

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

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And Office of Infectious Diseases

Centers for Disease Control and Prevention

IANPHI

November 2, 2010



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

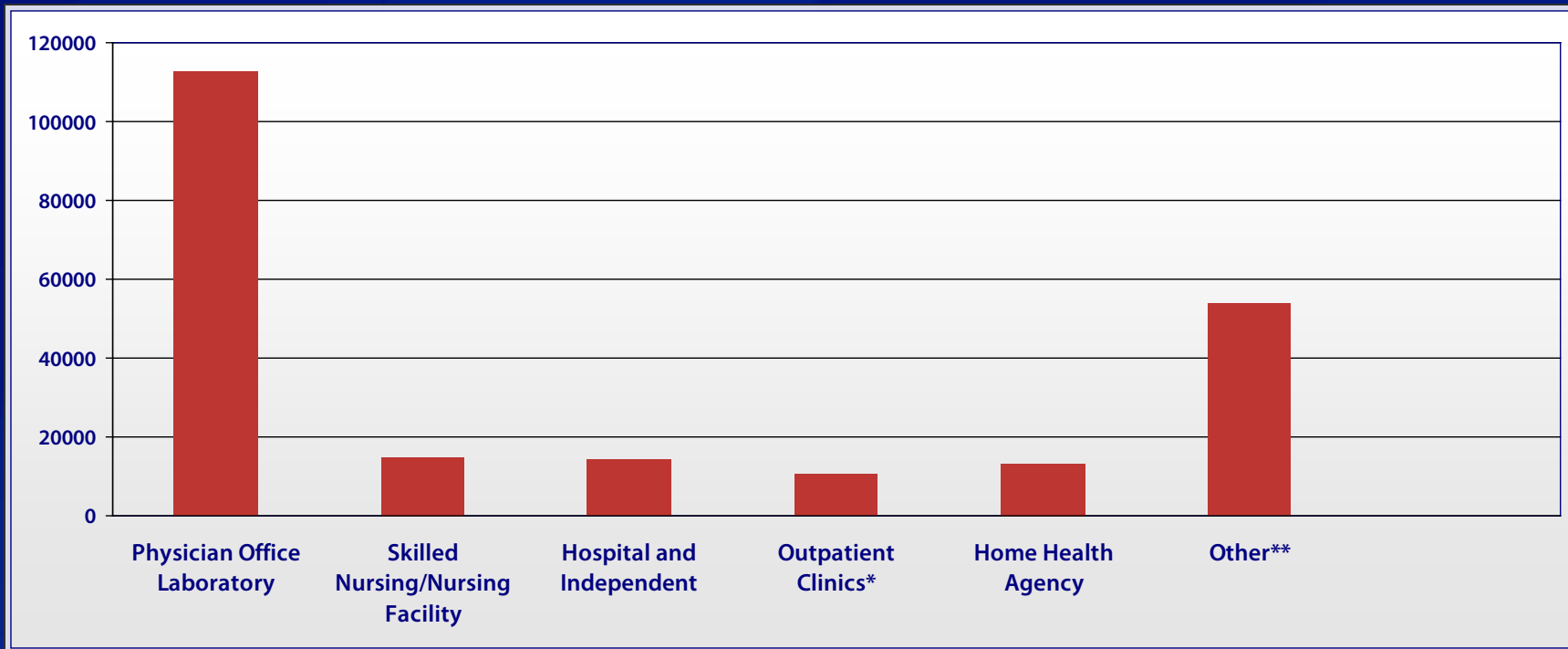
LABORATORY REGULATIONS AND QUALITY STANDARDS



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)

