

Public Health Laboratories & Luminex Anatomy of a Partnership

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Association of Public Health Laboratories

Luminex[®]



Is she dancing now?
I can't look.



Objectives

- Discuss the role of public health laboratories in the healthcare system
- Outline the partnership between APHL and Luminex
- Discuss how corporate partners like Luminex strengthen the public health laboratory system



“Take interest, I implore you, in those sacred dwellings which are designated by the expressive term: laboratories. Demand that they be multiplied; that they be adorned. These are the temples of the future...temples of well being and happiness. There it is that humanity grows greater, stronger, better.”

Louis Pasteur



Public Health Reports

**2010
Supplement 2
May/June 2010**



History of PHLs



- From laboratory testing to laboratory networks
- 2000: Life-expectancy gains in 21st century
- 2000: National Laboratory System model
- 2001: Core Functions Published

Public Health Laboratories

- Disease Prevention, Control & **Surveillance**
- Integrated **Data** Management
- Reference & Specialized **Testing**
- **Environmental** Health & Protection
- Food **Safety**
- Lab Improvement & **Regulation**
- **Policy** Development
- **Emergency Preparedness**
- Public Health Related **Research**
- **Training** & Education
- **Partnerships** & Communication



Association of Public Health Laboratories

Vision

A healthier world through quality laboratory practice.

Mission

To promote the role of public health laboratories in shaping national and global health objectives, and to promote policies, programs, and technologies which assure continuous improvement in the quality of laboratory practice and health outcomes.



Luminex Corporation

Vision

Worldwide Leader in MultiPlexed Solutions

Mission

Dedicated to improve the health, safety, and quality of life for people around the world



What is APHL?

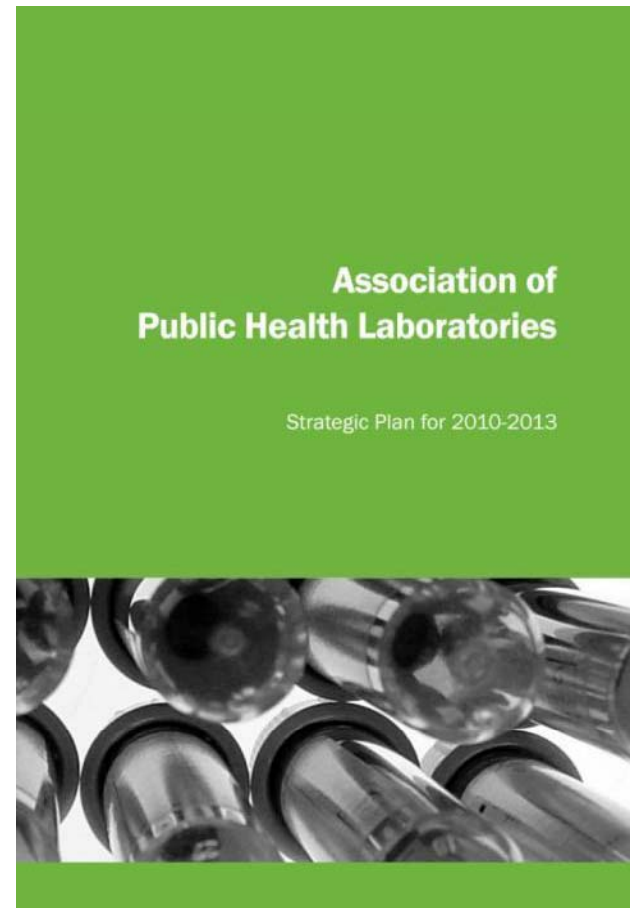
- A 501(c)(3) non-profit organization
- 800 members from state and local public health labs, state environmental and agricultural labs, corporations, federal agencies and academic institutions
- Advocates at the national level for critical laboratory issues and for increased support/resources for member labs
- Provides training and best practices for public health laboratory policy and programs.



