Improving Laboratory Systems and Services: CDC’s Role as a National Public Health Institute.

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Outline

- CDC Laboratory Activities
- Laboratory Regulations/Quality Standards
- Support for the Public Health Laboratory System
- Workforce development
- Research/Method evaluation and development
- Program support/Technology transfer
CDC’s Laboratory Activities

Major Functions/Focal Areas

- Outbreak assistance
- Reference laboratory testing
- Management and inventory of specimens
- Materials, reagents, equipment
- Research collaboration, technology development, transfer, and evaluation
- Quality assurance, standards, guidelines, and proficiency testing
CDC’s Laboratory Activities

Major Functions/Focal Areas

- Building infrastructure and laboratory capacity
  - Facilities design and construction
  - Safety and security
  - Training and workforce development
  - Laboratory information management systems

- Policy and partnership development, advocacy

- Strengthening public health testing capacity and integration with clinical labs
LABORATORY REGULATIONS AND QUALITY STANDARDS
Clinical Laboratory Improvement Amendments (CLIA)

1992 regulations implementing CLIA included requirements for:

- Patient test management (PTM)
- Quality control (QC)
- Proficiency testing (PT)
- Personnel
- Quality assurance (QA)
219,000 CLIA-certified laboratories
333,000 laboratory personnel
>6 billion tests/year
$52 billion/year in laboratory revenues

*Community clinic, rural health clinic, school/student health service
** Public health laboratories, insurance, pharmacy, tissue bank/repositories, blood banks, ambulance and mobile units, industrial, health fair, ancillary test sites, school/student health service, other not specified.
CDC Role – CLIA

- Develop/revise standards
- Assist Center for Medicare/Medicaid Services (CMS)
  - Evaluating accreditation/exemption applications
  - Reviewing proficiency testing programs (includes cytology)
- Conduct studies
- Manage/coordinate CLIA Advisory Committee
- Develop/distribute technical information and educational materials in conjunction with CMS
Clinical Laboratory Improvement Advisory Committee (CLIAC)

- Chartered and first members selected in 1992
- Provides scientific/technical advice on:
  - Revisions to the standards
  - Impact on medical and laboratory practice
  - Accommodating technological advances
CLIAC Structure and Membership

CLIAC
- 20 voting members
- 1 liaison member
- 3 ex officio members

Secretary
HHS

FDA

CMS

CDC

APPOINTS

ADVISES on CLIA

COMMITTEE SUPPORT
Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition
Rapid Diagnostic Tests for Malaria --- Haiti, 2010

Weekly
October 29, 2010 / 59(42);1372-1373

Plasmodium falciparum malaria is endemic to Haiti and remains a major concern for residents, including displaced persons, and emergency responders in the aftermath of the January 12, 2010 earthquake (1). Microscopy has been the only test approved in the national policy for the diagnosis and management of malaria in Haiti; however, the use of microscopy often has been limited by lack of equipment or trained personnel. In contrast, malaria rapid diagnostic tests (RDTs) require less equipment or training to use. To assist in the timely diagnosis and treatment of malaria in Haiti, the Ministry of Public Health and Population (MSPP), in collaboration with CDC, conducted a field assessment that guided the decision to approve the use of RDTs. This data-driven policy change greatly expands the opportunities for accurate malaria diagnosis across the country, allows for improved clinical management of febrile patients, and will improve the quality of malaria surveillance in Haiti.

The selection of diagnostic tests for malaria for a country’s national policy depends on multiple factors including the availability of health facility and laboratory infrastructure, financial resources, skilled personnel, and local epidemiology of the disease. For these reasons, national policies might differ from their recommended first-line diagnostic test. In the United States, both microscopy and RDTs are recommended, and at minimum, either test should be available at health-care facilities for malaria diagnosis; the only approved RDT in the United States, however, is BinaxNOW Malaria (Inverness Medical, Princeton, New Jersey). In addition, polymerase chain reaction can be used for malaria diagnosis and is most useful for species confirmation.

Until now, official MSPP policy for laboratory diagnosis of malaria has been to rely exclusively on microscopy. RDTs had not been incorporated into the MSPP malaria control strategy because of concerns that these newer tools, when compared with microscopy, were not sufficiently sensitive and were too expensive to implement on a larger scale.
Recommendations for Diagnosis of Shiga Toxin--Producing *Escherichia coli* Infections by Clinical Laboratories

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SUPPORT FOR THE PUBLIC HEALTH LABORATORY SYSTEM
State Public Health Labs
How CDC helps states....

