Summary Report: Harmonizing Test Platforms to Increase Efficiencies in Public Health Laboratories

Standardization of Platforms Focus Group Meeting:
April 11, 2012

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Standardization of Platforms Focus Group Meeting – April 11, 2012, Atlanta, GA

The Association of Public Health Laboratories (APHL) in collaboration with the Centers for Disease Control and Prevention (CDC) convened a focus group to develop strategies for improving platform selection and implementation in state and local public health laboratories. Following is a summary report of the first meeting of the Standardization of Platforms Focus Group.

I. Overview of Standardization of Platforms Project

The Laboratory Efficiencies Initiative (LEI) is a newly-formed initiative co-sponsored by APHL and CDC. **The goal of LEI is to build a sustainable public health laboratory system in the United States.** The strategy for achieving this goal involves supporting testing capacity through adoption of high-efficiency management practices. **Among the nine LEI identified key high-efficiency management practices is the standardization (harmonization) of testing platforms.** To learn more about LEI, visit: www.aphl.org/lei or http://www.cdc.gov/osels/lspppo/lei/index.html.

Multiple programs across the Centers for Disease Control and Prevention (CDC) work closely with the Association of Public Health Laboratories (APHL) and state and local public health laboratories (PHLs) to build local capacity for public health testing in support of surveillance, disease control and prevention. Recent state and federal funding cuts have brought attention to reducing costs and recognition of workforce limitations in supporting multiple testing platforms that require separate purchase, training, maintenance and proficiency testing for optimization of performance. Participants in the CDC Laboratory Program Forum and members of APHL standing committees on Infectious Diseases and Public Health Preparedness and Response have identified the priority of engaging CDC programs and subject matter experts (SMEs) to develop strategies for standardization of testing and extraction platforms and assays.

Standardizing testing platforms and reagents has long been the goal of the Laboratory Response Network (LRN) and represents a "gold standard". The LRN model of introducing, implementing and supporting standardized testing platforms could be leveraged more broadly across *all* laboratory program areas. Funding allocated via the CDC Public Health Emergency Preparedness (PHEP) Cooperative Agreement (the main state laboratory funding source) and other federal grants continues to decline. As such, there is an urgent need for standardization of assays and platforms across state and local PHLs.

To address this issue, CDC and APHL convened the Standardization of Platforms Focus Group which is tasked with engaging state and local PHLs, CDC programs, and relevant subject matter experts (SMEs) in the development of strategies to harmonize various testing and extraction platforms and assays currently in use in the public health laboratory setting. Working in partnership with staff from CDC's Office of Infectious Diseases (OID), the Office of Surveillance, Epidemiology and Laboratory Services (OSELS)/Laboratory Science, Policy, and Practice Program Office (LSPPPO) and the Division of Preparedness and Emerging Infections (DPEI), the Focus Group is identifying existing molecular testing assays and platforms in use across CDC and within PHLs. **Specifically, the focus is on molecular testing assays and platforms utilized for infectious disease and biological threat agents and will include extraction as well as pathogen identification/detection and characterization.**

Following is a summary of the major topics discussed during the first Standardization of Platforms Focus Group Meeting which was held on April 11, 2012 in Atlanta, Georgia. Additionally, the report serves to highlight the major accomplishments of the Focus Group meeting, which include the identification of specific parameters in the consideration of standardizing platforms and the development of proposed recommendations for CDC and APHL to address in moving toward platform standardization in the public health laboratory system.

II. Value of Standardization of Platforms for Public Health Laboratories:

Focus Group members addressed the perceived value of implementing a standardized testing environment across all PHLs.

Benefits of Standardized Platforms	Risks of Standardized Platforms
Easier to train staff	Lack of redundancy in testing ability/shortages during an event
More cross-trained staff	May stifle innovation and creativity
Easier to perform quality assurance activities	Adoption at laboratories may vary/cautious of a one-size-fits-all approach
Reduced or shared costs/Efficiencies of scale (ability to leverage buying power and purchase reagents and instruments in bulk; bundle preventative maintenance costs)	
Regulatory compliance (validation testing, Food and Drug Administration (FDA) clearance)	

While trying to mitigate costs through standardization is a good idea, Focus Group members stressed the importance of preserving some degree of flexibility for platform selection in the states.

