the influenza PCR assay posted on the APHL Web site. Klimov reminded the group that the CDC needs isolates from the public health laboratories to assist with strain surveillance and vaccine development. The H3 Fujian-like strain that will be used in next year's vaccine—due to its ability to grow well in eggs—was isolated in Wyoming.

The Infectious Diseases Committee also recommended that a small sub-committee be formed to oversee the formation and activities of an APHL Molecular Users Group. Dr. Romesh Gautam has agreed to chair this sub-committee; Patricia Blevins will provide APHL staff support. The purpose of the new group will be to assist public health laboratorians with method development, reagent sources, diagnostic applications, platform selection and funding resources. Once funding can be identified, APHL will establish a listserv or Web board to support the exchange of protocols and technical support for the group.

Finally, the members provided program suggestions for the 2005 APHL Infectious Diseases Conference. Drs. Patricia Somsel and Mike Loeffelholz will serve as co-chairs for the planning committee. ■

NEWBORN SCREENING

Newborn Screening and Genetics in Public Health Committee

The Newborn Screening and Genetics in Public Health Committee (NBS&GPH) continues to address the issues prioritized on its two-year agenda, established in March 2003:

- ◆ Role of APHL/state public health laboratory in broader genetic testing
- ◆ APHL/state public health laboratory preparedness/contingency plans for crisis issues
- ◆ Relationships with other organizations influencing newborn screening and genetics
- ◆ Outsourcing of newborn screening services

APHL/State Public Health Laboratory Preparedness/Contingency Plans for Crises

Committee members advocated for better contingency planning and preparedness in light of recent manufacturing issues and natural disasters that affected state newborn screening programs across the country. To further that goal by encouraging communication and collaboration, APHL has created a listserv specifically for laboratorians in the state newborn screening programs. The listserv will function primarily to disseminate current news directly affecting the newborn screening programs and will allow laboratorians to exchange information easily; it will also be used to survey surge capacities, quality assurance guidelines, and monitor supply trends in newborn screening programs. Additionally, to help avert future crises with newborn screening equipment or supplies, a task force of committee members will develop model contracts to serve as guides for solid agreements between screening programs and manufacturers, memorandums of understanding to help broker emergency arrangements with other testing sites and contingency plans to help support crisis response at the laboratory level.

Position Statements and Future Activities

The committee reviewed APHL member comments on three policy statements and aims to receive approval of these policies before the end of the year.

Future activities of the NBS&GPH committee include the 2004 Newborn Screening and Genetics Testing Symposium in Atlanta, GA, planning a newborn screening and genetics sessions during the APHL/

ASTHO joint meeting in September 2004, and finding new ways to integrate genetics into public health laboratories.

Federal Updates

Dr. Marie Mann, deputy chief of the Genetic Services Branch, Health Resources and Services Administration (HRSA), spoke to the committee, explaining HRSA's projects that will be implemented in the 2004 fiscal year. These programs include a regional genetic service and newborn screening collaborative that will enhance and support the genetics and newborn screening capacities of states within defined regions, quality assessment of newborn screening systems that will determine short and long term needs of screening programs (e.g. screening tests and follow up), and a health professional and family education initiative that would provide newborn screening educational materials for families and prenatal providers. During the Annual Clinical Medical Genetics (ACMG) meeting, HRSA announced that the ACMG project, "Standardization of Outcomes and Guidelines for State Newborn Screening (NBS) Programs," would be completed in the spring of 2004. The primary goal of the project is to develop a uniform panel for newborn screening programs. HRSA will facilitate the review process and the resulting recommendations; the final report will be released at the end of the year.

Dr. Joanne Mei, lead research chemist, Newborn Screening Quality Assurance Program at the CDC, updated the committee on the program's activities. She noted that the quality assurance program would be moving all the analytes to a Web-based platform in January 2005. Mei also noted that the *Tandem Mass Spectrometry Quality/Quality Control in Newborn Screening* Web conference was a great success with over 144 participants for each of the two conferences. The complete Web conference with PowerPoint presentations and panel discussions can be accessed through the APHL and CDC Web sites. Also, the Newborn Screening Quality Assurance Program will offer additional assistance to users of PerkinElmer products who need to re-evaluate their galactose quality controls protocols in light of QA/QC issues during the newborn screening crisis.