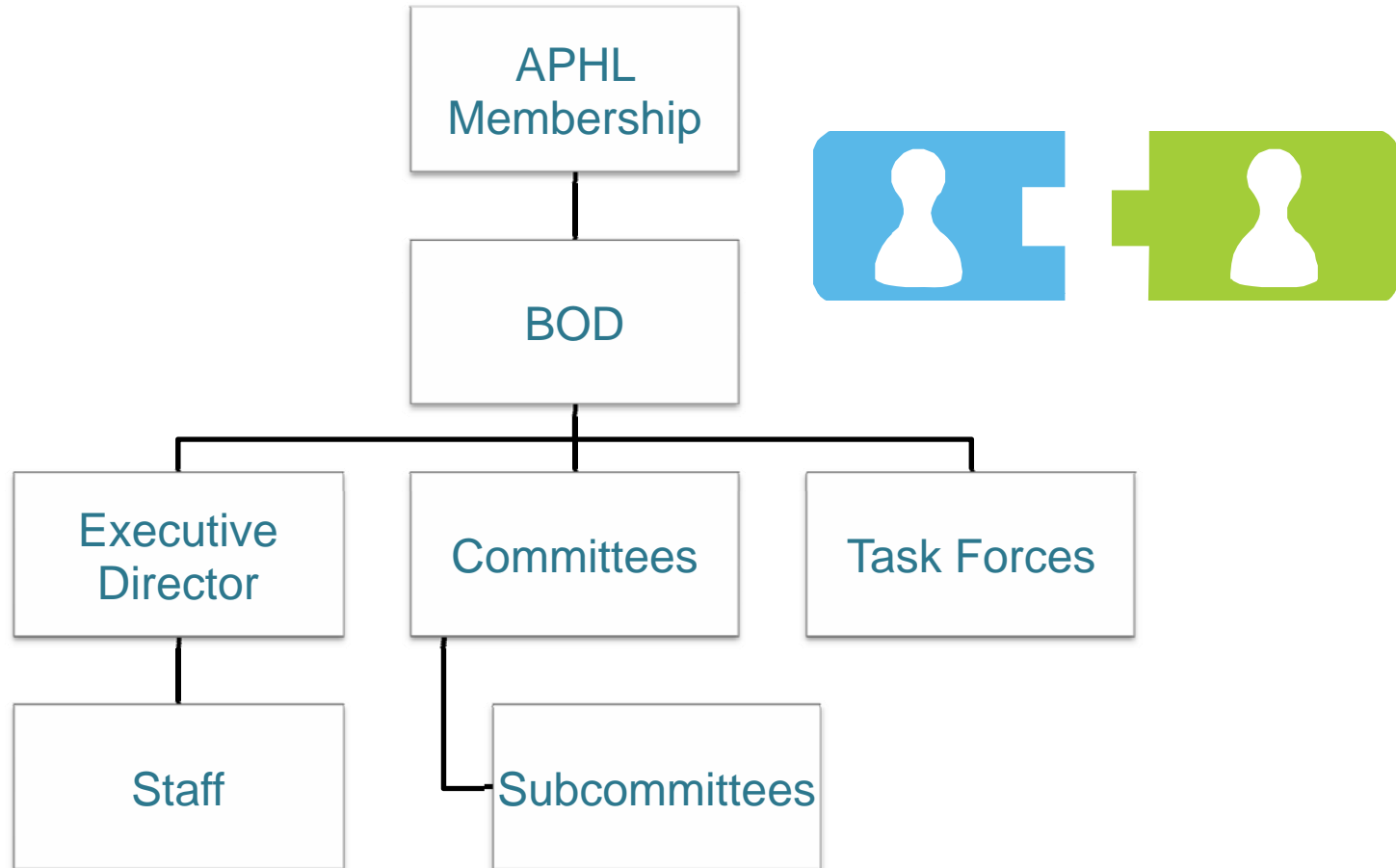
Strategic Plan

2010 -- 2013

- Goals
 - Workforce Development
 - Advocacy
 - Improved Collaboration Among Members & Partners
 - Bolstered Informatics Capabilities
 - Improved Laboratory Science, Standards & Practices
 - Capacity-Building to Assure Resources & Develop Partnerships



APHL Organizational Structure



APHL Membership

So who are we anyway?