III. Platforms Across Various CDC Laboratory Programs and in State and Local Public Health Laboratories:

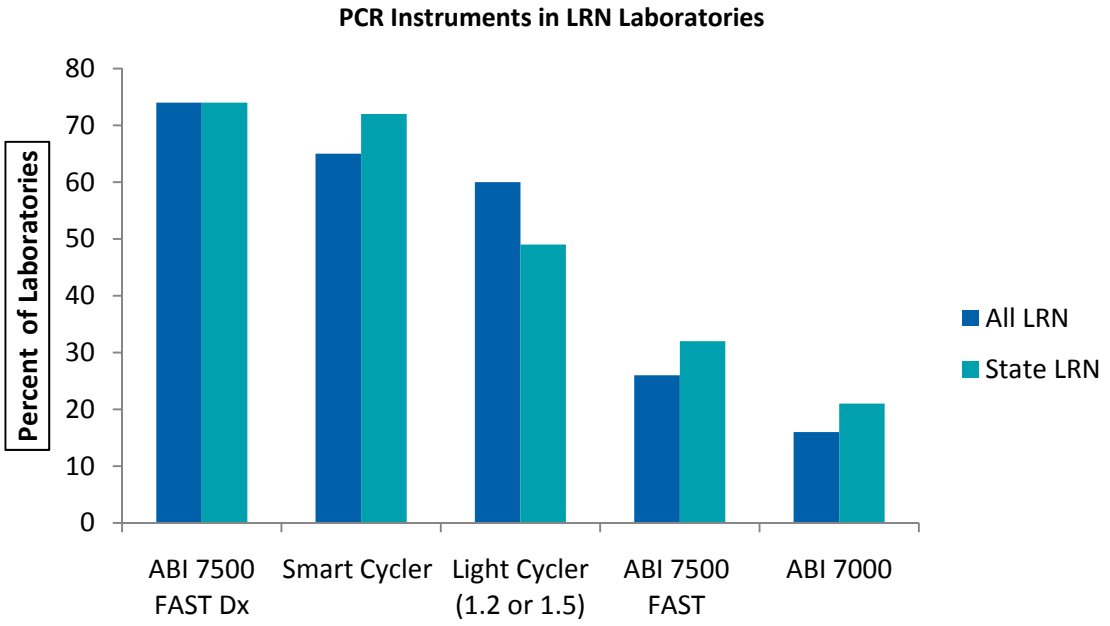
Over the past year, an attempt was made to obtain more comprehensive information on existing platforms in the various CDC infectious disease laboratories and state and local PHLs. However, this was difficult to ascertain as there is no central repository of laboratory information. Additionally, other than the preparedness survey, most APHL surveys did not collect information on instrumentation. As such, the data obtained in preparation for the Focus Group meeting was not all-inclusive and involved only a very cursory look at existing platforms in use across various CDC programs.