U.S. Laboratory Demographics - 2010



- ❑ 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

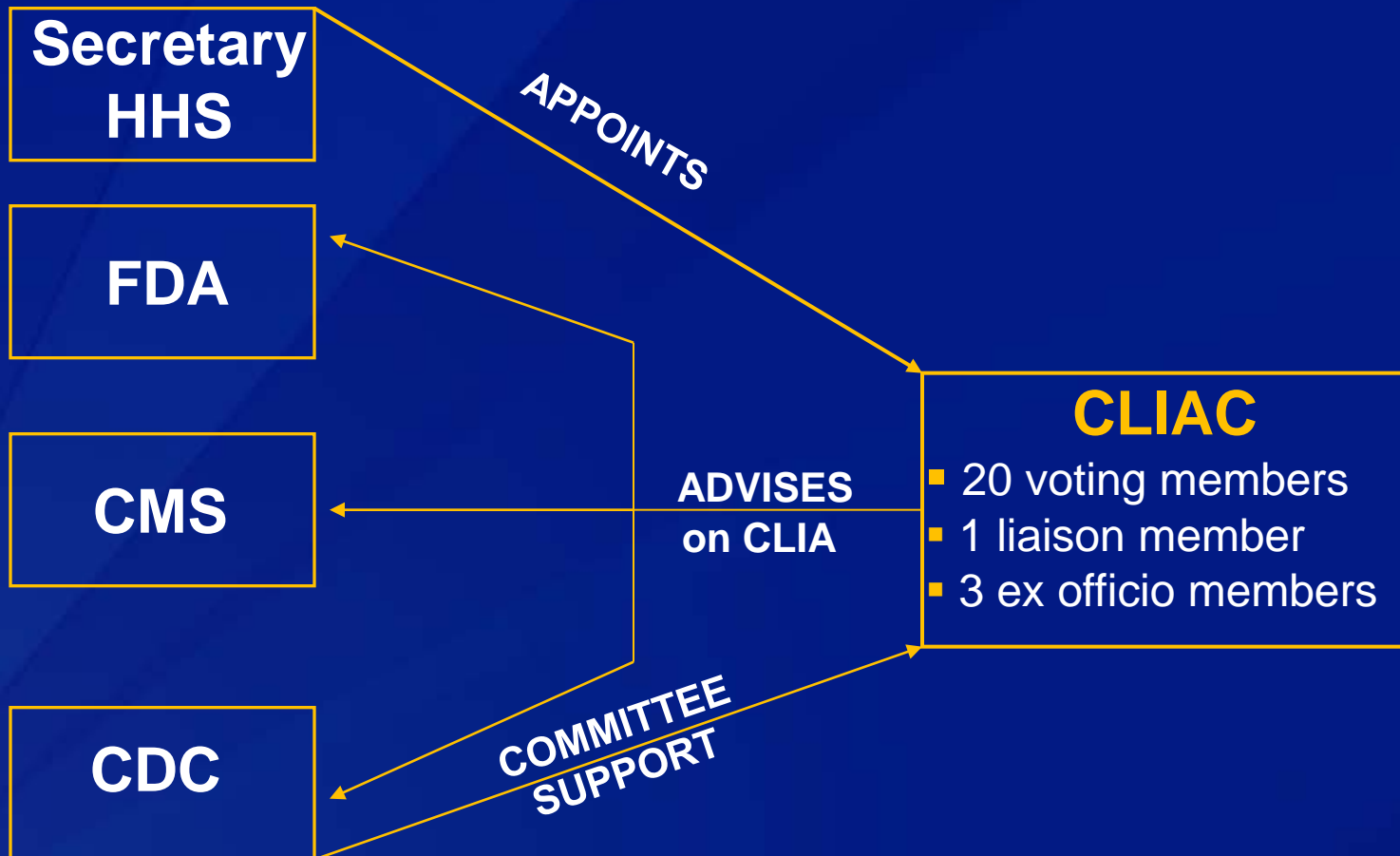


Clinical Laboratory Improvement Advisory Committee (CLIAC)

- ❑ 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

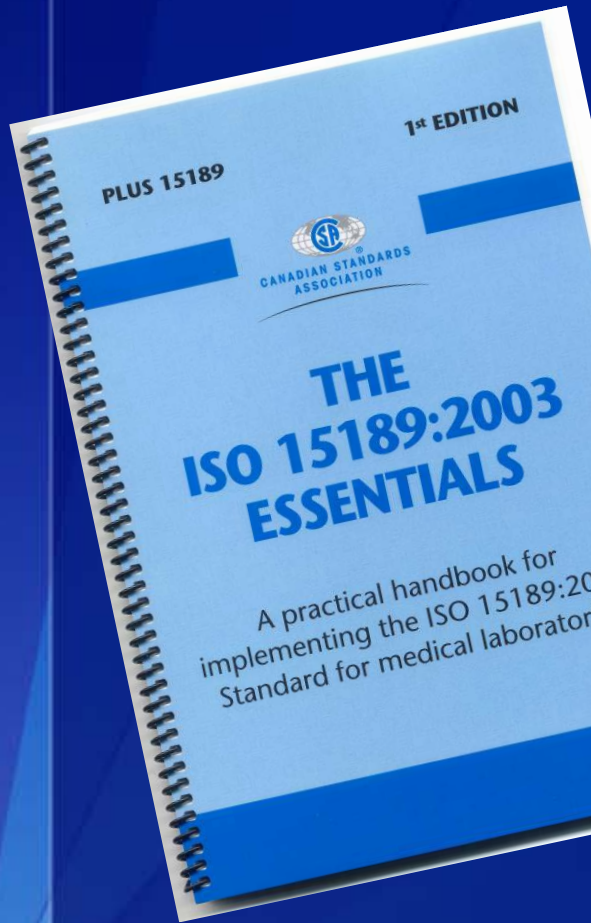


CLIAC Structure and Membership





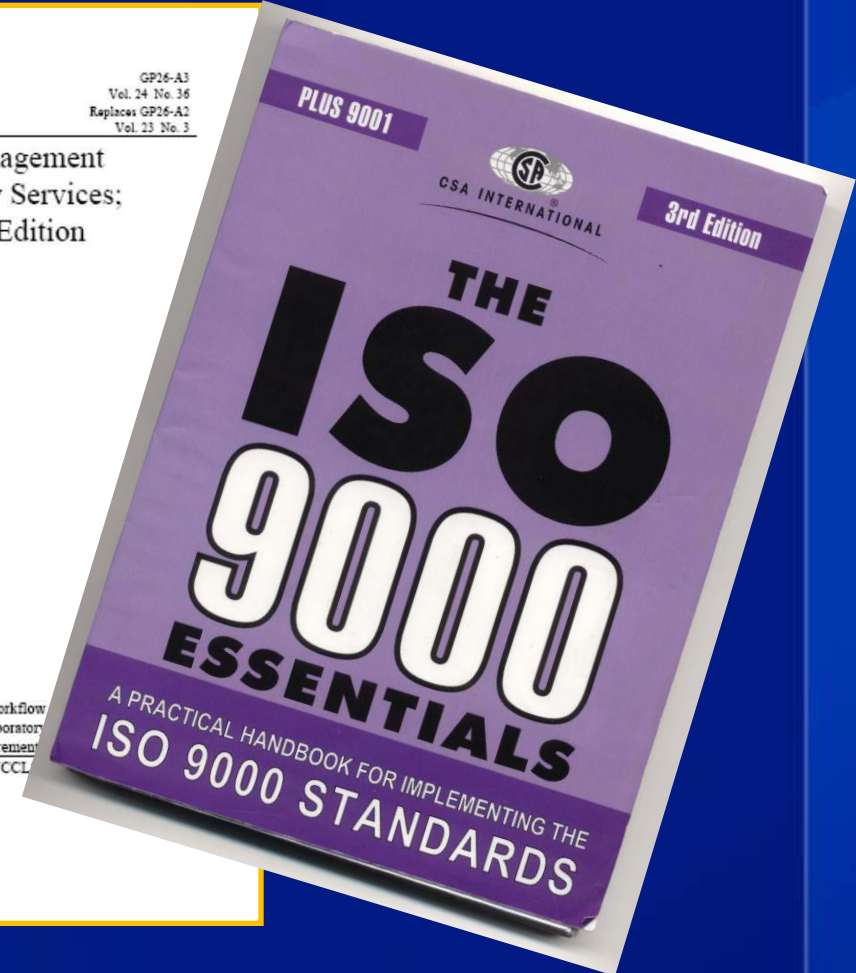

International Standards



GP26-A3
Vol. 24 No. 36
Replaces GP26-A2
Vol. 23 No. 3

Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition

This guideline describes the clinical laboratory's path of workflow information for laboratory operations that will assist the laboratory processes and meeting government and accreditation requirements. A guideline for global application developed through the NCCLS





Morbidity and Mortality Weekly Report (MMWR)

