



# Center for Point-of-Care Diagnostics

for global health

## First Annual Course on Point-of-Care Diagnostics for Global Health

July 14<sup>th</sup>–18<sup>th</sup>, 2008 Seattle, Washington, USA

<http://www.path.org/dxcenter/index.php>

### Day 1: Monday July 14, 2008

8:30 - 8:45	<b>Outline of Course and Welcome</b>	Pat Totten PhD and Karen Stephens PhD, Course Directors
8:45 - 9:15	<b>Get to know you</b>	
9:15 - 9:35	<b>Course pre-evaluation</b>	
9:35 - 10:20	<b>Welcome &amp; Introduction to activities of the <i>Center for Point of Care Diagnostics for Global Health</i></b> Introduction to Center, impact of Center, need for POC diagnostics for LRS, POC technologies in use, diagnostic test development	Bernhard H. Weigl PhD, Center Director
10:20 -10:45	<b>Discussion/coffee/break</b>	
10:45 -11:45	<b>Laboratory testing needs in developing countries</b>	Matt Steel PhD,MPH
11:45 -12:00	<b>Questions/Discussion</b>	
12:30 - 1:30	<b>Lunch</b>	
1:30 - 2:30	<b>Global epidemiology and significance of STDs/HIV</b> Prevalence of STDs worldwide and their repercussions Trends in STD incidence/prevalence worldwide Factors that affect STD prevalence and transmission Strategies for STD/HIV prevention and treatment Promotion of ABCs; STD treatment for HIV prevention? Condom promotion; Appropriate treatment in pharmacies? Risk reduction counseling; Microbicides STI screening in high risk populations Effect of POC tests on management of STIs Implementation challenges in LRS	King Holmes MD PhD
2:30 - 3:00	<b>Discussion/questions/break</b>	
3:00 - 4:00	<b>STD syndromes, transmission, and etiology</b> Basic epidemiology of STIs (sexually transmitted infections) Why define/identify STD syndromes? -Clue to cause, transmission, natural history, prevention, treatment Infections causing discharge: etiology, diagnosis, and treatment Vaginal Discharge –signs, symptoms, and etiology Mucopurulent cervicitis – signs, symptoms, and etiology Vaginitis/Bacterial Vaginosis Urethral Discharge – signs, symptoms, and etiology Infections causing genital ulcers-genital ulcer diseases – signs, symptoms, etiology Repercussions and Sequelae of selected STD syndromes Increased risk of HIV transmission Sequelae – PID, ectopic pregnancy, infertility Alternative screening and treatment strategies Syndromic, empiric, pathogen-based Outstanding Issues/Challenges; Need for POC diagnostics	Matt Golden MD
4:00 - 4:30	<b>Questions/discussion/break</b>	
4:30 - 5:00	<b>Focus group discussions</b> Experiences of participants; prevalent diseases and need for POC testing in their settings; types of tests needed. What are developers are working on? Challenges for implementation?	Pat Totten PhD and Karen Stephens PhD