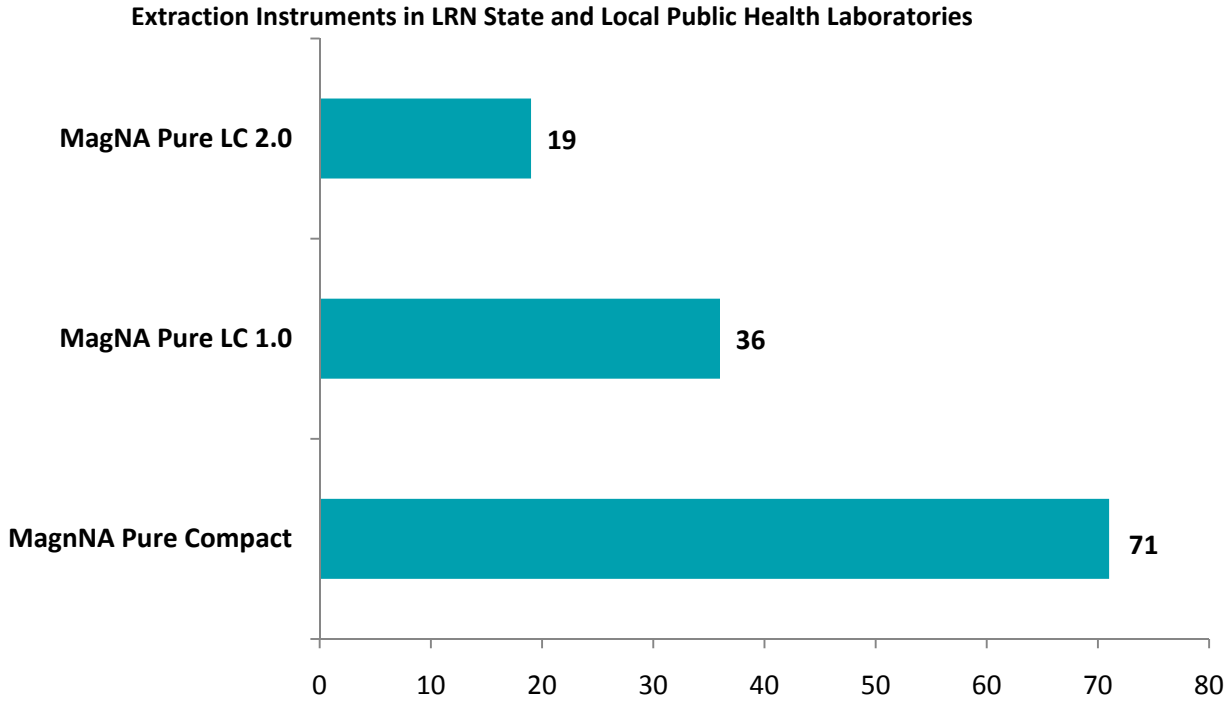
Situation at CDC

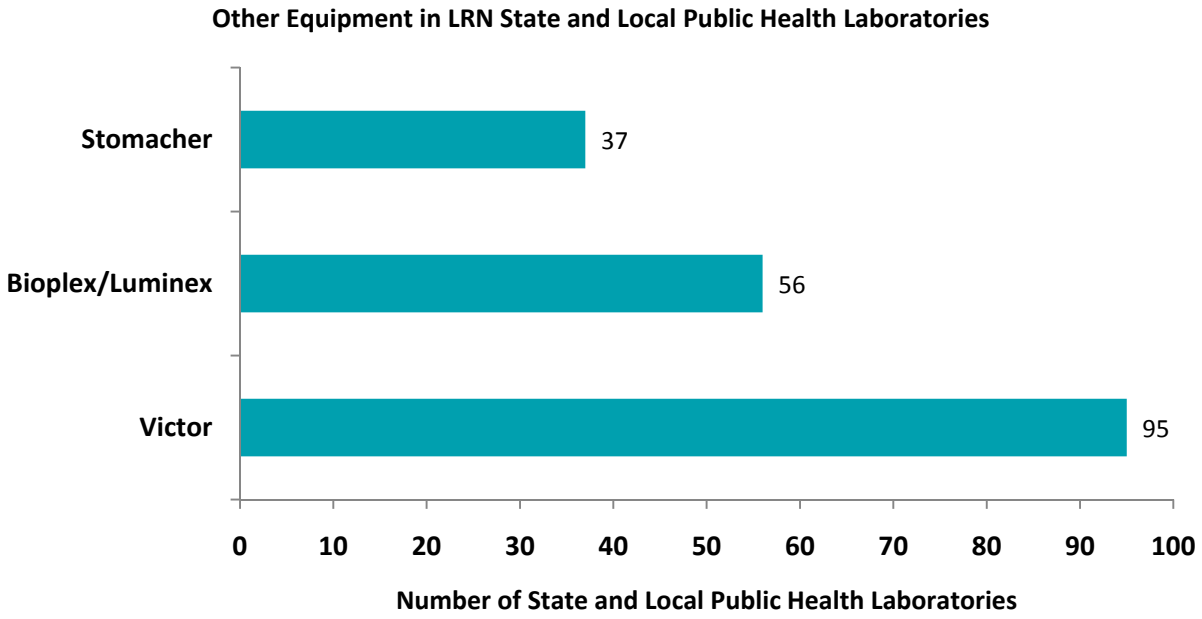
- ❑ Some infectious disease laboratory programs provide protocols to PHLs
- ❑ Some programs also provide reagents
- ❑ Fewer programs specify laboratory equipment for their protocols
- ❑ Few labs at CDC indicate they require specific PCR instrumentation for diagnostics
- ❑ Most LRN PHLs have the ABI 7500 FAST Dx and/or Smart Cycler
- ❑ LRN data is specific for LRN laboratories; use of LRN equipment for other lab activities is unknown

APHL conducted an assessment of LRN state and local PHLs in an effort to gather preliminary data on the platforms currently in use. Assessment results showed the Roche MagNA Pure to be the dominant

instrument used for extraction purposes in state and local PHLs. In terms of PCR platforms, both the ABI 7500 Fast Dx and the SmartCycler were most often reported as the instruments of choice in state and local PHLs. Other testing platforms commonly reported to be in use in state and local PHLs included the Stomacher, Bioplex/Luminex and VICTOR. Several PHL representatives noted that while many labs have the VICTOR for time-resolved fluorescence assays, many have not used this particular equipment in years.