[MMWR](#)Text size: [S](#) [M](#) [L](#)

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 in 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 Systems, 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 would

Recommendations for Diagnosis of Shiga Toxin--Producing *Escherichia coli* Infections by Clinical Laboratories
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5812a1.htm



MMWR™

Recommendations and Reports

October 16, 2009 / 58(RR12);1-14

Recommendations for Diagnosis of Shiga Toxin--Producing *Escherichia coli* Infections by Clinical Laboratories

Prepared by
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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)

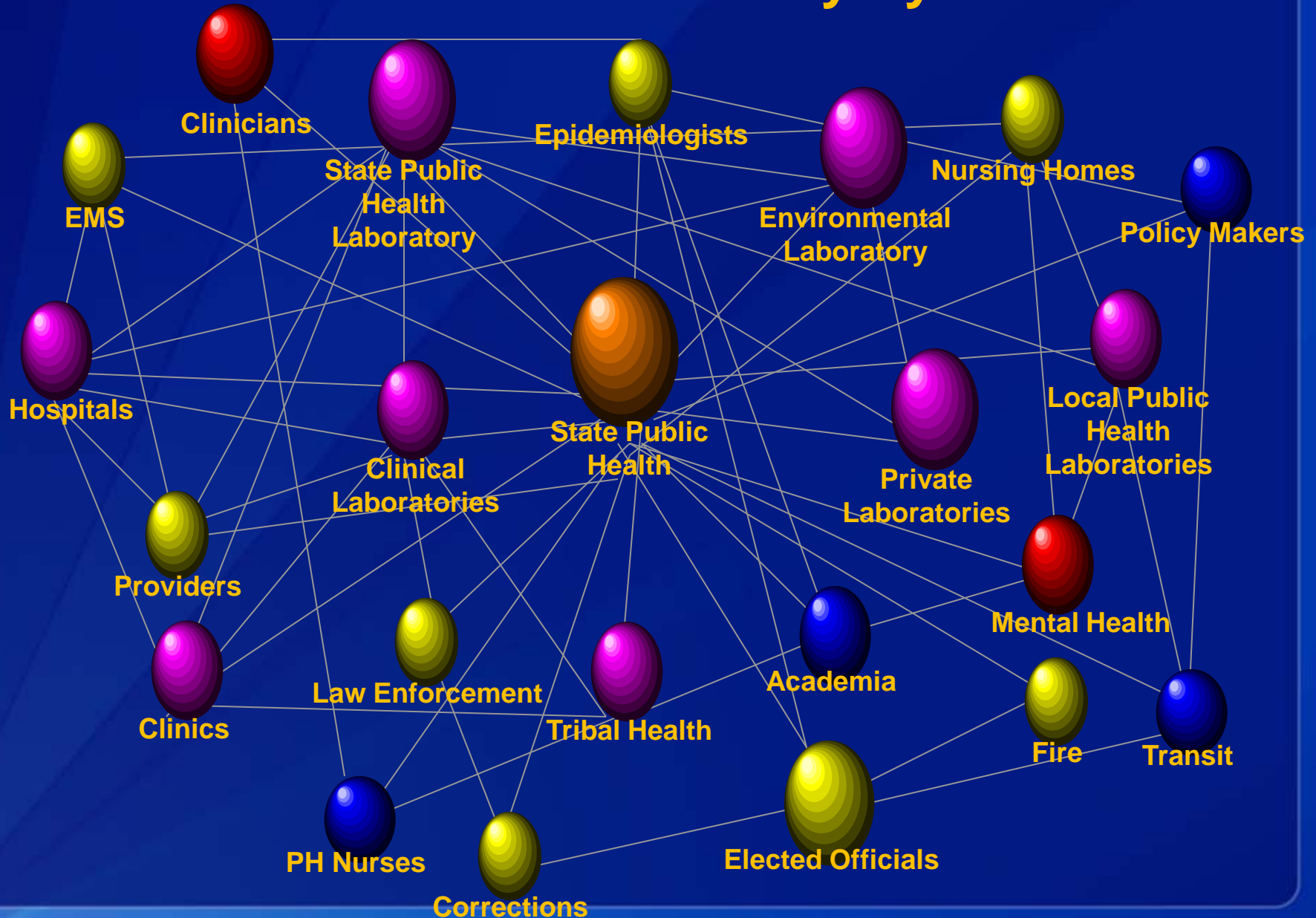
- Emergency Preparedness and Response
- Environmental Health
- Finance
- Food Safety
- Global Health
- Infectious Diseases
- Informatics
- Knowledge Management
- Laboratory Systems and Standards
- Membership and Recognition
- Newborn Screening and Genetics
- Public Policy
- Workforce