**Day 2: Tuesday July 15, 2008**

8:00 - 9:30	<p><b>Introduction to clinical laboratory process</b> Pre-analytical, Analytical and Post-analytical steps – including specimen handling, LIS, storage and disposal, lab safety</p> <p><b>Factors that favor POC vs. Core laboratory testing</b> Centralized vs. De-centralized model; Patient identification and specimen collection; Analytic considerations - Resource requirements – Test Complexity; Results reporting and data management; Quality management system for POC testing</p>	Tim Amukele MDPHD
9:30-10:15	<p><b>POC in US: Current state of the art &amp; future challenges</b> Major examples in infectious disease, hematology, chemistry, other</p>	Michael Astion MD PhD
10:15-10:40	<b>Questions/Discussion/Break</b>	
10:40 - 11:30	<p><b>Principles of test interpretation - Use of lab results in the clinic setting.</b> Reference ranges, Cutoff values, Clinical sensitivity and specificity, Predictive values, Therapeutic ranges</p>	Michael Astion MD PhD
11:30 - 11:45	<b>Questions/Discussion</b>	
11:45 - 12:30	<b>Lunch</b>	
12:30 - 1:15	<p><b>Principles of assay development/implementation</b> Method development; Method validation (Precision; Accuracy: method comparison, interference, recovery; AMR (analytical measurement range); clinical reportable range. Analytical sensitivity; Analytical specificity - cross reaction, interferences; Establishing reference ranges; Ongoing quality control Verification of performance and specifications; Instrument methods as part of topics above</p>	Tim Amukele MD PhD
1:15 - 1:30	<b>Questions/Discussion</b>	
1:30 - 1:45	<b>Introduction to STDs</b>	Pat Totten PhD
1:45 - 3:00	<p><b>Current technologies used for laboratory testing of infectious diseases, with emphasis on STIs: general considerations</b> Advantages/disadvantages of standard methods for STD diagnosis Microscopy, culture, antigen detection, serology Biochemical characteristics, clinical diagnosis DNA detection: principles and techniques (Hybridization and NAATs PCR, TMA, quantitative PCR) Which test to use? – cost/benefit analysis Rapid diagnosis vs. screening populations Technical expertise available; specimen type required Sensitivity, specificity, positive/negative predictive value; cost New Developments/Challenges Optimal Specimen type for screening, pooling specimens Special challenges for QC/QA for NAATs Challenges in developing NAAT tests Validation of NAAT test (Controversies of discrepant analysis) Idiopathic STDs –Discovery of novel organisms associated with STD syndromes Novel technologies on horizon – proteomics and DNA array</p>	Pat Totten PhD
3:00 - 3:15	<b>Questions/Discussion</b>	
3:15 - 4:00	<p><b>Study design and statistical analyses for evaluation of laboratory tests</b> Statistical methods for Comparing/validating two tests McNemar/kappa Verification Bias/Disreplant analysis</p>	Jim Hughes PhD

	Limit of Detection vs. Clinical Sensitivity General Principles of sample size calculations Selection of gold standard Considerations for Pooling of Specimens Randomization of swab collection order	
4:00 - 4:15	<b>Questions/Discussion</b>	
4:15 - 4:30	<b>Presentation/demonstration of WHO site for laboratory diagnostics of STDs</b> STI Diagnostic Reviews: <a href="http://csde.washington.edu/WHOSTI/literature_reviews/">http://csde.washington.edu/WHOSTI/literature_reviews/</a>	Jane Kuypers PhD
4:30 - 5:30	<b>Focus groups:</b> Homework assignments, evaluation of new POC test based, computer center.	Pat Totten PhD and Karen Stephens PhD
6:00 - 8:00	<b>Reception and Tour of PATH, <a href="http://www.path.org">www.path.org</a></b> (Transportation provided)	Host: Bernhard H. Weigl PhD, Center Director

**Day 3: Wednesday July 16, 2008**

8:00 - 9:30	<b>HIV and AIDS</b> Global significance, epidemiology, clinical presentation and progression to AIDs impact of treatment, mother to child transmission. STD/HIV interactions	Robert W. Coombs MD PhD
9:30 - 10:00	<b>Questions/Discussion/Break</b>	
10:00 - 12:00	<b>Current diagnostics for HIV/AIDS</b> Gold standard tests – detection of HIV DNA/RNA, detection of antibodies (screening, confirmation, “detuned” test for diagnosing incident infections), CD4 counts, quantitative PCR to follow treatment How tests can impact control of HIV, prevent mother to child transmission, why rapid POC testing for HIV has worked so well.	
12:00 - 12:30	<b>Questions/Discussion</b>	
12:30 - 1:30	<b>Lunch</b>	
1:30 - 2:20	<b>Syphilis</b> Characteristics of clinical syndrome and natural history Global significance and epidemiology Mother to child transmission and congenital Syphilis Accuracy of clinical diagnosis Current gold standard tests for diagnosis; sensitivity/specificity Rapid POC tests and their performance Treatment; outstanding issues/challenges	Sheila Lukehart PhD
2:20 - 2:45	<b>Questions/discussion</b>	
2:45 - 3:45	<b>Experience with development and deploying a syphilis POC test.</b> Economics of syphilis testing	Matt Steele MD MPH
3:45 - 4:15	<b>Challenges with implementation of POCT for syphilis in low resource settings</b> Report from WHO meeting	Jane Kuypers PhD
4:15 - 4:30	<b>Questions/discussion on syphilis POC tests</b>	
4:30 - 5:30	<b>Focus Group: Reports</b>	
5:30 - 7:00	<b>Optional Workshop: Practical help and advice on evaluation of diagnostic tests; bring questions/issues faced in your setting.</b>	Tim Amukele MD PhD and Zehava Chen-Levy PhD