For more information, contact Jelili Ojodu, program manager for newborn screening and genetics, jojodu@aphl.org, 202.822.5227 x235. ■

FUNDING OPPORTUNITY

Public-Private Laboratory Integration to Provide Funding Opportunities

APHL is pleased to provide funding for up to ten states to implement innovative project activities that encourage greater public-private laboratory integration. In 2001-2002, APHL provided support to Michigan, Minnesota and Nebraska for demonstration projects that evaluated the challenges and benefits of establishing ties between the state public health laboratory and private laboratories in the state. The project was designed to increase collaborative initiatives, ultimately benefiting the public's health by providing enhanced communication systems, such as blast faxes and reporting systems, educational workshops and advisory groups.

For the current project, states will be funded to initiate mechanisms that increase awareness and coordination between public health laboratories and hospital and independent laboratories, specifically for health threats such as infectious agents (foodborne pathogens or antibiotic resistant bacterial strains) and environmental toxins. The deadline for the submission of an application is May 7, 2004. Project completion must occur by June 30, 2004.

If you have any questions about this program or the application process, contact Doug Drabkowski, APHL's director of strategic initiatives and research, ddrabkowski@aphl.org, 202.822.5227 ext. 206. ■

IMPORTANT MEMBERSHIP ANNOUNCEMENT

Dues invoices have been mailed to members.

Payment is due before July 1, 2004.

Thank you for your continued support of APHL!

Please contact Emily Mumford with any questions, emumford@aphl.org or 202.822.5227 ext. 221.

CENTER FOR PHL LEADERSHIP

Orientation Program for New Laboratory Directors

APHL's National Center for Public Health Laboratory Leadership is developing a formal orientation program for "new" public health laboratory directors. This program provides the recently appointed laboratory director with an introduction to key resource people, materials and information sources. It also gives an overview of strategies to facilitate a successful transition to leadership positions. The program is being developed with the input and guidance of the National Center's Advisory Board and in collaboration with the Public Health Practice Program Office – Division of Laboratory Systems. The three-day program consists of multiple components, including an orientation to the association and to the CDC that surveys their respective organizational structures, function, missions, visions and principals. In addition, new lab directors will meet key partners at the CDC. Other elements of this orientation are a comprehensive session on establishing successful teams and a media workshop, building skills for immediate use. The orientation program will take place in Atlanta and will be delivered annually.

A handbook, "A Practical Guide to the Public Health Laboratory Leader," is nearing completion. This guide will provide practical, informative, and common sense strategies, tips, techniques and advice to new laboratory directors. This guide should be equally useful to rookie laboratory directors and seasoned professional laboratory directors.

Following the orientation program in Atlanta, Scott Becker, APHL executive director, will conduct site visits to public health laboratories with new laboratory directors. These site visits will offer opportunities for in-depth discussion, informational exchange, and will foster an understanding of the mission and role of the public health laboratory and the association.

Center staff is currently assembling the first team of new public health laboratory directors to participate in the orientation program in Atlanta, scheduled for June 2004. For additional information, contact Eva Perlman, APHL's senior director of professional development, at 202.822.5227 ext. 303. ■

FELLOWSHIPS

APHL's EID Fellows Make a Splash at the 2004 ICEID Meeting

APHL's EID fellows were a major presence at the International Conference on Emerging Infectious Diseases (ICEID) meeting in Atlanta, GA, February 29 – March 3, 2004. All EID fellows were invited to the meeting, and many presented posters or gave oral presentations.

Class IX EID Fellow **Melissa Allen** co-presented the poster "Laboratory Testing for Febrile Rash Surveillance, Virginia 2003." Allen works in Virginia's Division of Consolidated Laboratory Services.

Alejandro Castello presented "Molecular Epidemiology of Rotavirus Diarrhea among Children in Buenos Aires, Argentina: Emergence of the Genotype G12." Castello is a Class VI international EID fellow from Argentina, working in the CDC's Division of Viral and Rickettsial Diseases.