- Reference testing
- Methods development and transfer
- Reagents
- External quality assessment
- Technical consultation
- Domestic global networks (LRN, Pulsenet)
- Guidelines and recommendations
- Direct funding
APHL

- Non-profit organization
- More than 80 Staff
- Growing membership
  - ~800 members
  - State and Local Public Health Labs
    - Leadership, delegates
  - State Environmental Laboratories
  - Agricultural Laboratories
  - Individual Members
Committees
(many have subcommittees)

- Emergency Preparedness and Response
- Environmental Health
- Finance
- Food Safety
- Global Health
- Infectious Diseases
- Informatics
- Knowledge Management

- Laboratory Systems and Standards
- Membership and Recognition
- Newborn Screening and Genetics
- Public Policy
- Workforce
APHL/CDC Collaboration

- Wide and Deep
- Intersects Science, Practice, and Policy
Components of the Public Health Laboratory System

- Clinicians
- Epidemiologists
- Nursing Homes
- Environmental Laboratory
- Private Laboratories
- Local Public Health Laboratories
- Mental Health
- Fire
- Transit
- Policy Makers
- EMS
- State Public Health Laboratory
- Clinical Laboratories
- Clinical
- Labor
- State Public Health
- Clinics
- Providers
- Law Enforcement
- Tribal Health
- Academia
- Elected Officials
- Corrections
- PH Nurses
- Hospitals
Linking Laboratories and Epidemiology

CDC

Laboratory          Epidemiology

State Laboratory    State Epidemiology

Clinical Laboratory Hospital Epidemiology

Referral           Reporting

Referral           Reporting
Roles of Health Laboratories

Provide information for decision making

Clinical Labs
- Diagnostic testing
- Some reference testing
- Patient management
- Front line PH Response

Public Health Labs
- Some diagnostic testing
- Reference testing
- Surveillance and monitoring
- Information to Clinical labs

Individual health

Public health

Interdependent Network

National Laboratory System
The Old Paradigm

A loose association of public health (state, county and city), hospital, and independent laboratories throughout the country.

- Consensus Standards
- Funding
- Training
- Technology Transfer

50 State PHLs

Private Labs

Inconsistent Collaboration
Core Functions and Capabilities of State Public Health Laboratories

A Report of the Association of Public Health Laboratories

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Definition of a State Public Health Laboratory System

The State Public Health Laboratory System (SPHL Laboratory System) consists of all the participants in public health testing, including those who initiate testing and those who ultimately use the test results. The PHL Laboratory System is part of the larger state public health system. The System includes individuals, organizations, and agencies that are involved in ensuring that laboratory data support the 10 Essential Services of Public Health. The concepts of a SPHL Laboratory System are also embedded in the APHL Core Functions and Capabilities of State Public Health Laboratories. These documents are available on the APHL website at www.aphl.org. Within the SPHL Laboratory System are primary stakeholders who are directly involved in creating and using laboratory data. Additional stakeholders include those who are concerned with complementary essential services, such as Training and Education and Public Health Related Research. A successful National Laboratory System is dependent on the creation of fully integrated and coordinated networks in every state. The goal of the National Laboratory System is to support voluntary, interdependent partnerships of clinical, environmental, agricultural and veterinary laboratories through public-private collaborations for assurance of quality laboratory services and public health surveillance.

The SPHL Laboratory System should assure that:

1. Public health threats are detected and intervened upon timely;
2. stakeholders are appropriately informed of potential threats;
3. reportable conditions are monitored in a comprehensive statewide system;
4. specimens and tests for public health testing are sufficient to provide comprehensive public health surveillance and response;
5. public health laboratory data are transmitted to appropriate state and federal agencies responsible for disease surveillance and control.

The state public health laboratory (SPHL) has a leadership role in developing and promoting the SPHL Laboratory System through active collaboration with stakeholders, including epidemiologists, infectious disease control professionals in state and local departments of public health, private clinical and environmental laboratories; and federal public health laboratories. The SPHL provides leadership to ensure that essential and state-of-the-art laboratory services are provided and that clinical laboratories that perform public health testing are able to report infectious disease outbreak-related results to the public health surveillance system using national testing guidelines. To provide leadership, the SPHL monitors essential components of the SPHL Laboratory System, such as completeness of reporting and accuracy of laboratory testing results. The SPHL also assesses that accuracy results are reported in a manner that is appropriate and sufficiently timely for effective public health response. An effective SPHL Laboratory System requires proactive leadership by the SPHL to monitor public health testing processes by clinical and environmental laboratory. To assure that the SPHL Laboratory System is effective, the SPHL should:

1. have an integrated information system that includes all stakeholders that rely on accurate laboratory data;
2. employ a full-time public health laboratory system coordinator;
3. create a standing public health laboratory advisory committee;
4. provide an interactive website or other electronic system to maintain regular communication channels for system partners.