Other Equipment in LRN State and Local Public Health Laboratories
Stomacher
37
Bioplex/Luminex
56
Victor
95
0
10
20
30
40
50
60
70
80
90
100
Number of State and Local Public Health Laboratories

PCR Assays Provided by CDC to Public Health Laboratories

Meeting participants also discussed influenza platforms currently in use at CDC and in state and local PHLs. The primary platform for influenza testing remains ABI 7500 Fast Dx real-time PCR instrument as it has FDA 510(k) clearance. Other companies are submitting data packages for FDA clearance of platforms with QIAGEN receiving FDA 510(k) clearance of the Rotor-Gene MDx instrument and an instrument compatible test for the detection of influenza A/B. The Rotor-Gene MDx platform is an automated molecular detection instrument based on real-time PCR technology, using a unique centrifugal rotary design to amplify and quantify DNA molecules, enabling well-to-well and optical uniformity and a fast data acquisition rate. Besides the influenza test, other PCR-based assays are either under regulatory review or being prepared for FDA submission.

PCR Assays Provided by CDC to Public Health Laboratories

Division	Investigator	Agent	PCR tests	Instrument	Extraction Methodologies	Other Notes
Division of Viral Diseases	D Erdman	Non-influenza respiratory viruses	RT-PCR	Stratagene (MX 3000P, MX3005P), Applied Biosystems (7300,7900, or 7500 Standard or Fast Real-Time PCR System), Bio-Rad (iCycler IQ5, CFX96)	No recommendations	Protocol is on APHL website; primer/ probes not provided except for some studies
Influenza Division	S Lindstrom	Influenza (A, B, H1, H3, avian H5, H1 pandemic)	RT-PCR	ABI 7500 FAST DX; Light Cycler	QIAGEN, MagNA Pure	
Division of Bacterial Diseases	M Lucia Tondella	Bordatella spp	RT-PCR	AB (7500 or FAST)	MagNA Pure LC	Protocol on CDC website
Division of Bacterial Diseases	L Mayer	N. Meningitidis	RT-PCR	Agilent (Stratagene Mx3005P)	QIAampDNA mini kit	Protocols in WHO manual

Division of Bacterial Diseases	L Mayer	Haemophilus influenza	RT-PCR	Agilent (Stratagene Mx3005P)	QIAampDNA mini kit	Protocols in WHO manual
Division of Prepared-ness and Emerging Infections	J Chaitram	Multiple (LRN)	PCR	ABI 7500 FAST DX; Smart Cycler	QIAGEN QIAamp DNA Blood Mini Kit, MagNA Pure Compact, MagNA Pure LC, MasterPureTM Complete DNA and RNA Purification kit (Epicentre)	
Division of Bacterial Diseases	B Beall	Streptococcal spp	Conventional RT-PCR			Protocols on CDC website
Division of Vector-Borne Diseases	R Lanciotti	Arboviruses	PCR	Not specified	No recommendations	Protocols and some reagents provided
Division of Foodborne, Water-borne, and Environmental Diseases	B Raphael	Botulinum toxin	PCR	ABI 7500 and Light Cycler		

CDC noted that FDA clearance is a requirement for influenza platforms at CDC in order to distribute kits. For states, an FDA-cleared kit is preferred if it can provide the same performance data (e.g., accuracy, sensitivity) as their laboratory developed test (LDT). However, FDA clearance, while the "gold standard," is not required by most states unless a test kit will cross state lines. At this time, PHLs do not have to conform to a specific extraction platform or method.

Focus Group members discussed current molecular testing and extraction platforms for testing of infectious disease and biothreat agents. The following table provides a snapshot of both existing and emerging platforms available in state and local PHLs:

CURRENT AND FUTURE/EMERGING MOLECULAR TESTING AND EXTRACTION PLATFORMS	
CURRENT PLATFORMS	***EMERGING PLATFORMS***
iCyclers	Various sequencing technologies, e.g., QIAGEN Pyro-sequencing
Stratagene	Mass Spec/MassTag PCR
ABI ViiA 7	Plex-ID (Abbot)
EasyMag	Microfluidics chip for DNA fingerprinting and strain typing analysis (Biomerieux)
QIAGEN Robotics *(Various types mentioned, e.g. BioRobot)*	Bio Rad LightCycler/microplex (This is a reagent, not a platform)
QIAGEN QIAcube	ColumbiaNastag
Sequencers (pyro-sequencing, e.g. PyroMark Q96ID, etc.)	Grouper System
Eppendorf pipetter	OpenArray System
Liquid handler-type instrumentation, e.g. Biomek FX, etc. *(These are more accessories as opposed to platforms, but were mentioned often.)*	Low-density array (gene expression)
SmartCycler	Multi-assay/Multi-plex Technology, e.g., Multi-plex PCR
Light Cyclers *(Many PHLs are currently phasing these out.)*	Vitek
GeneXpert® System	MALDI-TOF Mass Spectrometry
MagNA Pure	
Small extractors	
Roche96ID	
Luminex/Bioplex	
ABI platforms *(Various mentioned, including ABI 31/30, ABI 31/32, 7500 Fast Dx, etc.)*	
GC-MS	

IV. Proposed Parameters for the Standardization of Platforms:

Focus Group members proposed a list of parameters to be considered by state and local PHLs and CDC in the standardization of testing platforms.

