

The New Landscape of HIV Testing in Laboratories, Public Health Programs and Clinical Practice

AGENDA

Monday, March 21 2016

- 3:00 PM 7:00 PM On-site Registration
- 6:00 PM 6:15 PM The New Landscape of HIV Testing Monica M. Parker, PhD, Conference Co-Chair; New York State Department of Health
- 6:15 PM 8:00 PM HIV Testing 101 Workshop Moderator: Monica M. Parker, PhD, New York State Department of Health
 - 6:15 PM 6:30 PM Update on HIV Testing Technology S. Michele Owen, PhD, Centers for Disease Control and Prevention
 - 6:30 PM 6:45 PM Why HIV Tests are Regulated as They Are, and Understanding the Package Insert *Pradip Akolkar*, PhD, U.S. Food and Drug Administration
 - 6:45 PM 7:00 PM **Evaluating HIV Test Performance** Bernard M. Branson, MD, Scientific Affairs
 - 7:00 PM 7:15 PM Health Department HIV Testing Programs: Status and Opportunities Liisa M. Randall, PhD, National Alliance of State and Territorial AIDS Directors
 - 7:15 PM 7:30 PM Uses of HIV Laboratory Data in Surveillance and Challenges with Reporting *Albert Barskey*, *MPH*, *Centers for Disease Control and Prevention*
 - 7:30 PM 7:45 PM Use of Lab Data for Prevention AD McNaghten, PhD, MHSA, Centers for Disease Control and Prevention
 - 7:45 PM 8:00 PM Moderated Q & A

Tuesday, March 22 2016

7:00 AM – 6:00 PM	On-site Registration
7:00 AM – 8:15 AM	Satellite Breakfast Symposium Presented by ASHA and ASTDA
	HIV NAAT versus 4th Generation Antigen-Antibody Testing for Acute HIV Infection
	Joanne Stekler, MD, MPH, University of Washington
	Adding a Diagnostic Claim to HIV Prognostic Assays: Why not NAT?
	Elliot Cowan, PhD, Partners in Diagnostics, LLC
	Sponsored by Hologic Inc.
8:15 AM – 8:20 AM	Break
8:20 AM – 8:30 AM	Welcome
	Eugene McCray, MD, Director of the Division of HIV/AIDS Prevention in CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
8:30 AM — 9:30 AM	Roundtable Discussion
	Overcoming the Challenges and Barriers to Implementing the HIV Diagnostic Testing Algorithm in your Laboratory
	Moderator: Monica M. Parker, PhD, New York State Department of Health
	Michael A. Pentella, PhD, D(ABMM), Massachusetts State Public Health Laboratory
	Anne M. Gaynor, PhD, Association of Public Health Laboratories
9:30 AM – 10:45 AM	Session A: Performance of HIV Screening Tests in the Laboratory
	Moderator: Barbara Body, PhD, D(ABMM), Laboratory Corporation of America
9:30 AM – 9:45 AM	A1. Performance Evaluation of Two Recently FDA-approved Antigen/antibody Combo Assays in Early HIV-1 Infections
	Silvina Masciotra, MS, Centers for Disease Control and Prevention
9:45 AM – 10:00 AM	A2. HIV Subtype and Acute Infection Sensitivity of Abbott Architect HIV Combo, Bio-Rad BioPlex 2200 HIV Ag-Ab and ADVIA Centaur HIV Ag/Ab Combo (CHIV)
	Teal Clocksin, MS, Tricore Reference Laboratories
10:00 AM – 10:15 AM	A3. Performance of the Abbott Architect HIV Ag/Ab 4th Gen Combo Assay in the US Army HIV Diagnostic Algorithm
	Sheila Peel, PhD, US Military HIV Research Program, WRAIR
10:15 AM – 10:30 AM	A4. Performance Evaluation of Determine [™] HIV-1/2 Ag/Ab Combo in Plasma and Whole Blood from Early HIV-1 Infections
	Silvina Masciotra, MS, Centers for Disease Control and Prevention
10:30 AM – 10:45 AM	Moderated Q &A