APHL/CDC Collaboration

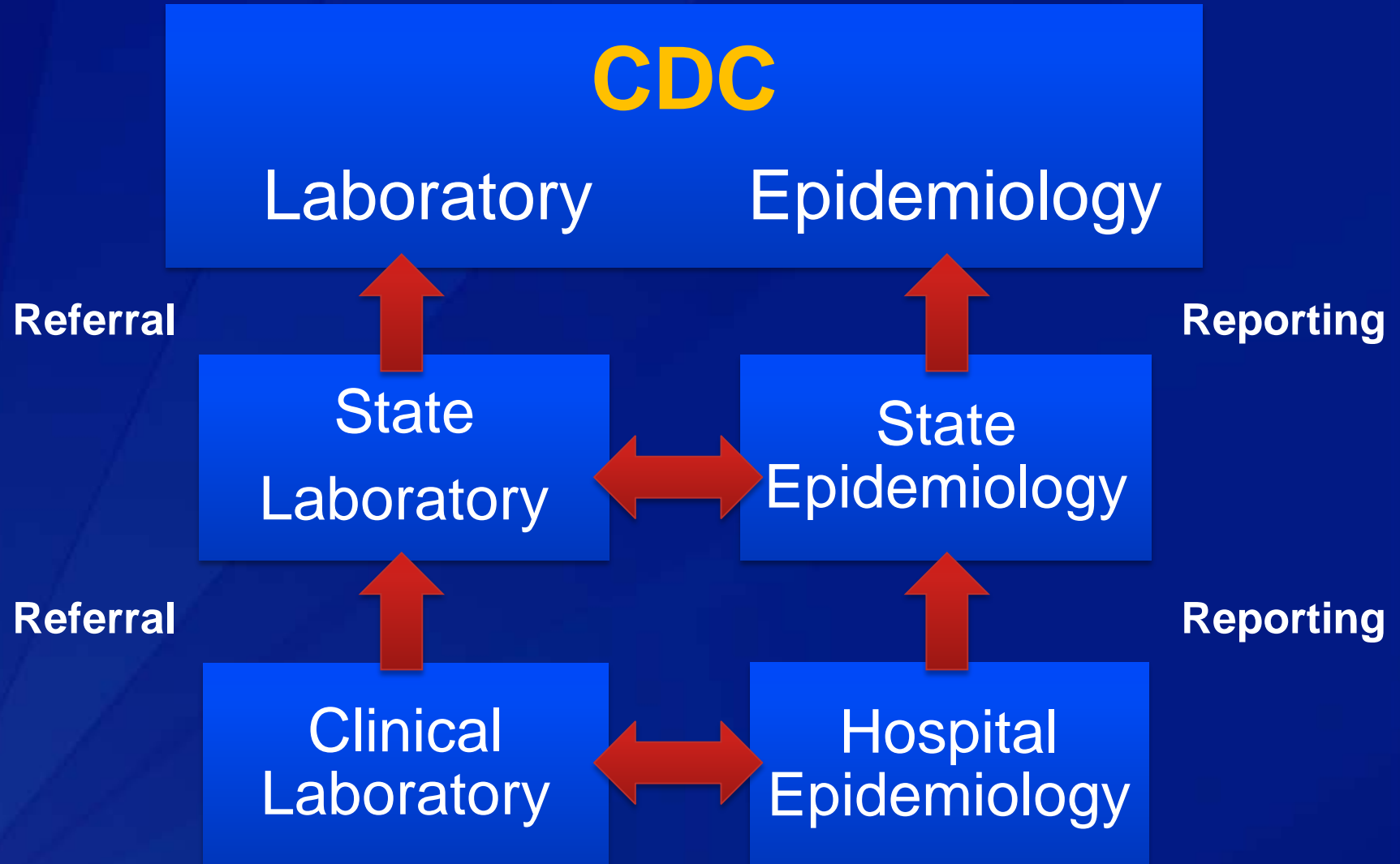
- ❑ Wide and Deep
- ❑ Intersects Science, Practice, and Policy



Components of the Public Health Laboratory System



Linking Laboratories and Epidemiology



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

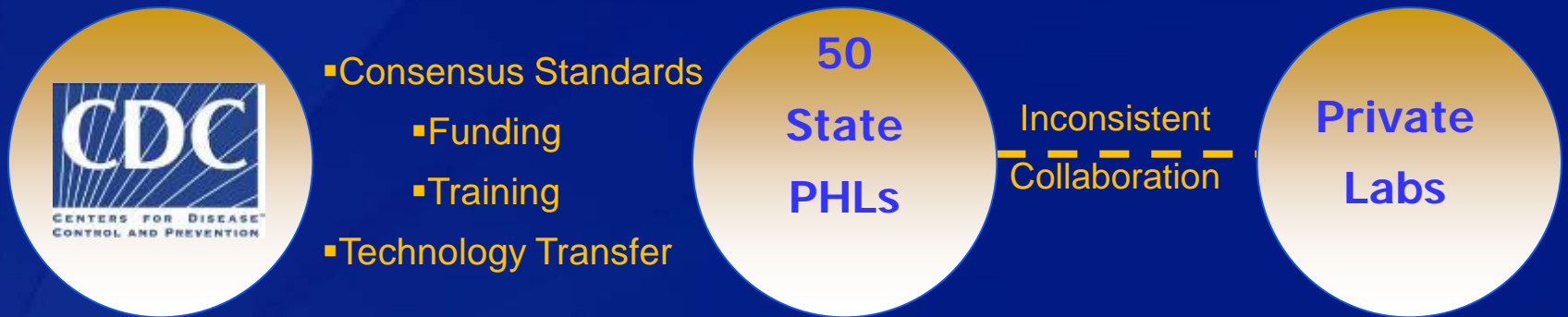
Public health

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.



http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5114a1.htm

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Core Functions and Capabilities of State Public Health ...

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MMWR™

Recommendations and Reports

September 20, 2002 / 51(RR14);1-8

Core Functions and Capabilities of State Public Health Laboratories

A Report of the Association of Public Health Laboratories

Prepared by

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Defining the State Laboratory System, 2007

Definition of a State Public Health Laboratory System

Association of Public Health Laboratories

June 2007

The State Public Health Laboratory System (SPH 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 SPH Laboratory System is part of the larger state public health system. The System includes individuals, organizations and agencies that are involved in assuring that laboratory data support the 10 Essential Services of Public Health. The concepts of a SPH Laboratory System are also embodied 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 SPH 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 goals of the National Laboratory System are to support voluntary, interdependent partnerships of clinical, environmental, agricultural and veterinary laboratories through public-private collaboration, for assurance of quality laboratory services and public health surveillance.

The SPH Laboratory System should assure that:

1. public health threats are detected and intervention is timely
2. stakeholders are appropriately informed of potential threats
3. reportable conditions are monitored in a comprehensive statewide system
4. specimens and isolates 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 SPH Laboratory System through active collaboration with stakeholders, including epidemiologists; first responders; environmental professionals in water, food and air surveillance activities; private clinical and environmental laboratories; and local public health laboratories. The SPHL provides leadership to assure that essential and state-of-the-art laboratory services are provided and that clinical laboratories that perform public health testing on reportable infectious diseases submit results to the public health surveillance system using national testing guidelines. To provide leadership, the SPHL monitors essential components of the SPH Laboratory System, such as completeness of reporting and accuracy of laboratory testing results. The SPHL also assures that accurate results are reported in a manner that is appropriate and sufficiently timely for effective public health response. An effective SPH Laboratory System requires proactive leadership by the SPHL to monitor public health testing processes by clinical and environmental in-state laboratories. To assure that the SPH Laboratory System is effective, the SPHL should at a minimum:

1. maintain 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 Systems & Standards Committee. It was adopted by the APHL Board on May 24, 2007.