Membership Type:

- Public Health Institutional - States
- Public Health Institutional - Locals
- Associate Institutional
- Delegate
- Individual
- Student/Fellow
- Emeritus
- Honorary
- Corporate
- **Total**

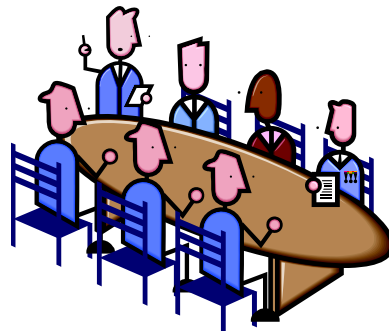
Number:

56
40
14
370
157
76
33
8
39 (from 25 companies)
793

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 FY11 Legislative Priorities



- Preparedness
- Infectious Diseases
 - Epi Lab Capacity
 - Food Safety
 - TB/HIV/TB
- Environmental Health
 - Biomonitoring
 - Newborn Screening
- Electronic Lab Messaging
- Health Reform

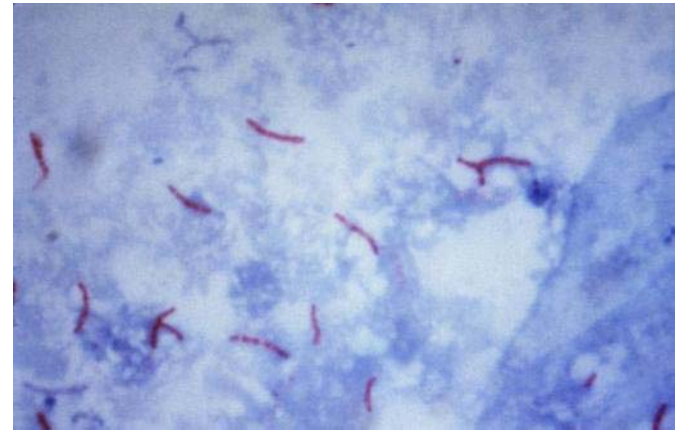
Preparedness

- Threat detection
 - LRN (Biological & Chemical)
 - Luminex in 100 LRN labs
- Outbreaks
 - Foodborne (PulseNet)
 - Luminex in Salmonella serotyping
- Natural disasters
- Industrial accidents



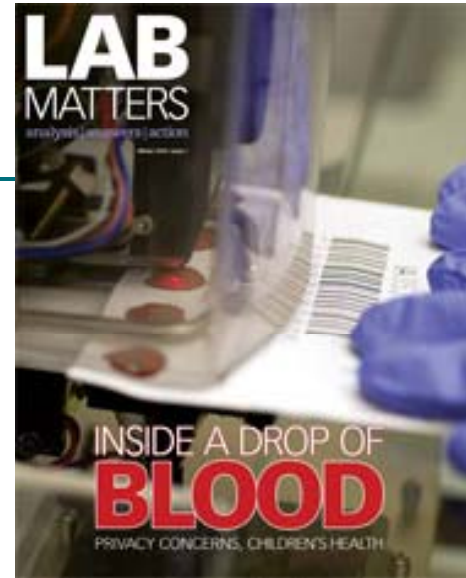
Infectious Diseases

- HIV/AIDS
- Tuberculosis
- Vaccine-Preventable Diseases
- Vector-Borne Diseases
- Influenza