This document was developed by a subcommittee of the APHL Laboratory Services & Standards Committee. It was adopted by the APHL Board on May 24, 2007.
Building State Laboratory Systems for all Programs

- Surveying Clinical Labs
- Establishing linkages
- Education
- Proficiency Testing

MINNESOTA LABORATORY SYSTEM
A PUBLIC AND PRIVATE COLLABORATION
WORKFORCE DEVELOPMENT
National Laboratory Training Network (NLTN)

Training system sponsored by the Centers of Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL)
Laboratory Training Modalities

- Teleconferences & Webconferences
- Hands-On Workshops
- Seminars
- Train-the Trainers
- On-Demand Programs
  - Online courses, Laboratory Workshops To Go, CD/DVD’s, Previously recorded teleconferences, Podcasts
## NLTN Laboratory Training Topics

- Bioterrorism Preparedness
- Biosafety/Biosecurity
- Chemical Terrorism Preparedness
- Packaging & Shipping
- Bacteriology
- Influenza
- Molecular Testing
- Mycobacteriology
- Mycology
- Parasitology
- Rabies
- Virology
- Foodborne Disease
- Other Infectious Diseases
- Antimicrobial Susceptibility Testing
- Newborn Screening
- Quality Assurance
- Others...
Training and Fellowships

James A. Ferguson
Emerging Infectious Diseases Fellowship
for graduate students

The Centers for Disease Control and Prevention (CDC) and the James A. Ferguson Emerging Infectious Diseases Fellowship Program, CDC, are pleased to announce the availability of the James A. Ferguson Emerging Infectious Diseases Fellowship Program, 2012. This fellowship program is an 8-12 month, paid, postgraduate training experience for medical and public health professionals in the fields of infectious diseases and public health. Fellows will participate in a broad array of public health activities. The program is administered through a cooperative agreement between the Division of Global Emerging Infections System and the National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases (NIAID). Fellows are paid a salary based on their level of experience and qualifications. They are required to present and deliver a formal scientific presentation on their work in CDC science and staff at the end of the program and receive a letter of recommendation. The students assume responsibilities, learning and training and will return to their home institutions.

The program is designed to broaden students’ knowledge of public health and infectious disease issues and to enhance fellow’s skills in a spectrum of research activities and public health strategies. The primary goal of the program is to encourage students to pursue careers in public health and infectious diseases. NIAID scientists and other CDC scientists work closely with fellows to develop personalized training plans.

The deadline for submitting applications is February 15, 2012. For additional information about the program, visit the NIAID website at www.niaid.nih.gov or call 301-594-6233. For more information about the CDC fellowship program, visit www.cdc.gov/neri/ff/ff.htm.

Products and Services of the Division of Scientific Resources

EMORY UNIVERSITY

Labor Animal Medicine Services

DAR LINKS

Lab Animal Medicine Services

Animal Resources

Clemmer Research Animal Facility
Contact: Dr. Allison Williams, 770.482.4028

Lawrenzveille Research Animal Facility
Contact: Dr. Gregory Langham, 770.335.3914

Royal Research Animal Facility
Contact: Dr. Brian Wallin, 423-491-4650

High Containment Animal Facility
Contact: Dr. Allison Williams, 770.482.4028

Preparation and Submission of Animal Protocols
Contact: Elizabeth Matherly, 423-491-4650

Biologics

Specialized Diagnostics Support
Custom cell culture media
Protein purification/analysis/conjugation
Dispensing/lab utilization labeling
Contact: John P. Klabunde, 770.482.1320

EMORY UNIVERSITY

Administration

Promoting the health and well-being of people everywhere by providing the finest animal care and support for Emory University Scientists.