Association of Public Health Laboratories

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Fax: 240.485.2700

Web: www.aphl.org

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)



NLTN

Laboratory Training Modalities

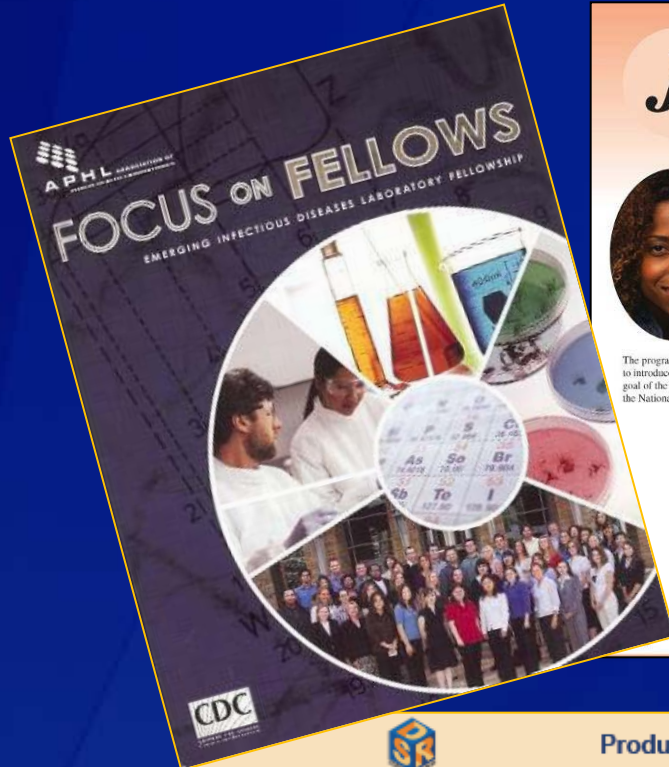
- ❑ Teleconferences & Webconferences
- ❑ Hands-On Workshops
- ❑ Seminars
- ❑ Train-the Trainers
- ❑ On-Demand Programs
 - Online courses, Laboratory Workshops To Go, CD/DVD's, Previously recorded teleconferences, Podcasts

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



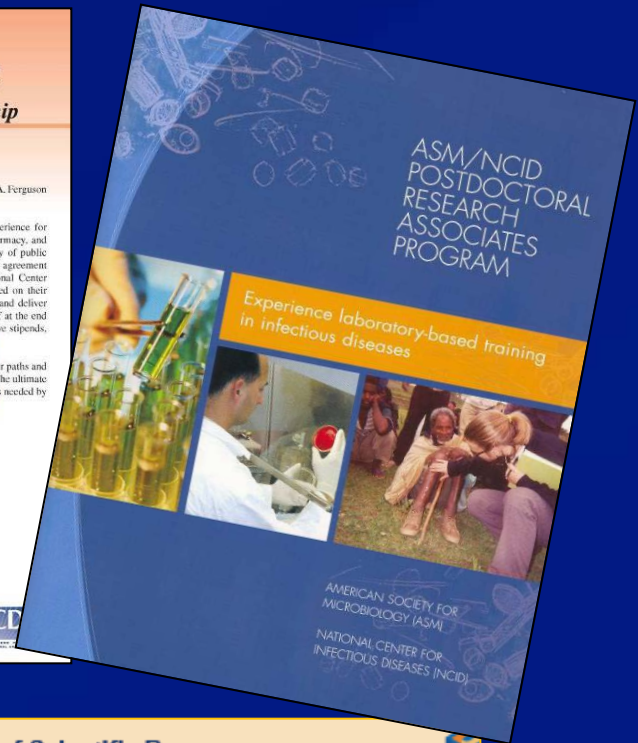
The Centers for Disease Control and Prevention (CDC) announces the James A. Ferguson Emerging Infectious Diseases Fellowship Program, 2005.

This fellowship program is an 8-week professional development experience for racial and ethnic minority students in medical, dental, veterinary, pharmacy, and public health graduate programs. Fellows participate in a broad array of public health activities. The program is administered through a cooperative agreement between the Minority Health Professions Foundation and the National Center for Infectious Diseases, CDC. Fellows are paired with a mentor based on their statement of interests and qualifications. They are required to prepare and deliver a formal scientific presentation on their work to CDC scientists and staff at the end of the program and to submit a formal research paper. The students receive stipends, housing, and transportation to and from Atlanta.

The program is designed to increase the students' knowledge of public health and public health career paths and to introduce fellows to careers addressing infectious diseases and racial and ethnic health disparities. The ultimate goal of the program is to encourage students to pursue careers in public health and specific disciplines needed by the National Center for Infectious Diseases to strengthen and diversify the workforce.

The deadline for submitting applications for this fellowship is February 28, 2005. For additional information about the program, please contact NCID's Office of Minority and Women's Health at 404-371-5308 or visit our website: www.cdc.gov/ncidod/omwh/ferguson.htm.

CDC/NCID/OWM/H
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL CENTER FOR INFECTIOUS DISEASES
OFFICE OF MINORITY AND WOMEN'S HEALTH



Products and Services of the Division of Scientific Resources

The Division of Scientific Resources
askdsr@cdc.gov (NCID/DSR askdsr)

Animal Resources

Chamblee Research Animal Activity
Contact: Dr. Allison Williams, 770.488.4357

Lawrenceville Research Animal Activity
Contact: Dr. Gregory Langham, 770.339.5504

Royal Research Animal Activity
Contact: Dr. Brianna Skinner-Harris, 404.639.1551

High Containment Animal Activity
Contact: Dr. Allison Williams, 404.488.4357

Preparation and Submission of Animal Protocols
OCSO/ACUPO
Contact: Elizabeth Mothershead, 404.639.4780

Biologics

Specialized Diagnostics Support
Hybridoma/monoclonal antibody production
Custom cell culture media
Protein purification/isolation/conjugation
Dispensing/lyophilization/labeling
Contact: John Hart, 404.639.3358

EMORY UNIVERSITY

Administration Husbandry Lab Animal Medicine (Vet) Vet Pathology

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

Custom peptide synthesis, protein sequencing, macromolecular binding analysis, mass spectrometry

Department of Scientific Resources

Taylor, Branch Chief
Laboratory Services, Acetylene Laboratory waste management
Contact: Curtis Taylor, 404.639.4344