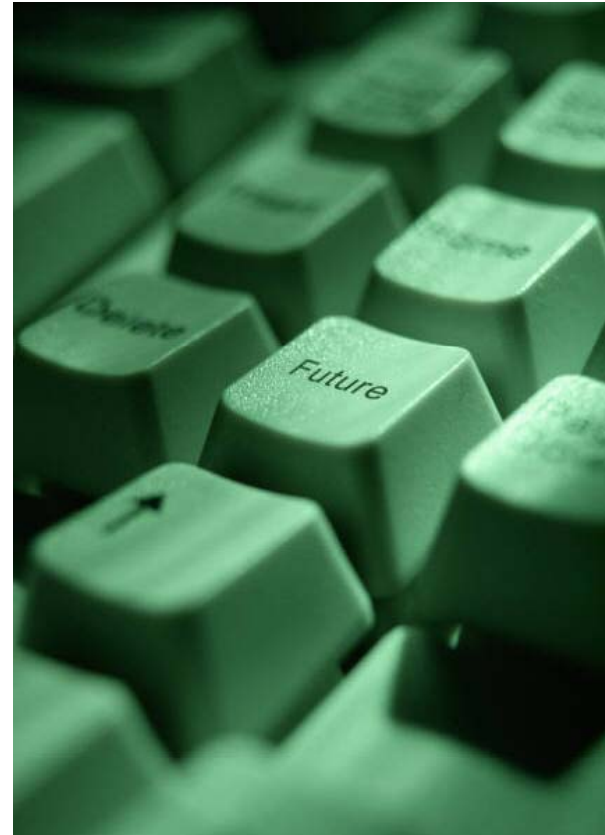
Environmental Health

- Biomonitoring
- Newborn Screening
 - Panel of tests-Luminex capability
 - SCID
 - Cystic Fibrosis
 - Retention of blood spots



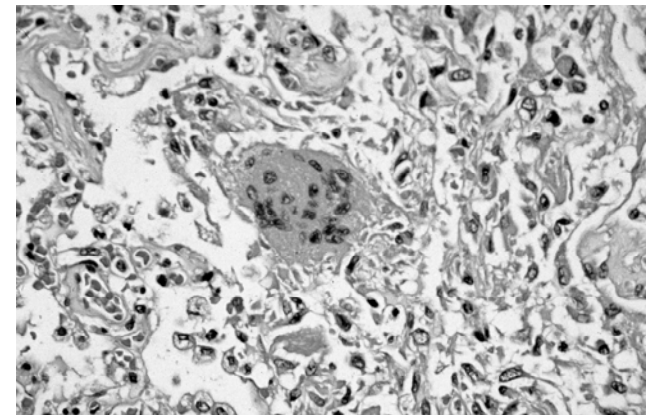
Electronic Laboratory Messaging

- Electronic messaging systems
- Data exchange
- Standard protocols
- Surveillance reporting vs result reporting



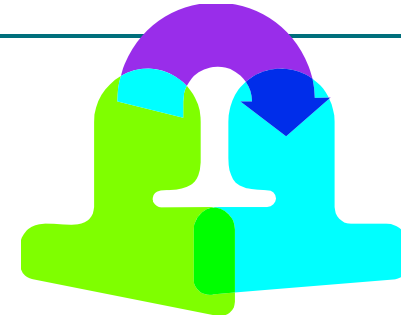
APHL Public Health Programs

- Emergency Preparedness & Response
 - LRN
- Environmental Health
 - Environmental Labs
 - Newborn Screening & Genetics
- Infectious Diseases
 - Food Safety
 - HIV, TB & STDs
 - Flu, EIDs
- Strategic Initiatives & Research
 - Informatics
 - Knowledge Management
 - Surveys
- Laboratory Systems and Standards
 - L-SIP



APHL Program Activities

- Information broker
 - CDC ↔ Member labs
 - CDC ↔ CDC
 - Member labs ↔ Member labs
 - Member labs ↔ CDC ↔ Other federal agencies
- Technology transfer
 - CDC ↔ Member labs
 - Training
- Policy
- Exemplary practices
- Partnership development & relationship management



APHL Global Health

APHL has worked in 23 countries on 4 continents to help build laboratory capacity