Class IX Fellow **Laurie Dizney** from the Oregon State Public Health Laboratory presented "Epizootiology of Sin Nombre Hantavirus and Population Dynamics of Small Mammals in Urban Parks: Human Health Implications of Host Ecology and Viral Incidence." Dizney also gave an oral presentation of her research at the Oregon Chapter of the Wildlife Society meeting in February. The presentation, "The Link Between Diversity and Disease," focused on how the density and diversity of mammalian species in a given ecosystem relates to the prevalence of Hantavirus.

Class V International EID Fellow **Gang Liu** presented the poster "Burden of Chlamydia pneumoniae and Mycoplasma pneumoniae Infection in Community-acquired Pneumonia Affecting Children under 5 Years Old in China." Liu recently completed her CDC fellowship and returned to China.



*L to R:
Jonathan Duczowski (Class IX T),
Nina Glass (Class IX T),
Kumapley Lartevi (Class IX T),
Nikole Goldsmith (Class IX T)*

Lindsay Edwards, a Class VIII fellow in the CDC's Division of Viral and Rickettsial Diseases presented the poster "Serological Diagnosis of Human Infection with Avian Influenza (H7N2) Virus."

Class IX Fellow **Nina Glass** presented the poster "Opportunities to Reduce Inappropriate Use of Antibiotics in Obstetric Care, 2001." Glass works in the CDC's Division of Bacterial and Mycotic Diseases.

Ivan Kuzmin, co-authored the poster "Newly Described Lyssaviruses from Eurasia: Failure of Pre- and Post-exposure Prophylaxis with Rabies Biologics"

and gave an oral presentation entitled "Identification of Nipah Virus as the Source of Encephalitis Outbreaks in Bangladesh." Kuzmin is a Class V international EID fellow in the CDC's Division of Viral and Rickettsial Diseases.



Back Row from L to R: Ana Roberts (Class VIII Training), William Glover (Class VIII T), Darci Hansen (Class VIII T), Lindsay Edwards (Class VIII T), Dieter Hoffmann (Class V International), Bulent Taysi (Class V Int.) Front Row L to R: Travis Henry (Class VIII T), Nhi Khuong (Class VIII T), Marie-jo Medina (Class VIII T)

Class VIII Fellow **Darci Hansen** gave the presentation "Influence of GB Virus C (GBV-C) Co-infection on HIV-1 Peak Viremia and Viral Set Point among Injecting Drug Users (IDU) in Bangkok." Hansen is a Class VIII fellow in the CDC's Division of AIDS, STD, and TB Laboratory Research.

EID fellowship program alumni were also well represented at the ICEID meeting. Former EID fellows whose research was presented in posters at the ICEID conference included **Ray King, Jennifer Kleene, Kristy Kubota, Marie-jo Medina, and Jessica Versage.**

Congratulations to all of the EID fellows whose research was showcased at the meeting!

Katie Kurkjian, a Class IX research fellow in the CDC's Division of Parasitic Diseases recently returned from a four-week field assignment in Bangladesh where she assisted in processing over 1,300 samples for detection of visceral leishmaniasis. Kurkjian met with field staff, observed data and blood collection, interacted with study participants, and visited local health complexes.



L to R: Gang Liu and Yuping Ran (Class V Int.), Shuming Zhao (Class VI Int.), Jianguo Lin (Class VI Int.), Zhian Zhang (Class IV Int.)

Of her trip she said, "I became more aware of the strengths and weaknesses within our project and within the overall local health system."

APHL Launches Environmental Health Fellowship and Traineeship Program

APHL and DLS/NCEH are pleased to provide an opportunity for state public health laboratories to enhance environmental health laboratory testing capabilities through a new Environmental Health Traineeship and Fellowship Program. The traineeship program provides short-term (2-6 week) specialized training in environmental health technology and testing methods for current laboratory staff (at another state health department, NCEH/CDC, or other state or federal agencies (such as ATSDR, EPA, NIEHS or NIOSH). The fellowship program provides an opportunity for the recruitment and placement of a pre- or post-doctoral fellow for one-two year assignments to address specific environmental health technology needs.