1. Costs (e.g., equipment purchases, maintenance contracts)
2. Purchasing mechanisms (e.g., leasing, direct assistance from CDC)
3. Familiarity with Equipment
4. Company Characteristics • Customer Service • Customer Familiarity with Company • Compatibility with Current Platforms • Company Stability
5. Validation Processes
• FDA Clearance
• Lab Developed Tests
6. Quality Control Requirements
7. Software and Middleware
• Ease of use/compatibility
• Link between instrument and Laboratory Information Management System
• Interface with other instruments
8. Instrument Accessories (e.g. liquid handling)
9. Flexibility and Scalability
• Practicality/Multiple Agents/Low and High volumes
10. Degree of Automation
11. Equipment has to be appropriate
• Answer the right questions, surveillance versus diagnostic, turnaround time, sample volume
• Future proofing/life-span of instruments
12. Produces high quality results
13. Biosafety Considerations (safety) and Contamination Potential
14. Footprint within the laboratory
15. Impact on Personnel
• Amenable to cross-training in order to increase efficiencies
• Specialized expertise
• Hands-on time required

A related topic that emerged was assay development at CDC. **Presently, assay development is done on a program-by-program basis with little to no cross-coordination between and among individual programs at CDC.** In addition, the majority of assays developed at CDC are not currently submitted for FDA clearance. However, there is an effort underway to move toward the development of assays for FDA clearance and to gain more experience at preparing and submitting all of the data associated with obtaining FDA clearance. Similar to CDC, state and local PHLs did not have standard criteria for selecting a particular testing platform.

V. Recommendations for Moving Toward Standardization of Platforms:

At the conclusion of the meeting, Focus Group members formulated a list of recommendations for CDC and APHL to assist with moving toward standardization of platforms in the public health laboratory setting.

1. (CDC) Explore Purchasing Mechanisms
    - Direct assistance, rental/leasing agreements, carry-over funds for leasing, etc.
2. (CDC and APHL) Inform PHLs about equipment maintenance options
    - "Bundle" insurance for equipment maintenance contracts (as available through Remi Group, Specialty Underwriters Groups)
3. (CDC) Address internal strategy for assay development, validation, instrument selection and deployment to PHLs
4. (CDC and APHL) Collaborate with state and local PHLs on the evaluation of emerging technologies
5. (CDC and APHL) Communicate/inform PHLs of new technologies under consideration
6. (CDC and APHL) Collaborate with manufacturers, PHLs and FDA to address regulatory requirements for assays and platforms
7. (CDC) Collaborate with other federal agencies to explore strategies for assay development, deployment, implementation (full-use) and support of PHLs
8. (CDC and APHL) Support outreach and training on specialized platforms
9. (CDC and APHL) Create a forum for information exchange on assays and equipment
10. (CDC) Define a process for how vendors can engage CDC in the evaluation of new platforms
    - Technology agreements, contacting CDC, restrictions on CDC endorsement, etc.
11. (CDC) Maintain a database of available instruments and assays at CDC and in PHLs
    - Value for surge

Next Steps:

At the conclusion of the meeting, all participants were in agreement that the Focus Group succeeded in meeting the charge to develop recommendations for CDC with relation to standardization of molecular testing and extraction platforms for infectious disease and biothreat agents.

Overall, Focus Group members shared the belief that this first meeting represented a promising step in the process of moving toward standardization of testing platforms. CDC staff also recognized that there is much work to be done on standardization of platforms, noting that the process will present challenges and may not proceed along perfectly. CDC staff also emphasized that there is much support within CDC for enhancing and sustaining public health laboratory capacity.

Immediate next steps encompass: (1) sharing the summary report with APHL member state and local PHLs and CDC staff and (2) prioritizing and addressing the recommendations.