Tuesday, March 22 2016

10:45 AM – 11:00 AM	Morning Break
11.00 AM – 12.15 PM	Session B: Performance of Supplemental Tests and Nucleic Acid Tests Moderator: Richard L. Hodinka, PhD, University of South Carolina School of Medicine Greenville
11:00 AM – 11:15 AM	 B1. Comparative Performance of the Geenius HIV-1/HIV-2 Supplemental Test in Florida's Public Health Testing Population S. Berry Bennett, MPH and Sally Fordan, BSMT, ASCP, Florida Bureau of Public Health Laboratories
11:15 AM – 11:30 AM	B2. Performance Evaluation of FDA-approved HIV Supplemental Assays <i>Wei Luo</i> , MS, Centers for Disease Control and Prevention
11:30 AM – 11:45 AM	B3. Diagnosis of Human Immunodeficiency Virus Type 2 (HIV-2) Infection by a HIV-2 Total Nucleic Acid Qualitative Assay Using Abbott m2000 platform <i>Ming Chang</i> , <i>PhD</i> , <i>MB</i> (ASCP), University of Washington
11:45 AM – 12:00 PM	B4. Validation of a Droplet Digital PCR Assay That Provides Sensitive Detection and Accurate Quantification of HIV-2 DNA in Whole Blood or Blood Cell Pellets <i>Linda M. Styer</i> , <i>PhD</i> , <i>New York State Department of Health</i>
12:00 PM – 12:15 PM	Moderated Q &A
12:15 PM – 1:30 PM	Lunch on your own
1:30 PM – 2:45 PM	Session C: CDC/APHL Laboratory Testing Algorithm Moderator: Laura G. Wesolowski, PhD, Centers for Disease Control and Prevention
1:30 PM – 1:45 PM	C1. Promoting the Recommended HIV Diagnostic Algorithm: Practical Information for Laboratories Laura D. Russell, MPH, New York State Department of Health
1:45 PM – 2:00 PM	C2. Evaluation of Newly Approved HIV Antigen-Antibody Tests Individually and When Used in the CDC/APHL HIV Diagnostic Algorithm <i>Kevin P. Delaney</i> , <i>PhD</i> , <i>Centers for Disease Control and Prevention</i>
2:00 PM – 2:15 PM	C3. Is It Always Necessary for the ARCHITECT 4th-Generation HIV-1/2 Ag/Ab Combo Assay to be Repeatedly Reactive before Moving Forward in the Centers for Disease Control and Prevention (CDC) HIV Screening Algorithm?
2:15 PM – 2:30 PM	<i>Eric M. Ramos</i> , <i>MD</i> , <i>MS</i> , <i>University of Washington</i> C4. APHL/CDC Project for Referral of HIV Nucleic Acid Amplification Testing (NAT) for US Public Health Laboratories (PHLs) <i>Anne M. Gaynor</i> , <i>PhD</i> , <i>Association of Public Health Laboratories</i>

Tuesday, March 22 2016

2:45 PM – 3:00 PM Afternoon Break

3:00 PM – 4:00 PM Session D: CDC/APHL Laboratory Testing Algorithm (Part 2) Moderator: Kelly Wroblewski, MPH, MT(ASCP), Association of Public Health Laboratories

3:00 PM – 3:15 PM **D1. Efficacy of 4th Generation HIV Screening Algorithm in Detecting Acute HIV** Infection and the Utility of Abbott Architect Signal-to-cutoff Ratio in that Regard

Thomas P. Giordano, MD, MPH, Baylor College of Medicine

3:15 PM – 3:30 PM **D2. Real-world Performance of the New US HIV Testing Algorithm in Medical** Settings

Christopher D. Pilcher, MD, University of California, San Francisco

3:30 PM – 3:45 PM **D3. Comparison of Turn-around Time and Total Cost of HIV Testing Before and** After Implementation of the 2014 CDC/APHL Laboratory Testing Algorithm for Diagnosis of HIV Infection

Joseph D.C. Yao, MD, Mayo Clinic and Mayo Medical Laboratories

3:45 PM – 4:00 PM Moderated Q&A

4:00 PM – 5:00 PM Roundtable Discussion

Challenges and Successes of Implementing the HIV Diagnostic Testing Algorithm: Reports from Four HIV Surveillance Programs

Moderator: Irene Hall, PhD, Centers for Disease Prevention and Control

Bridget J. Anderson, PhD, New York State Department of Health

Marianne O'Connor, MPH, MT (ASCP), Michigan Department of Health and Human Services