For more information or application materials for these programs, please contact Heather Roney, fellowship program manager, at hroney@aphl.org.

APHL Fellow Assists with Avian Influenza Outbreak in Asia

For the past 18 months, International EID Fellow Doan Cong Nguyen has been working in the influenza branch of the CDC's Division of Viral and Rickettsial Diseases. When the recent avian influenza outbreak hit his home country of Vietnam, Nguyen was in a unique position to assist with the investigation. With the support of his CDC host laboratory Nguyen returned to Hanoi in early 2004 to facilitate collaboration among the CDC, WHO, and his home country laboratory on the outbreak. He brought reagents, supplies, and equipment from the CDC laboratory to his home laboratory to help with the investigation. Doan describes the experience:

The emerging avian influenza outbreak in a number of Asian countries 2003-2004 is historically unprecedented in terms of extent and scale. Vietnam, my home country, is one of the hardest-hit nations by the poultry outbreaks and is also the hardest-hit country by number of human infection and fatality. My home laboratory, the Influenza Laboratory of the National Institute of Hygiene and Epidemiology (NIHE), is the unique laboratory for this work in the north of Vietnam and has been in front of the investigation. Both the Influenza Branch, CDC and my home institution, NIHE, were fully supportive of my trip to assist in the outbreak investigation with both laboratory and epidemiology colleagues there. This is a unique opportunity and challenge for me to gain experience on emergence response, to apply knowledge and skills that I have learned from CDC, to assist my home colleagues in the laboratory and the field, to contribute my time and energy in the fight of my home country against the outbreaks, and to continue to facilitate the collaboration between CDC and my home institution.

Following his experience during the outbreak, Nguyen's CDC mentor Jackie Katz commented, "His training on avian influenza under the fellowship is paying off for all." ■

The EID Fellowship Program Celebrates its Tenth Birthday!

APHL received over 250 applications for the 2004 EID Fellowship Programs. We look forward to selecting the Class X fellows in June!

MEMBER NEWS

Oregon State Public Health Laboratory: A Typical Lab?

Celebrating its centennial in 2003, the Oregon State Public Health Laboratory (OSPHL) continues its long tradition of supporting public health by participating in infectious disease control efforts, operating a regional newborn screening program and ensuring that clinical laboratories in Oregon continue to meet national standards.

Facility, Moving Forward

The OSPHL occupies part of a 1970's-era university building on the Portland State University campus. Under the same roof are the Oregon Department of Environmental Quality (DEQ) laboratory and the university's biology and chemistry departments. The division of responsibility between the OSPHL and the DEQ lab is clear: the state public health lab conducts microbiological or medical environmental testing and the DEQ chemists handle all of the environmental chemistry. Still, separated physically by only a single wall, the inherent relationship is one of strong collaboration and positive association.

This sense of collaboration and shared purpose has guided the two separate agencies to plan a joint relocation into a sparkling new facility. Both have outgrown their space; both have also discovered that re-fitting the current space would be more expensive than starting fresh. A definite location has not been determined for the move, but Michael Skeels, PhD, MPH, laboratory director, says the OSPHL will benefit from the recent tech sector overbuilding. Large, new, empty buildings surround Portland, "vanilla shells" waiting to be outfitted by a buyer. The two laboratories plan to share a reception area, conference rooms and other general spaces.

Community Interaction and Accreditation

An expanded space has become a necessity as the lab grows and changes in response to modern developments in public health. In addition to the increased need for biosafety and emergency preparedness, the laboratory operates a large, regional

newborn screening program that screens for 26 metabolic disorders. In addition to testing Oregon's newborns plus those from Alaska, Idaho, Nevada and Hawaii, the program is also responsible for babies born on some military installations in the Northwest and in locations abroad. Oregon has the distinction of maintaining the oldest regional newborn screening program in the

country, dating back to the 1970s. Skeels also points out that, in 1962, Oregon was the first state to mandate universal screening for phenylketonuria (PKU).