- Technical Assistance
- WHO Twinning Project
- International Institute for Public Health Laboratory Management (collaboration with GWU)
- Laboratory Information Systems

Information

- Web/Communication
 - Member-only web content (e.g. protocols, survey data)
 - Listservs & Web boards
 - Email Communications
- Publications
 - Lab Matters
 - E-Update
 - Promotional Brochures
- Survey/Data Collection
 - Issue Briefs



Workforce

- National Center for Public Health Laboratory Leadership
- Fellowships
- National Laboratory Training Network
- APHL's Department of Continuing Education & Training



Workforce Accomplishments 2009

- 35 Emerging Infectious Disease Fellows
- 20th Anniversary of APHL/CDC's National Laboratory Training Network
- ARRA Funding for Vaccine-Preventable Diseases Training to over 400 PH Scientists
- 2nd Cohort of Emerging Public Health Lab Leaders
- Development of Curriculum for HS students as Intro to PH Lab Science

APHL Conferences



2010 APHL Annual Meeting - *June 6-9, 2010 - Cincinnati, OH*

6th National TB Conference - *June 21-22, 2010 - Atlanta, GA*

2010 Food Emergency Response Network National Training Conference – *June 29-July 1, 2010 – Minneapolis, MN*

2010 Emergency Response Chemical Laboratory Conference – *July 27-30, 2010– Salt Lake City, UT*

14th Annual PulseNet Update Meeting – *August 30-September 2, 2010 - Chicago, IL*

APHL Partners



Federal

- CDC, FDA, USDA, EPA, HRSA, HHS, NIH, FBI, DHS, DoD, USPS, GAO

Non-Federal

- CLSI, ACLA, ASM, ASCP, CLMA, CAP, AACC, ABSA, A2LA, ACMG

Veterinary

- AAVLD, NAHLN

Public Health

- ASTHO, NACCHO, CSTE, NASTAD, NTCA, NCSD, ASPH, TFAH, PHII, APHA, PHLI

Unique Corporate Membership

- APHL's Sustaining Member Program
- ASAE's August publication
- Corporate Leadership Council
- Alignment with APHL's mission



Luminex + APHL



- Platinum Sustaining Member 2008
- October 2008 – Corporate Leadership Council
- November 2008 – NBSGTS
- May 2009 – Annual Meeting
- October 2009 – Corporate Leadership Council
- May 2010 – NBSGTS
- June 2010 – Annual Meeting

2009: Racing a Pandemic

- 4/7 – 4/16/09: APHL/CDC Trains PHL scientists
- 4/21/09: First confirmed case by CDC
- 4/23/09: APHL hosts 1st of 5 50-state calls
- 4/26/09: Declaration of Public Health Emergency
- **4/27/09: Luminex Press Release on xTag RVP Result Interpretation**
- 4/29/09: Shipment of CDC Test Kits to PHLs
- 5/2/09: > 430 School Closures in 18 US states
- 5/5/09: 1st US citizen dies of 2009 H1N1
- 5/11/09: Unique LOINC identifier approved for electronic transfer
- 5/14/09: NLTN offers free one-hour webcast
- 6/10/09: Confirmed cases reported in 74 countries
- 6/11/09: Phase 6 Global Pandemic
- 6/16/09: After action assessment



April 2009

Public Health Labs Respond to H1N1

Susan U. Neill, Ph.D., M.B.A.
Director, Laboratory Services Section
TX Dept of State Health Services



State of TX



The Stage is Set

- Two original cases detected in Southern California
- One of those, a 10-year-old boy, traveled to Dallas for an extended visit with relatives
- April 23 press release stated that swine flu had been confirmed by the CDC in two 16-year-old boys from Guadalupe County near San Antonio
- We received our first specimens on 4/24/09, one was reported as “Influenza A – Unable to type” on an 18-year-old boy from Guadalupe County
- Confirmed by the CDC as Swine Flu

And It Goes On....