Appendix I-Focus Group Agenda:

Standardization of Platforms Focus Group Meeting

Atlanta Marriott Marquis

Meeting Room A707 (Atrium Level)

265 Peachtree Center Avenue Northeast

Atlanta, Georgia 30303

Tel: 1-404-521-0000

April 11, 2012

Purpose: To provide a forum for subject matter experts from public health laboratories and the Centers for Disease Control and Prevention (CDC) to discuss current infectious disease and biothreat molecular testing and extraction platforms in use in public health laboratories.

Agenda:

- 8:30am – 9:00am: Light Breakfast
- 9:00am – 9:10am: Welcome and Introductions (Jane Getchell and Eric Blank)
- 9:10am – 9:20am: Overview of Focus Group Scope (Chris Mangal and John Ridderhof)
- 9:20am – 9:40am: Value of Standardization for Public Health Laboratories (Moe Sullivan and Sandy Smole)
- 9:40am – 10:00am: CDC Collected Data (Jan Nicholson)
- 10:00am – 10:15am: Break
- 10:15am – 10:30am: APHL Data (Chris Mangal and Sadira Daher)
- 10:30am – 12:00pm: Open Discussion (All Participants, discussion facilitated by Jane Getchell)
    - Current Molecular Testing and Extraction Platform in Public Health Laboratories
    - Parameters for Standardizing Platforms
- 12:00pm – 1:30pm: Lunch (Room # A708)
- 1:30pm – 2:30pm: New Technologies in Development (All Participants, discussion facilitated by Eric Blank)
- 2:30pm – 3:00pm: Capturing Information on Platforms in Public Health Laboratories (All Participants, discussion facilitated by Deborah Kim)
    - What's needed and how will the data be utilized?
- 3:00pm – 3:15pm: Break
- 3:15pm – 4:15pm: Standardization of Platforms: Recommendations for CDC (All Participants, discussion facilitated by Chris Mangal)
- 4:15pm – 4:30pm: Summary and Next Steps (Chris Mangal, John Ridderhof and Jan Nicholson)
- 4:30pm - Adjourn

Appendix II-Focus Group Members:

APHL Members	CDC Subject Matter Experts and Invited Representatives	APHL Staff
Patricia Blevins (APHL/TX – San Antonio)	*Bill Bellini (CDC/NCIRD) unable to attend*	Eric Blank
Christina Egan (APHL/NY - Wadsworth)	Efrain M. Ribot (CDC/NCEZID)	Sadira Daher
Romesh Gautom (APHL/WA - Shoreline)	Senthil Sakthivel (CDC/NCIRD)	Jane Getchell
Grace Kubin (APHL/TX – Austin)	Mike Farrell (CDC/DPEI)	Deborah Kim
Stephanie Mayfield (APHL/KY - Frankfort)	Tracy Dalton (CDC/NCHHSTP)	Chris Mangal
Justin Nucci (APHL/CO - Denver)	Steve Lindstrom (CDC/NCIRD)	Lauren Bradley (Contractor)
Dee Pettit (APHL/VA - Richmond)	Jan Nicholson (CDC/OID)	
Bonnie Rubin (APHL/IA – Iowa City)	Tonia Parrott (CDC/NCEH)	
Sandy Smole (APHL/MA – Jamaica Plain)	John Ridderhof (CDC/OSELS)	
Moe Sullivan (APHL/MN – St. Paul)	Renee Ned (CDC/OSELS)	
	Tiffany Brunson (CDC/OID) Emerging Leader	
	Maryam Daneshvar (CDC/OSELS)	
	Arunmozhi Balajee (CDC/CGH/DGDDER)	
	Roger Nasci unable to attend	
	Ben Beard and Marty Schriefer unable to attend (Ft. Collins, CO)	

Contact Information for Focus Group Members

CDC

S. Arunmozhi Balajee, Ph.D.
Senior Advisor for Laboratory Sciences
Division of Global Disease Detection and Emergency Response
Center for Global Health
Centers for Disease Control and Prevention
Mail Stop: DPDM, Building 24, Room 9-460, 1600 Clifton Road N.E., Atlanta, GA 30329-4018
Email: fir3@cdc.gov

Ben Beard, Ph.D.
Chief, Bacterial Diseases Branch
Division of Vector Borne Diseases
National Center for Emerging and Zoonotic Diseases
Office of Infectious Diseases
Centers for Disease Control and Prevention
Mail Stop: 3150 Rampart Road, Fort Collins, CO 80521
Email: cbb0@cdc.gov

William Joseph Bellini, Ph.D.
Chief, MMR and Herpes Laboratory
Measles, Mumps, Rubella and Herpes Virus Laboratory Branch
Division of Viral Diseases
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Mail Stop: MS C-22, BLDG 18/5164, 1600 Clifton Road, N.E., Atlanta, GA 30333
Tel: 404.639.4183
Email: wjb2@cdc.gov