Lab Animal Medicine Services

Lab Animal Medicine Services
Personnel Requirements for High Complexity Testing

- Laboratory Director - MD Pathologist or PhD with board certification
- Clinical Consultant - MD
- Technical Supervisor - MD, PhD or MS in technical area or BS (just more experience required)
- General Supervisor - MT or MLT
- Testing Personnel - MT or MLT or BS/AS in Science (biology, chemistry, physical science) (60 semester hours in the sciences)
RESEARCH/METHOD EVALUATION AND DEVELOPMENT
CDC Laboratory Research Activities

- Characterization of organisms
- Development of new diagnostic and epidemiologic methods
- Evaluation of methods
- Testing in support of epidemiology studies
- Biomonitoring
- Occupational exposures

- National Institutes of Health (NIH) supports majority of clinical and basic research, but some overlap with CDC
Characterization of a Novel Coronavirus Associated with Severe Acute Respiratory Syndrome

Paul A. Rota,1,2 M. Steven Oberste,1 Stephanie Peñaranda,1 Bettina Bankamp,1 Kaija M. Mankinen,1 Luis Lowe,1 Michael Frace,1 Joseph L. DeRisi,1 Cara Burns,1 Thomas G. Kräsek,1 Pierre E. Rollin,1 Josef Limor,1 Karen McCausland,1 Melissa G. Farley,1 Albert D. M. E. Osterhaus,2,3 Christian Drosten1

The Genome Sequence of the SARS-Associated Coronavirus

Marco A. Marra,1,2,4 Steven J. M. Jones,1 Caroline R. Astell,1 Robert A. Holt,1 Angela Brooks-Wilson,1 Yaron S. N. Butterfield,1 Jaswinder Khattria, Jennifer K. Asano,1 Sarah A. Barbor,1 Susanna Y. Chan,1 Alison Cloutier,1 Shaun M. Coughlin,1 Doug Freeman,1 Noreen Girm,1 Obi L. Griffith,1 Stephen R. Leach,1 Michael Mayo,1 Helen McDonald,1 Stephen E. Montgomery,1 Pawan K. Pandoh,1 Anca S. Petrescu,1 A. Gordon Robertson,1 Jacqueline E. Schein,1 Asim Siddiqui,1 Duane E. Smallis,1 Jeff M. Stott,1 George S. Yang,1 Franck van Apeldoorn,1 Donald Williamson,1 Michael O. Zink,1 Susan L. Lindsey,1 Robert G. Webster1
PROGRAM SUPPORT/TECHNOLOGY TRANSFER
Improving Emergency Response

More than 160 public health, military, federal, food, veterinary, and international laboratories
PulseNet Laboratory Network

- Participating Labs
- Local Databases
- PFGE Patterns & Demographic Data
  TAT from receipt to upload: ~4 working days
- PulseNet National Databases (CDC)
- Cluster Follow-Up/Communication w/Epis
- Database Management & Reports
- Cluster Detection
The Newborn Screening Quality Assurance Program

July 1978 – July 2008

DBS proficiency testing, quality control, and consultation services worldwide
Newborn Screening Quality Assurance Program

Services provided
- Filter paper evaluation
- Reference materials
- Quality control materials
- Proficiency testing
- Training, consultations, network resources

Partners
- Association of Public Health Laboratories (APHL)
- 73 domestic screening laboratories
- Laboratories in 54 countries
- 400 plus screening laboratories worldwide
Influenza: New diagnostics developed for 2009 H1N1

- 2007 - PCR Test for detecting Avian H5 on “LightCycler”
- 2008 - PCR Test for detecting A, B, H1, H3, and H5 on “AB 7500”
- 2008 - Experimental Point of Care Test on “Mesoscale Diagnostics” device
April 15
First U.S. Case Identified
A/California/4/2009

May 1
First Diagnostic Kits Shipped to State Labs

May 3
First Diagnostic Kits Shipped to WHO Network

May 27-28
Vaccine Strain Shipped to Manufacturers

First cases in Mexico: Late February–Early March
WA: At the forefront of development of more rapid methods for Foodborne disease detection for use throughout the country.

IA: Responded to a Cryptosporidiosis outbreak including more than 1,000 confirmed and probable cases.

CT: Trapped and tested 206,405 mosquitoes—isolations included Jamestown Canyon virus, WNV, and EEE.

NC: Established an online course that allows users who have already been trained in CD/STD reporting to complete TB/LTBI training.

CO: Extracts 11,000 electronic lab reports from state public health laboratories per month, and makes results available to appropriate surveillance programs.

Palau: Data from RDSS was used to declare a National Low-Emergency Outbreak for Dengue Fever (DF) in August 2008.

NV: Submitted 8,314 mosquitoes to the Department of Agriculture for arbovirus testing in 2009. 220 mosquitoes tested positive for WNV.

IN: First state in the country to receive PHIN Certification (for Varicella 1.0 messaging) on January 12, 2009.

Puerto Rico: Submitted 8,314 mosquitoes to the Department of Agriculture for arbovirus testing in 2009. 220 mosquitoes tested positive for WNV.
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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.