Inventory/ordering
Lawrenceville; clean/sterile
Contact: Frank Foreman, 404.639.4344

Library Services
Contact: Charles Thomas, 404.639.4344

Dr. Beth Neuhaus, Acetylene Laboratory
Acetylene modeling/graphic information management
Contact: Dr. Beth Neuhaus, 404.639.4344

Acetylene Laboratory
Acetylene printing; acetylene
Contact: Robin Scarborough, 404.639.4344

Genomic Sequencing Lab
Large scale primer walking



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

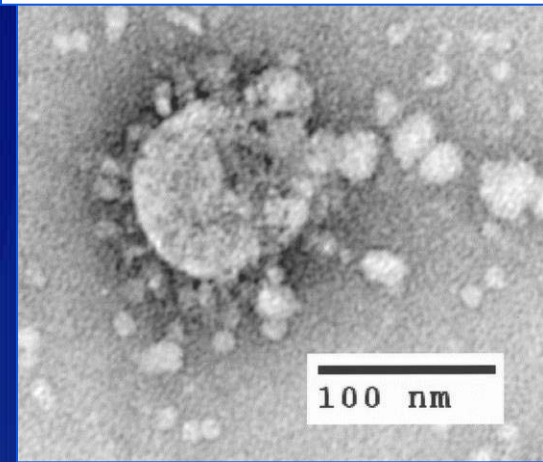
- ❑ National Institutes of Health (NIH) supports majority of clinical and basic research, but some overlap with CDC

Originally published in Science Express as 10.1126/science.1085952 on May 1, 2003

Science, Vol. 300, Issue 5624, 1394-1399, May 30, 2003

Characterization of a Novel Coronavirus Associated with Severe Acute Respiratory Syndrome

Paul A. Rota,^{1*} M. Steven Oberste,¹ Stephan
 Silvia Peñaranda,¹ Bettina Bankamp,¹ Kaija M
 Luis Lowe,¹ Michael Frace,¹ Joseph L. DeRisi
 Cara Burns,¹ Thomas G. Ksiazek,¹ Pierre E. R
 Josef Limor,¹ Karen McCaustland,¹ Melissa C
 Albert D. M. E. Osterhaus,³ Christian Drosten



SARS Regional Laboratory Network

Originally published in Science Express as 10.1126/science.1085953 on May 1, 2003

Science, Vol. 300, Issue 5624, 1399-1404, May 30, 2003

The Genome Sequence of the SARS-Associated Coronavirus

Marco A. Marra,^{1,2} Steven J. M. Jones,¹ Caroline R. Astell,¹ Robert A. Holt,¹ Angela Brooks-Wilson,¹
 Yaron S. N. Butterfield,¹ Jaswinder Khattri,¹ Jennifer K. Asano,¹ Sarah A. Barber,¹ Susanna Y. Chan,¹
 Alison Cloutier,¹ Shaun M. Coughlin,¹ Doug Freeman,¹ Noreen Ginn,¹ Obi L. Griffith,¹ Stephen R. Leach,¹
 Michael Mayo,¹ Helen McDonald,¹ Stephen B. Montgomery,¹ Pawan K. Pandoh,¹ Anca S. Petrescu,¹
 A. Gordon Robertson,¹ Jacqueline E. Schein,¹ Asim Siddiqui,¹ Duane E. Smailus,¹ Jeff M. Stott,¹ George S. Yang,¹

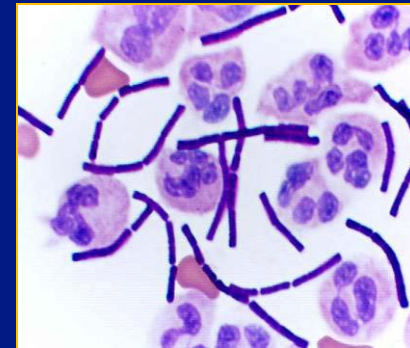
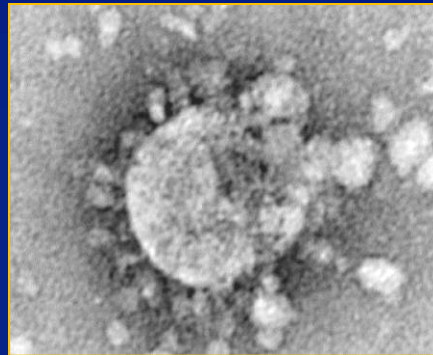
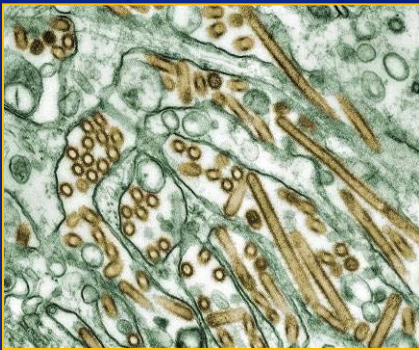
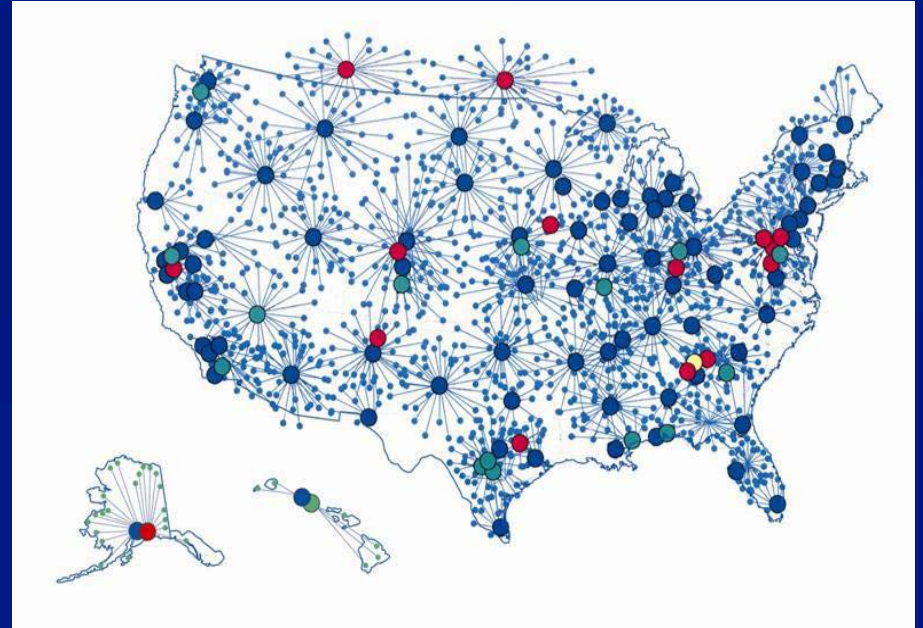