The OSPHL and the DEQ laboratory jointly manage the Oregon Environmental Laboratory Accreditation Program (ORELAP). ORELAP is the local version of

the EPA's National Environmental Laboratory Accreditation Program, designed to maintain a national standard for American environmental laboratories. The public health laboratory accredits the microbiological elements of the testing while the DEQ laboratory handles the chemical aspect.

In addition to its authority with ORELAP, the state public health laboratory certifies 2,000 clinical laboratories. The OSPHL upholds the Clinical Laboratory Improvement Amendments (CLIA) program across the state. It also enforces state regulations for clinical laboratory testing, substance abuse testing and health screen testing.



Entrance to the Oregon state public health laboratory in Portland, OR.

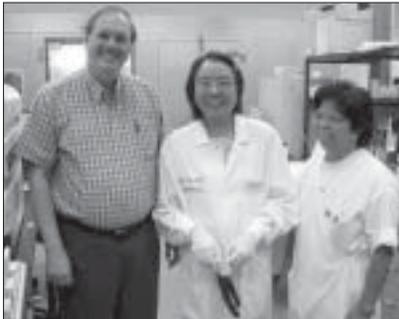
Laboratory At-A-Glance

Founded: 1903
Location: Portland, OR
Labs: 1
Constructed: 1977
Staff: 76
Size: 25,000 square feet
BSL Rating: 2
Test Volume: 6 million tests on 375,000 samples annually
Divisions: Newborn Screening, Virology/Immunology, General Microbiology, Laboratory Operations, Laboratory Compliance and Quality Assurance

Uniquely, the OSPHL is one of the few state public health laboratories that has acquired accreditation with the College of American Pathologists (CAP). CAP typically accredits private medical laboratories, but the OSPHL has found it very useful for laboratory improvement projects and internal quality assurance.

Challenges Ahead

Workforce shortage and funding concerns are the issues that Skeels, a former APHL president and board member, identifies as key challenges. He notes that it is always a challenge to find, recruit and retain qualified staff when salary levels are not top-tier. Funding, in a more general sense, is always a pressing concern.



The OSPHL receives 13% of its funding from the

Dave Sesser, Olivia Cosme, and Rose Houtchens of the Oregon lab.

state government, 37% from the federal government and 50% from testing fees, almost all from newborn screening. The federal funds are all categorical; fifty percent of the federal funds are earmarked for bioterrorism. Skeels points out that running the laboratory efficiently, like a business can be run, is a difficult undertaking within the constraints of the state and federal governments.

Skeels contends that in some ways the Oregon laboratory could be considered a *typical* one. The OSPHL is certainly a reflection of other public health laboratories as it confronts workforce shortage, funding worries, regulatory changes and emergency preparedness, in addition to the ongoing and vital public health work



Missy Yungclas looks into a microscope at the lab.

performed for years. And, typically, like other public health laboratories, the Oregon state public health laboratory has forged its own unique identity as challenges have been met. ■

Oregon Department of Environmental Quality Laboratory

The laboratory division of Oregon's Department of Environmental Quality (DEQ) monitors, samples and analyzes air, water, soil, hazardous and solid waste, and pollutant discharges to determine whether environmental standards have been attained. The laboratory staff has expertise in environmental chemistry, biological assessments, air and water measurements, analytical methods and quality assurance.

New Facility in the Works

Oregon's DEQ laboratory facility is located on the urban campus of Portland State University, its home since 1977. "It's a wonderful urban campus," notes Mary Abrams, PhD, laboratory division administrator. "The laboratory is accessible by mass transit, integrated into the heart of the city and convenient to the Department of Environmental Quality headquarters."

Despite the comforts of the university campus, Abrams is enthusiastic about the upcoming move to a new facility, planned to occur by 2007. The DEQ lab will move in tandem with its current neighbor, the Oregon State Public Health Laboratory; the two agencies believe the co-location will improve efficiency and lower certain operating costs. Laboratory staff will undoubtedly be giving up the central Portland location, but will gain office space, new equipment and a modern facility. "There will be an adjustment at first," Abrams admits. "But it will be worth it." The new facility will introduce modular laboratory benches and an HVAC system that "*really* works well." A new HVAC system will allow the DEQ lab to perform ultra-clean sampling and analysis for compounds that are problematic even at extremely low levels, such as estrogen mimickers and some trace metals like mercury.