- Outbreak began in Mexico
- Cases quickly identified in Texas
- No understanding early in response of:
 - Severity of disease
 - Populations affected
 - How quickly the virus would spread
- Leadership requested health care practitioners submit specimens on all patients presenting with influenza like illness

Practitioners Respond..

Date

- Day 1, April 24th
- Day 2, April 27th
- Day 3, April 28th
- Day 4, April 30th

Number Received

- 8
- 34
- 530
- 1,139

Overwhelmed...

- Front Page of Austin American Statesman on May 2, 2009
 - “Flood of flu tests clogs up state lab”
- Received over 11,150 specimens total
- Requested assistance from other state laboratories, Tennessee and Virginia agreed to help with testing

How Many Specimens?

During a typical influenza season (between October and May of each year) the DSHS laboratory typically receives ...

1,500 specimens total

During the response to the H1N1 outbreak in Spring - Summer 2009, the DSHS laboratory received...

1,000 to 1,500 specimens per day

Understaffed...

- PCR testing personnel– 2 staff originally trained
 - Identified **22** additional staff internal
 - Hired **15** temporary staff through temp agency
- Non-testing personnel
 - Specimen acquisition
 - Media Prep (VTM)
 - Shipping
 - Call Center
- QA officers
 - Screened staff background, resumes, transcripts
 - Placed in appropriate positions
 - Developed and distributed training forms
 - Assured completion of training forms as staff assumed additional duties

Testing Performed

- QA officer involved in all discussions of testing protocols
- Modified testing algorithm as appropriate
- Assays used
 - Seasonal influenza PCR
 - H1N1 PCR
 - **Luminex RVP**
- Developed a modified establishment study for assays based on panels of 20 specimens
- Used package inserts as interim SOPs

Comparison

CDC's H1N1 Test

- EUA of H1N1 Test on FastDX Platform
- Able to increase capacity from one to four
- Compare results