PROGRAM SUPPORT/TECHNOLOGY TRANSFER

Improving Emergency Response

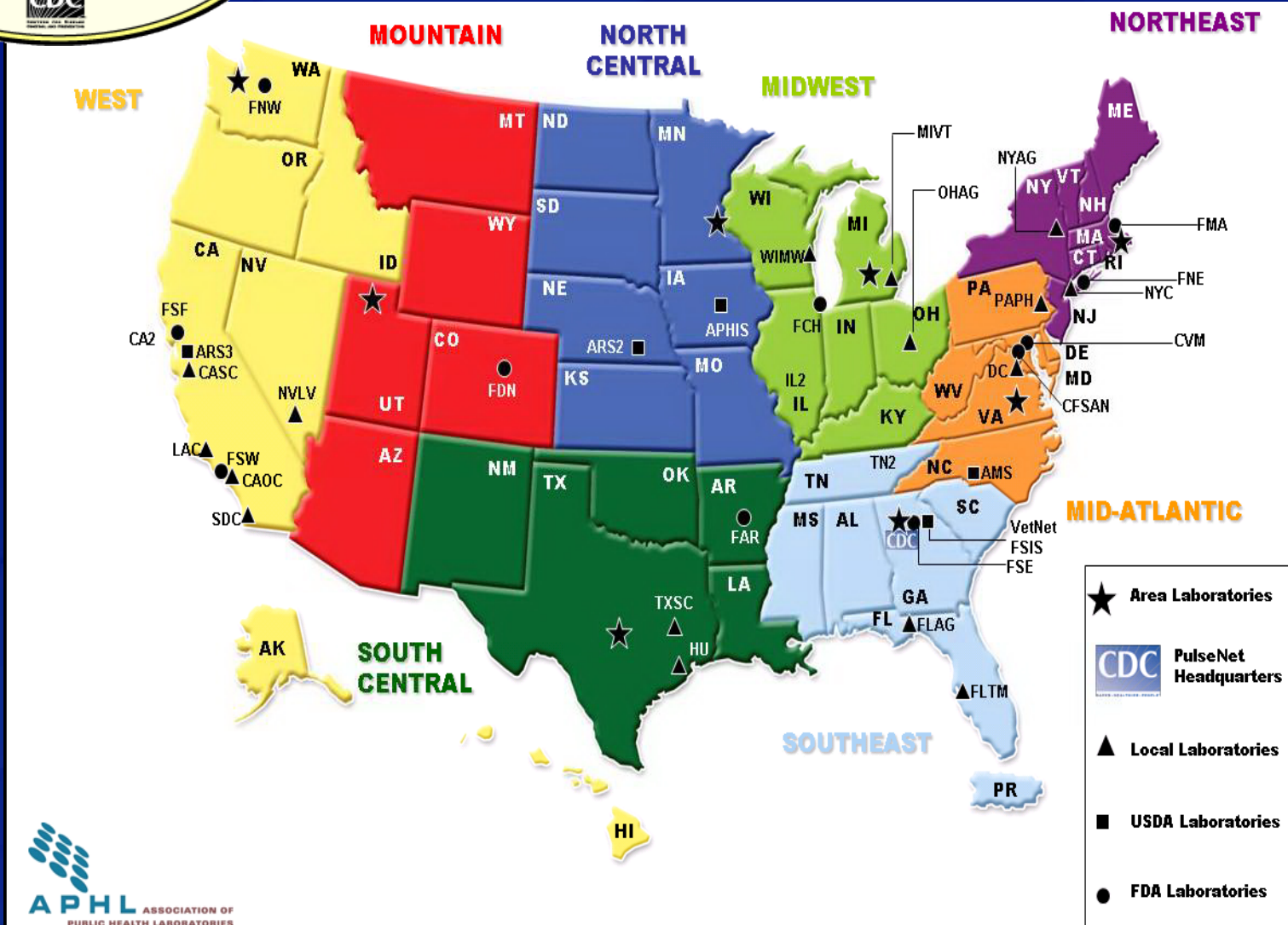


More than 160 public health, military, federal, food, veterinary, and international laboratories





PulseNet 2010



PulseNet Laboratory Network

Participating Labs

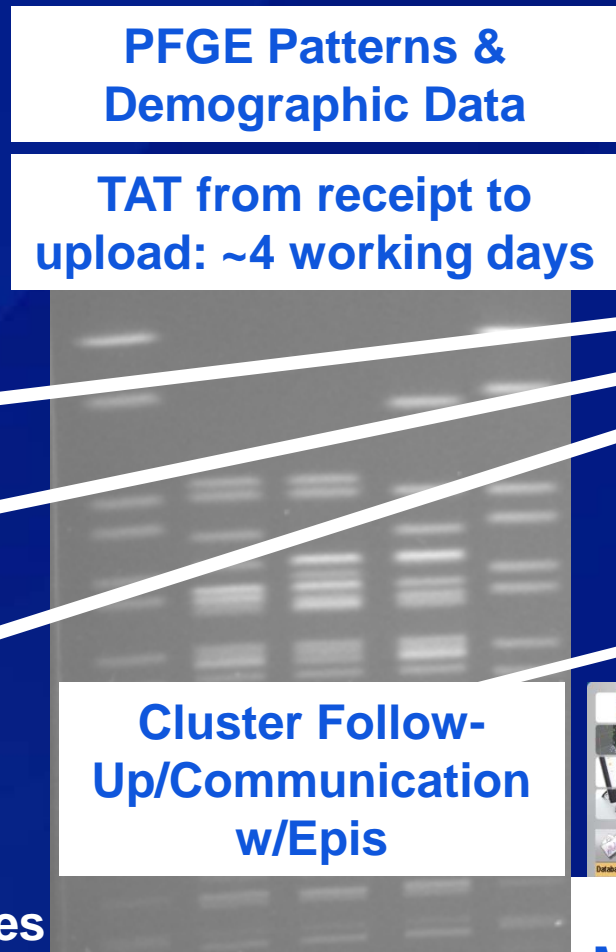
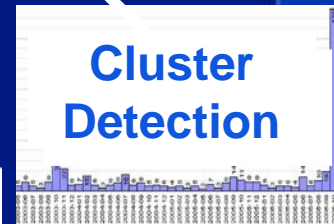
PFGE Patterns & Demographic Data