Abrams points out that the shared space with the state public health laboratory will also allow for a significant improvement with unknown sample triage. Currently when an unknown and potentially dangerous sample arrives at the DEQ, a chemist will unpack and examine it; if the sample is microbiological, it must then be re-packed and transferred to the state public health laboratory. This laborious process will change in the new facility: the labs will utilize a communal space for the reception of unknown samples.

Ties to the Community

Like most laboratorians, DEQ chemists typically perform their jobs behind the scenes. Their work in turn fuels other important community efforts. The chemists analyze and monitor laboratory data produced by tested samples, flagging statistics that warn of potential or current environmental problems. These red flags are forwarded to other DEQ departments or local agencies for further investigation.

The laboratory coordinates with numerous external partners, including the state public health laboratory, the local branch of the U.S. Geological Survey, regional offices of the EPA, the FBI and the state police. The DEQ lab has equipment that enables it to assist the state agricultural laboratory with some of its testing needs.

The public has access to a comprehensive database built and maintained by the DEQ laboratory. The Laboratory Analytical Storage and Retrieval (LASAR) database contains all of the information stored in the DEQ lab's LIMS, as well as additional data collected from various sources, such as the volunteer water quality monitoring system in Oregon. The LASAR database allows the public to find data on water quality in a particular location in Oregon: for instance, an avid fisherman could investigate the pH or the temperature on a given spot in the Snake River.

On occasion lab staff does have the opportunity to interact directly with the community. During a large-scale industrial fire, laboratory staff was on site with police and investigators to help monitor the environmental consequences. Abrams explained that the DEQ laboratory employees were able to recommend the best testing locations to measure the extent of the "downstream" of the actual site.

Funding is a Challenge

Abrams agrees with the state public health laboratories: funding is a challenge. The DEQ laboratory is considered a service organization within the department as a whole, and therefore does not have an independent budget. Lab staff is tasked to respond to the needs of the wider DEQ and therefore funding comes piecemeal

from a given division that needs something accomplished. Abrams spends time ensuring that her colleagues in the DEQ understand how essential the laboratory services are. In times of fiscal crisis, Abrams worries that there are some that perceive lab services as "low-hanging fruit that can be chopped at any time."

While such worries are prevalent, the lab has enjoyed long-due, if brief, moments in the spotlight. At the

The Oregon Department of Environmental Quality Laboratory Division is divided into five official sections. Additionally, there is a section that consists of administrative personnel and quality assurance/quality control staff.

Organic Analysis & General Chemistry	Chemists who test all of the samples delivered to the DEQ lab.
Inorganic Chemistry	
Watershed Assessment	Employees headquartered at the DEQ lab who sample water and air quality around the state. Although often working externally, these employees are on site to calibrate their instruments and turn over samples to the Chemistry Sections.
Air Quality Monitoring	
Technical Services	This section tracks samples within the laboratory and manages all data produced by the testing.

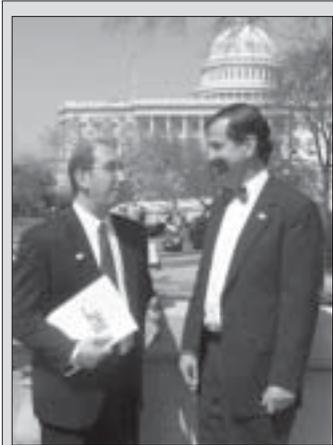
conclusion of a recent environmental crime trial, the presiding judge attributed the success of the prosecution directly to the quality of the data provided by the DEQ laboratory. This credit for careful work did make it onto the public record, enforcing the clear correlation between solid laboratory data and civic impact. ■

Richard Jackson to Leave CDC for Post as CA State Health Officer

After a decade with the CDC and its national effort to improve environmental health, Dr. Richard Jackson, senior advisor to the CDC director, is returning to California as the newly appointed state public health officer for the California Department of Health Services. Since joining the CDC in 1994, Jackson has vigorously addressed a full range of environmental health issues, including cancer, asthma, radiation effects, pesticide exposure, toxicology and lead poisoning in children. He introduced numerous innovations and enhancements in environmental health that leave a lasting legacy for the CDC and the nation. ■