Tiffany Brunson
Health Scientist/Emerging Leader
Office of Infectious Disease
Centers for Diseases Control and Prevention
1600 Clifton Road N.E., Atlanta GA 30329-4018
Tel: 404.639.7204
Email: iqa7@cdc.gov

Tracy Dalton, Ph.D.
Senior Science Fellow, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
Mail Stop: MS e-86, 1600 Clifton Rd, N.E., Atlanta, GA 30333
Tel: 404.639.3904
Email: dvx7@cdc.gov

Maryam Daneshvar, Ph.D.
Associate Director of Science
Office of Surveillance, Epidemiology and Laboratory Services
Centers for Disease Control and Prevention
Mail Stop: Bldg: CLFT, Room: LSPPPO, 1600 Clifton Road N.E., Atlanta GA 30329-4018
Tel: 404.498.2661
Email: maryam.daneshvar@cdc.hhs.gov

Michael Farrell, Ph.D.
Team Leader, Bioterrorism Rapid Response and Advanced Technology Laboratory
Laboratory Preparedness and Response Branch
Division of Preparedness and Emerging Infections
National Center for Emerging and Zoonotic Infections
Centers for Disease Control and Prevention
Mail Stop: MS-G25, 1600 Clifton Road, N.E., Atlanta, GA 30329
Tel: 404.639.4923
Email: mqf2@cdc.gov

Stephen Lindstrom, Ph.D.
Team Lead, Diagnostic Development Team
Virus Surveillance and Diagnosis Branch
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Mail Stop: MS-G16, 1600 Clifton Road N.E., Atlanta, 30333
Tel: 404.639.1587
Email: sql5@cdc.gov

Roger Nasci, Ph.D.
Chief, Arboviral Diseases Branch
Division of Vector Borne Diseases
National Center for Emerging and Zoonotic Diseases
Office of Infectious Diseases
Centers for Disease Control and Prevention
Mail Stop: Building FTCL, Room NCEZID, 3150 Rampart Road, Fort Collins, CO 80521
Tel: 970.221.6432
Email: RNasci@cdc.gov

Renée M Ned, M.M.Sc., Ph.D.
Health Scientist
Laboratory Science, Policy and Practice Program Office
Office of Surveillance, Epidemiology and Laboratory Services
Centers for Disease Control and Prevention
Mail Stop: E-61, 1600 Clifton Road N.E., Atlanta, GA 30333
Tel: 404-498-0125
Email: rin1@cdc.gov

Janet K.A. Nicholson, Ph.D.
Associate Director for Laboratory Science
National Center for Infectious Diseases
Office of Infectious Diseases
Centers for Disease Control and Prevention
Mail Stop: MS D-10, 1600 Clifton Road N.E., Atlanta, GA 30333
Tel: 404.639.4155
Email: jkn1@cdc.gov

Tonia Parrott, Ph.D.
Fellow
National Center for Environmental Health
Office of Noncommunicable Diseases, Injury, and Environmental Health
Centers for Disease Control and Prevention
Mail Stop: Bldg CHAM, Room NCEH, 1600 Clifton Road N.E., Altlanta, GA 30333
Tel: 770.488.4372
Email: tparrott@cdc.gov

Efrain M. Ribot, Ph.D.
Team Leader, PulseNet USA
Enteric Diseases Laboratory Branch
Division of Foodborne, Bacterial and Mycotic Diseases
National Center for Emerging and Zoonotic Infectious Diseases
Mail Stop: MS C-03, 1600 Clifton Road, Atlanta, GA 30333
Tel: 404.639.3521
Email: eribot@cdc.gov

John Ridderhof, DrPH
Senior Advisor for Planning
Laboratory Science, Policy and Practice Program Office
Office of Surveillance, Epidemiology and Laboratory Services
Centers for Disease Control and Prevention
Mail Stop: E-94, 1600 Clifton Road N.E., Atlanta, GA 30333
Tel: 404.498.0469
Email: jcr0@cdc.gov

Senthil Kumar Sakthivel, PhD.
Research Scientist, Battelle Contractor
Gastroenteritis and Respiratory Viruses Laboratory Branch
Division of Viral Diseases
National Center for Immunization and Respiratory Diseases (NCIRD)
Centers for Disease Control and Prevention
Mail Stop: G04, 1600 Clifton Road, N.E., Atlanta, GA 30333
Tel: 404.639.3252
Email: hyu6@cdc.gov