Joanne Gerber, MS, RN, New York State Department of Health

Deepa T. Rajulu, MS, New York State Department of Health

5:00 PM – 6:30 PM "Meet the exhibitors" Use this opportunity to visit with the exhibitors and learn about the latest HIV tests. (Evening Reception Sponsored by Chembio Diagnostic Systems)

Wednesday, March 23 2016

10:45 AM – 11:00 AM	Morning Break
10:30 AM – 10:45 AM	Moderated Q &A
	Pollyanna R. Chavez, PhD, Centers for Disease Control and Prevention
10:15 AM – 10:30 AM	E4. Perceptions and Performance of Self-administered Rapid HIV Tests Conducted by Untrained Users in Real-World Settings
	Steve Gradus, PhD, City of Milwaukee Health Department Laboratory
10:00 AM – 10:15 AM	E3. Implementation of 4th Generation HIV Antigen-Antibody Testing Algorithm at a Public Health STD Clinic for <i>Real-time</i> Screening and Confirmation
	Bridget J. Anderson, PhD, New York State Department of Health
9:45 AM – 10:00 AM	E2. Using Reported HIV Diagnostic Testing Results to Identify Cases of Acute HIV Infection: Lessons Learned from New York State
	Debbie Mohammed, DrPH, Saint Michael's Medical Center
9:30 AM – 9:45 AM	E1. Rapid HIV Testing and Linkage to Medical Care, New Jersey, 2007-2011
9:30 AM – 10:45 AM	Session E: Streamlining Test Result Turnaround Time and Linkage to Care Moderator: Liisa M. Randall, PhD, National Alliance of State and Territorial AIDS Directors
	Christopher D. Pilcher, MD, University of California, San Francisco
	Joanne Stekler, MD, MPH, University of Washington
	Eugene G. Martin, PhD, Rutgers University - Robert Wood Johnson Medical School
	Moderator: Kevin P. Delaney, PhD, Centers for Disease Control and Prevention
	Improving the Impact of HIV Testing Through Better Linkage to Care and More Timely Viral Suppression
8:30 AM — 9:30 AM	Roundtable Discussion
8:15 AM – 8:30 AM	Break
	Sponsored by Bio-Rad Laboratories
	Thomas S. Alexander, PhD, D(ABMLI), Summa Health System
	HIV Testing: Evolution of the Species
7:00 AM – 8:15 AM	Satellite Breakfast Symposium Presented by ASHA and ASTDA
7:00 AM – 5:00 PM	On-site Registration

Wednesday, March 23 2016

11:00 AM – 12:15 PM	Session F: Performance of CLIA-Waived HIV Tests
	<i>Moderator: Benjamin Tsoi</i> , MD, MPH, New York City Department of Health and Mental Hygiene
11:00 AM – 11:15 AM	F1. Implementing HIV Testing in Nonclinical Settings: Updating CDC Guidance and Program Resources for HIV Testing
	Kristina L. Grabbe, MPH, Centers for Disease Control and Prevention
11:15 AM – 11:30 AM	F2. Performance Evaluation of the INSTI HIV-1/2 Antibody Point-of-Care Test in Early and Established Infections
	Sarah Adams, BS, Centers for Disease Control and Prevention
11:30 AM – 11:45 AM	F3. Performance of the NJ Rapid 4th Generation HIV POC Testing Algorithm
	Eugene G. Martin, PhD, Rutgers University - Robert Wood Johnson Medical School
11:45 AM – 12:00 PM	F4. Evaluation of New HIV Testing Technologies in a Clinical Setting with High Incidence: Rationale, Study Design and Preliminary Results from Project DETECT
	Kevin P. Delaney, PhD, Centers for Disease Control and Prevention
12:00 PM – 12:15 PM	Moderated Q & A
12:15 PM – 1:30 PM	Lunch on your own
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Wednesday, March 23 2016

2:45 PM – 3:00 PM	Afternoon Break
3:00 PM – 4:15 PM	Session H: Testing Alternatives Using Dried Blood Specimens Moderator: Joanne Mei, PhD, Centers for Disease Control and Prevention
3:00 PM – 3:15 PM	H1. Evaluation of the Performance of the Bio-Rad GS HIV Combo Ag/Ab EIA and Bio-Rad Geenius™ HIV-1/2 Supplemental Assay Using Dried Blood Spots as an Alternative Specimen Type
	Silvina Masciotra, MS, Centers for Disease Control and Prevention
3:15 PM – 4:15PM	Roundtable Discussion
	Dried Blood Spots (DBS) May Have High Utility Both in Resource Limited Settings and in Hard to Reach Populations for Diagnosis and Treatment Decisions
	Moderator: Joanne Mei, PhD, Centers for Disease Control and Prevention
	Silvina Masciotra, MS, Centers for Disease Control and Prevention
	Levinia Crooks , BA, Dep Ed, MBA, Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine
	<i>Philip Cunningham</i> , MSc Med, New South Wales State Reference Laboratory for <i>HIV</i>
	Bernard M. Branson, MD, Scientific Affairs
4:15 PM - 5:45 PM	Poster Session and "Meet the Exhibitors"