Luminex RVP

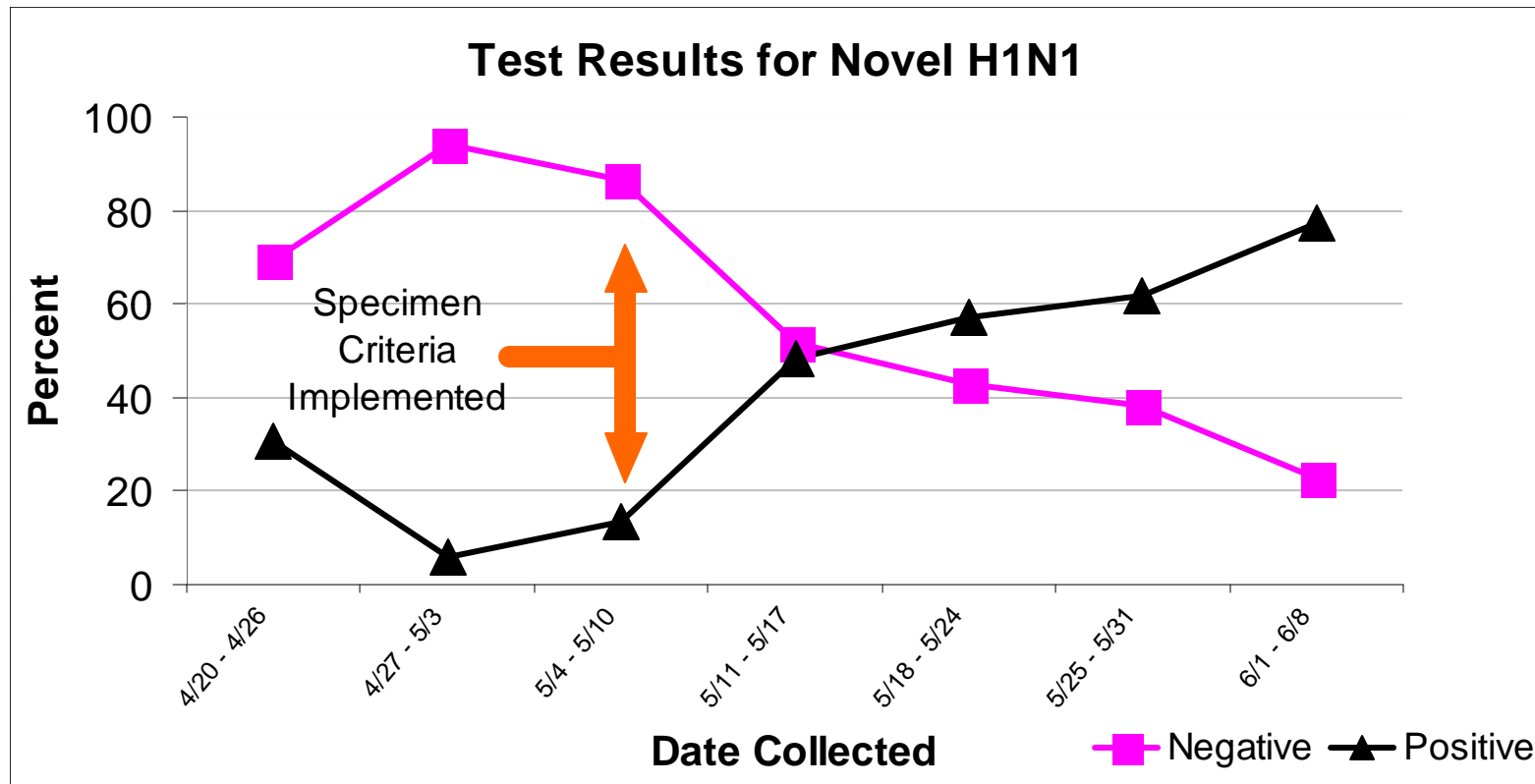
Results compared with CDC's test

Able to use as rule-out test for H1N1

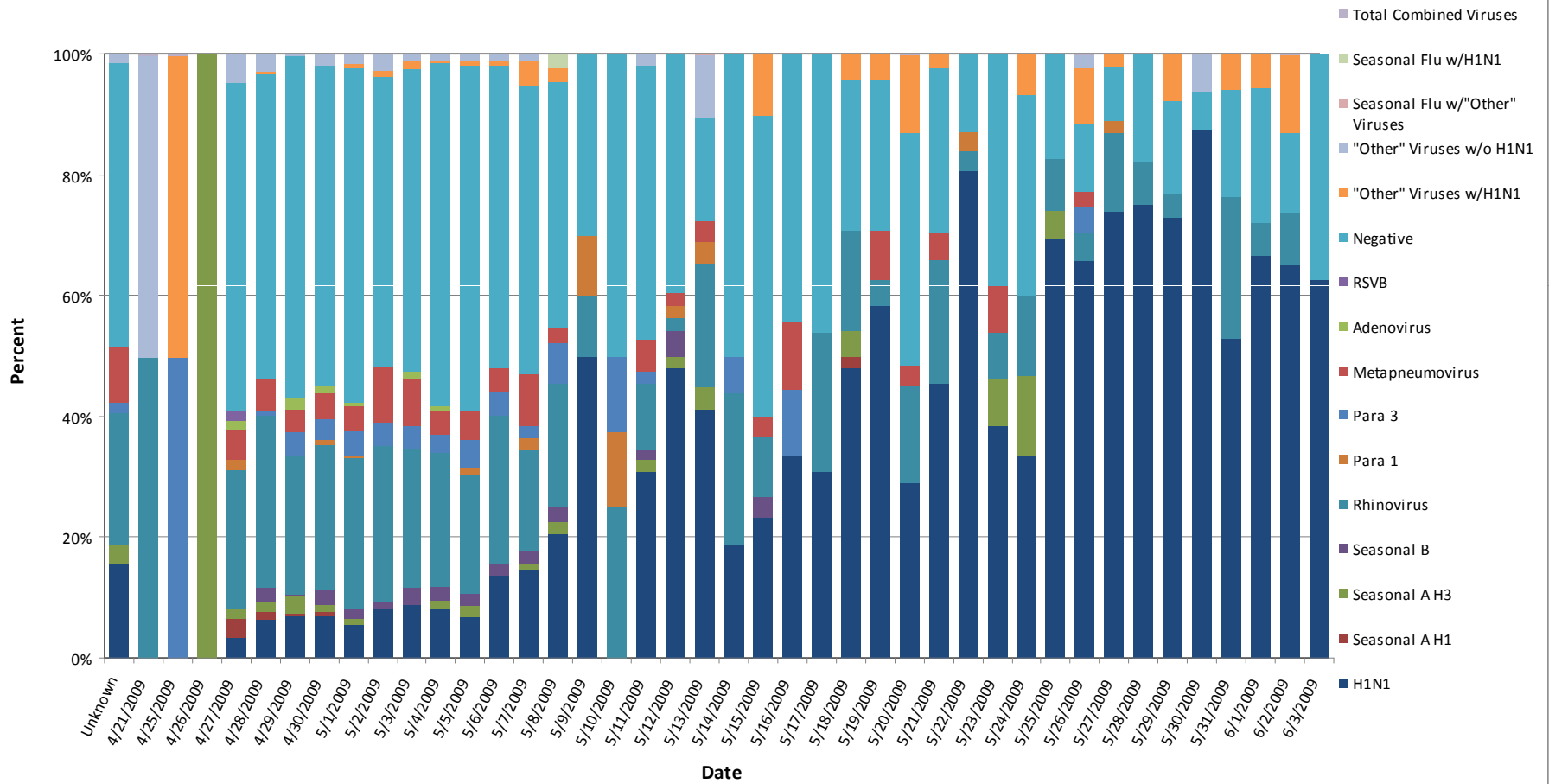
Reporting

- Distributed Healthcare Provider and Patient Information Sheets required by EUA
- Modified patient reports as algorithm changed to reflect testing performed
 - No influenza detected
 - No influenza A detected
 - Influenza A, unsubtypeable
 - Influenza A, suspect novel H1N1
 - Influenza A, confirmed H1N1

Specimen Criteria Implemented



Viruses Detected - Luminex Testing



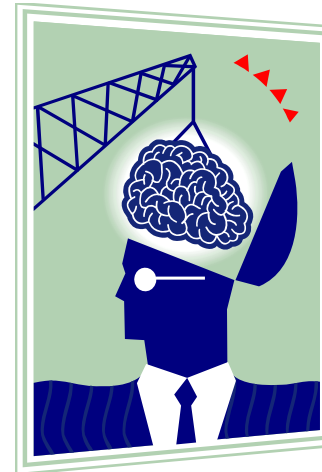
Fall 2009 – Back to Normal

- Detect novel influenza viruses
- Identify antiviral resistance
- Monitor changes in virus type



Lessons Learned

- Communications efforts
- Cross Training Plan
 - Internal staff identified
 - Training nearly completed
- Staffing
 - Universities
 - Temporary Agencies
- Sorting and Triage Plan
- Specimen Storage Plan
- Specimen Acquisition Plan
- Media Preparation Plan
- Testing algorithms defined
 - Workflow mapped
 - LIMs modified
- Incident Command Team



More Lessons Learned

- Corporate Partners Responded
- Luminex Responded
- Surveillance for Circulating Viruses
- Analysis / Answers



APHL Responds to H1N1-New Staff



Public Health

"Health care is vital to all of us some of the time, but public health is vital to all of us all of the time."

C. Everett Koop

Or

As said so eloquently by Labs Are Vital scholarship winner, Amanda Roscoe, on her winning T-shirt—

**Because the pay-off is more
than a paycheck!**

Thanks for your attention!



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Believe



Laugh



Appreciate

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