Martin Schriefer, Ph.D.
Laboratory Chief (TL)
Division of Vector Borne Diseases
National Center for Emerging and Zoonotic Diseases
Centers for Disease Control and Prevention
Mail Stop: 3150 Rampart Road, Fort Collins, CO 80521
Tel: 970.221.6479
Email: martin.schriefer@cdc.hhs.gov

APHL Members

Patricia Blevins, MPH
Coordinator, Bioterrorism Laboratory
San Antonio Metro Health District Laboratory
Mail: 2509 Kennedy Circle Bldg. 125 B-level, Brooks City-Base, TX 78235
Tel: 210.207.5883
Email: patricia.blevins@sanantonio.gov

Christina Egan, Ph.D.
Director, Biodefense Laboratory
Wadsworth Center, New York State Department of Health
Mail: NYSDOH, David Axelrod Institute, Room 3022, PO Box 22002, Albany, NY 12201-2005
Tel: 518.473.6900
Email: cte01@health.state.ny.us

Romesh K. Gautom, Ph.D.
Laboratory Director
Washington Public Health Laboratories
Mail: 1610 NE 150th Street, Shoreline, WA 98155-9701
Tel: 206.418.5450
Email: romesh.gautom@doh.wa.gov

Grace E. Kubin, Ph.D.
Director of Laboratory Services Section
Texas Department of State Health Services
Mail: Laboratory Services Section, MC 1947, PO Box 149347, Austin, TX 78714-9347
Tel: 512.776.2468
Email: grace.kubin@dshs.state.tx.us

Stephanie M. Mayfield Gibson, MD
Laboratory Director
Kentucky Division of Laboratory Service
Department for Public Health
Mail: 100 Sower Boulevard, Suite 204, Frankfort, KY 40601
Tel: 502.564.4446
Email: StephanieK.Mayfield@ky.gov

Justin Nucci
Scientist
CO Dept of Public Health & Environment
Lab Services Division, Molecular Lab
Mail: 8100 Lowry Boulevard, Denver, CO 80230
Tel: 303.692.3099
Email: justin.nucci@state.co.us

Denise A. Pettit, Ph.D.
Lead Scientist
Virginia Division of Consolidated Laboratory Services
Mail: 600 North 5th Street, Richmond, VA 23219
Tel: 804.648.4480
Email: Dee.Pettit@dgs.virginia.gov

Bonnie D. Rubin, MBA, MHA
Assistant Director
State Hygienic Laboratory at the University of Iowa
Mail: 2490 Crosspark Road, Coralville, IA 52241
Tel: 319.335.4500
Email: bonnie-rubin@uiowa.edu

Sandra C. Smole, Ph.D.
Director, Division of Molecular Diagnostics & Virology
William A. Hinton State Laboratory Institute
Department of Public Health
Mail: 305 South Street, Room 810A, Jamaica Plain, MA 02131
Tel: 617.983.6966
Email: sandra.smole@state.ma.us

Maureen M. Sullivan, MPH
Bioterrorism Preparedness Laboratory Coordinator
Minnesota Public Health Laboratory Division
Department of Health
Mail: 601 Robert Street North/PO Box 64899, St Paul, MN 55164-0899
Tel: 651.201.5582
Email: Maureen.sullivan@state.mn.us

APHL Staff

Eric C. Blank, DrPH
Senior Director, Public Health Systems
Association of Public Health Laboratories
Mail: 8515 Georgia Avenue, Suite 700, Silver Spring, MD 20910
Tel: 240-485-2785
Email: eric.blank@aphl.org

Sadira Daher, MA
Senior Specialist, Quality Systems
Association of Public Health Laboratories
Mail: 8515 Georgia Avenue, Suite 700, Silver Spring, MD 20910
Tel: 240-485-2702
Email: sadira.daher@aphl.org

Jane P. Getchell, DrPH, MT (ASCP)
Senior Director, Public Health Programs
Association of Public Health Laboratories
Mail: 8515 Georgia Avenue, Suite 700, Silver Spring, MD 20910
Tel: 240-485-2792
Email: jane.getchell@aphl.org

Deborah Kim
Manager, Survey and Research
Association of Public Health Laboratories
Mail: 8515 Georgia Avenue, Suite 700, Silver Spring, MD 20910
Tel: 240.485.2742
Email: Deborah.kim@aphl.org

Chris N. Mangal, MPH
Director, Public Health Preparedness and Response
Association of Public Health Laboratories
Mail: 8515 Georgia Avenue, Suite 700, Silver Spring, MD 20910
Tel: 240.485.2769
Email: chris.mangal@aphl.org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