Thursday, March 24 2016

7:00 AM – 8:15 AM	Satellite Breakfast Symposium Presented by ASHA and ASTDA
	Reducing Missed Opportunities: Reconnecting HIV & STI Screening
	Barbara Van Der Pol, MD, PhD, University of Alabama at Birmingham School of Medicine
	HIV Testing in the STD Clinic Setting
	Cornelis A. Rietmeijer , MD, PhD, American Sexually Transmitted Diseases Association
	Sponsored by Roche
8:15 AM – 8:30 AM	Break
8:30 AM — 9.30 AM	Session I: Integrated Testing for Multiple Pathogens
	<i>Moderator: Cornelis A. Rietmeijer</i> , MD, PhD, American Sexually Transmitted Diseases Association
8:30 AM — 8:45 AM	I1. Evaluation of an Emergency Department HIV and Syphilis Screening Program Using Rapid Point of Care Diagnostics in Detroit, Michigan, 2015
	David Cal Ham, MD, MPH, Centers for Disease Control and Prevention
8:45 AM — 9:00 AM	I2. Multiplex Screening Assays - Advancing Targeted Screening of Co- morbidity via DPP® HIV-Syphilis Multiplex Rapid Test
	Tom Ippolito, BS, ChemBio Diagnostic Systems, Inc.
9:00 AM — 9:15 AM	I3. Performance of a Rapid, 60 second Multiplex Test for Simultaneous Detection of Antibodies to HIV-1, HIV-2 and <i>T. pallidum</i> in Serum, Plasma and Whole Blood
	Richard A. Galli, BS, bioLytical Laboratories
9:15 AM — 9:30 AM	Moderated Q &A
9:30 AM – 9:45 AM	Morning Break
9:45 AM – 11:15 AM	Session J: New Tests for Diagnosis, Clinical Staging, and Surveillance
	Moderator: Eugene G. Martin , PhD, Rutgers University - Robert Wood Johnson Medical School
9:45 AM – 10:00 AM	J1. The Effects of MDRI Updates and Transition to a New Recency Assay on HIV incidence Estimates in a Selected Number of HIV Surveillance Areas, United States
	Angela L. Hernandez, MD, MPH, Centers for Disease Control and Prevention
10:00 AM –10:15 AM	J2. Development and Evaluation of a Bead-Based Multiplex Assay for HIV Detection, Serotyping and Estimation of Recent Infection
	Ernest L. Yufenyuy, PhD, Centers for Disease Control and Prevention

Thursday, March 24 2016

10:15 AM – 10:30 AM	J3. Unmodified Diagnostic Assay Provides Similar Performance to Avidity Modification for Surveillance and Clinical Recency Staging Applications
	Eduard Grebe, PhD, Stellenbosch University
10:30 AM – 10:45 AM	J4. A Generalizable Method with Improved Accuracy for Estimation of HIV Infection Duration, Using Clinical HIV Testing Histories
	Christopher D. Pilcher, MD, University of California, San Francisco
10:45 AM – 11:00 AM	J5. Use of the Avioq VioOne Profile Assay for Detection of Recent HIV-1 Infection
	Don E. Lockwood, PhD, Avioq, Inc.
11:00 AM – 11:15 AM	Moderated Q &A
11:15 AM – 12:15 PM	Feedback Session: New Technology and its Impact on the CDC/APHL Laboratory Testing Algorithm
	S. Michele Owen, PhD, Centers for Disease Control and Prevention
	Monica M. Parker, PhD, New York State Department of Health
	Laura G. Wesolowski, PhD, Centers for Disease Control and Prevention
12:15 PM – 12:30 PM	Closing Statements
	S. Michele Owen , PhD, Conference Co-Chair, Centers for Disease Control and Prevention