Hill Day March 25, 2004: Members Advocate for Funding

At APHL's Hill Day on March 25, 2004, representatives of six states joined the association's leadership team of Paul Kimsey (CA) and Norman Crouch (MN) in visiting with key members of Congress and their staff. In addition to providing background and information on the issues that related directly to their states, the APHL delegates articulated the primary legislative areas of concern to the association for federal fiscal year 2005. Of paramount concern is the proposed \$105 million reduction in federal funding from



Scott Becker, APHL executive director, and Dr. Paul Kimsey, APHL president-elect, pause to discuss strategy before meeting with Members of Congress.

CDC for state and local preparedness. APHL members offered detailed explanations of the challenges to preparedness that a reduction of this magnitude would have and encouraged the maintenance of funding at the federal fiscal year 2004 level of \$934 million.

Another key discussion topic was the importance of increasing biomonitoring funding by \$20 million, with half of the funding increase going to states to provide grants for the implementation of approved biomonitoring plans and half to the CDC's environmental laboratory. This funding increase would allow about 20 additional laboratories to increase capacity and capability for human biomonitoring.

Last, but certainly not least, APHL members called attention to the need for a \$10 million increase in funding

Dr. Bill Becker, APHL board member, discusses bioterrorism funding with Rep. Ralph Regula (R-OH).



for the Epidemiology and Laboratory Capacity Program to improve detection and prevention of current and emerging infectious diseases. This funding increase will be critical to the development of essential laboratory capabilities.



Dr. Mary Gilchrist, former APHL president, defines biomonitoring for a Sen. Tom Harkin (D-IA) staff member.

In addition to Drs. Kimsey and Crouch, APHL members who participated in Hill Day 2004 included: Drs. Kati Kelley (CT), Mary Gilchrist (IA), Jack DeBoy (MD), Patricia Somsel (MI), Lawrence Sturman (NY), William Becker (OH), Susan Neill (TX), James Pearson (VA) and Mr. Tim Monson (WI). Thanks to all for your fine work and dedication to advancing these matters.



Dr. Norman Crouch, APHL president, meets with Sen. Mark Dayton, (D-MN) to discuss APHL priorities in Crouch's home state.

For more information on Hill Day activities, contact Peter Kyriacopoulos, APHL's director of public policy, pkryriacopoulos@aphl.org. ■

STAFF NEWS

Jeremy Gillissen, JD, a recent graduate of Howard University Law School, has been hired on a short-term basis as the food safety program manager. Gillissen will work at APHL until July. As a former employee of the American Society of Clinical Pathologists, he is familiar with laboratory issues; his interest in food safety has been developed through a course in environmental law and subsequent research into pesticides. Gillissen will leave APHL to continue his work in civil rights.

Rosemary Humes, MS, MT(ASCP)SM, has accepted the title of director of infectious disease and preparedness, which better reflects her role within APHL's infectious disease and emergency preparedness and response programs. The two programs have a cooperative nature, overlapping in the area of preparedness.

Chris Mangal, MPH, has been promoted to a more senior manager level to reflect her increased responsibility within the organization. Mangal will continue as APHL's emergency preparedness and response program manager, working with the Laboratory Response Network, federal agencies, and on select chemical terrorism preparedness and response issues.

Areana Quiñones, MPH, resigned from her position as global health program manager on April 16, 2004, to accept a position as malaria coordinator with the Child Survival Collaborations Resources Group in Washington, DC. APHL wishes her well as she continues her public health career.

Patina Zarcone, MPH, has been promoted to a more senior manager level. She will continue to serve as the informatics and LIM system manager as she provides leadership, training, and oversight to the project activities of the National Electronic Disease Surveillance System (NEDSS). ■

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The Association of Public Health Laboratories (APHL) is a national, non-profit dedicated to working with its members to strengthen public health laboratories. By promoting effective programs and public policy, APHL strives to provide public health laboratories with the resources and infrastructure needed to protect the health of U.S. residents and to prevent and control disease globally.

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