PulseNet National Databases (CDC)

TAT from receipt to upload: ~4 working days

Cluster Follow-Up/Communication w/Epis

Local Databases



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

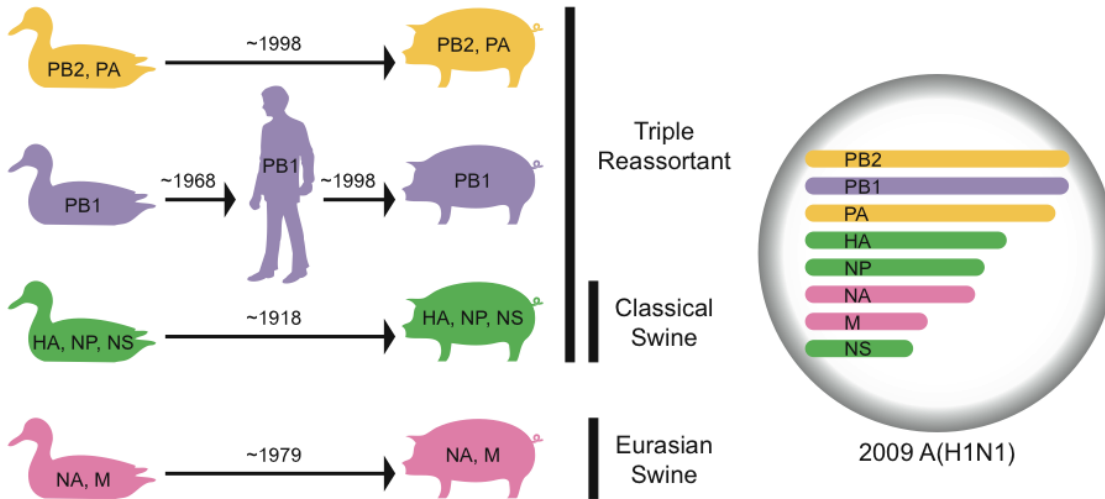


Influenza: New diagnostics developed for 2009 H1N1

- ❑ 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



Gene Segments, Hosts, and Years of Introduction



First cases in Mexico: Late February–Early March

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

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.

ELC

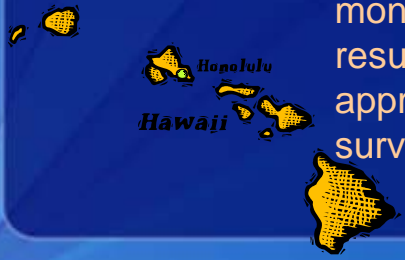
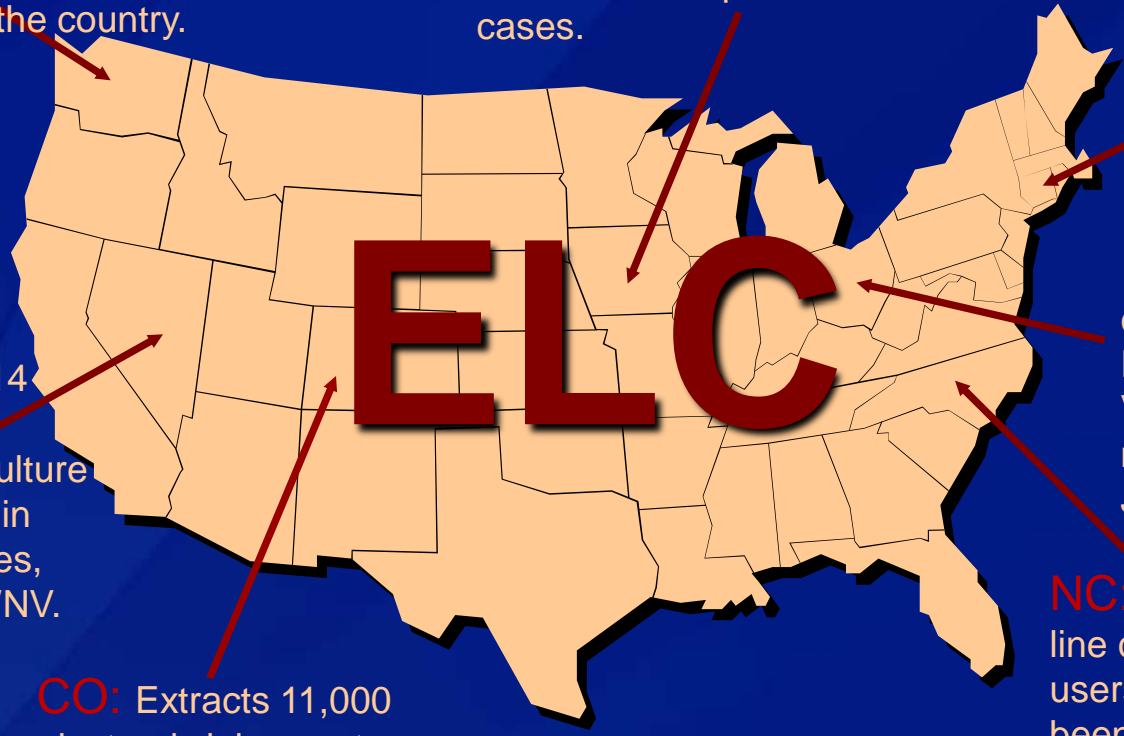
IN: First state in the country to receive PHIN Certification (for Varicella 1.0 messaging) on January 12, 2009.

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

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

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

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



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Tom Hearn
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Scott Becker
Rex Astles
Harry Hannon
Olen Kew
Rima Khabbaz
Jessie Clippard
Sydney Hubbard
Christine Ford

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1600 Clifton Road NE, Atlanta, GA 30333

Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

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.