**Day 4: Thursday July 17, 2008**

8:00 - 9:30	<b>Bacterial vaginosis</b> Global significance, clinical presentation, is it sexually transmitted? Repercussions/sequelae of infection, organisms associated with syndrome, standard and novel POC diagnostic tests, detection of novel organisms associated with BV, novel gold standard and POC tests. Why test for BV?	David Fredricks MD Jeanne Marrazzo MD
9:30 - 9:45	<b>Questions/Discussion</b>	
9:45 - 10:45	<b>Herpes Simplex Virus</b> Clinical Syndromes associated with HSV-1 and HSV-2 in adults Pathogenesis of HSV infections Effect of HSV on HIV transmission Shedding and transmission dynamics of HSV Mother to child transmission of HSV Effect of HSV on mother to child transmission of HIV State of the art gold standard testing for HSV Differentiation of HSV-1 and HSV-2 – why needed? State of the art and need for POC testing for HSV	Rhoda Ashley Morrow PhD
10:45 - 11:00	<b>Questions/Discussion/Break</b>	
11:00 - 12:00	<b><i>Chlamydia trachomatis</i></b> Global significance, clinical syndrome, sequelae, characteristics of bacterium (developmental cycle), sequelae, treatment, gold standard and POC diagnostic tests; selection of strains that are not detected by standard diagnostic test. Development of POC tests for CT	To Be Named
12:00 - 12:15	<b>Questions/Discussion</b>	
12:15 - 1:00	<b>Lunch</b>	
1:00 - 2:00	<b>Malaria</b> Clinical syndrome, epidemiology, morbidity/mortality, global impact, life cycle of organism	Wes Van Voorhis MD
2:00 - 3:00	<b>Challenges in diagnosis of malaria.</b> When are diagnostics needed – asymptomatic carriage vs. fever, Gold standard rapid test (thick smear) vs. gold standard tests (NAATs), rapid diagnostic tests, detection of drug resistance; WARN" (world anti-malaria resistance network	Carole Sibley PhD
3:00 - 4:00	<b>Development of POC tests for malaria</b> Example of a test with perfect technology that was not adapted by health care providers. Why?	Gonzalo Domingo PhD
4:00 - 4:30	<b>Question/discussion on malaria</b>	Gonzalo Domingo PhD
5:30 - ?	<b>Course Social: Gasworks Park</b> (Transportation provided)	

**Day 5: Friday July 18, 2008**

8:00 - 9:00	<b>Tuberculosis</b> Global significance, epidemiology, clinical presentation, treatment, challenges	Tom Hawn MD
9:00 - 9:15	<b>Questions/Discussion</b>	
9:15 - 10:15	<b>Tuberculosis diagnostics</b> Gold standard diagnostics, drug resistance, development of POC tests for TB, value of POC diagnostics	Jerry Cangelosi PhD
10:15 - 10:30	<b>Questions/Discussion</b>	
10:30 - 10:50	<b>TB case study:</b> Development of an improved test for detection of multiple drug resistant TB.	Chris Crudder PhD
10:50 - 11:20	<b>Questions/Discussion on TB</b>	
11:20 - 1:00	<b>Lunch</b>	
1:00 - 2:00	<b>Diagnostic development of neglected diseases in a commercial environment.</b> Discovery, motivation, discovery, implementation	Syamal Raychaudhuri PhD
2:00 - 2:30	<b>Questions/Discussion/Break</b>	
2:30 - 3:30	<b>Clinical needs assessment in low resource settings</b> The process; critical government contacts; surveys. Potential challenges to introduce a POC test/device in a low resource setting. Different paradigms of access to healthcare;	Tala de los Santos MBA MS
3:30 - 4:00	<b>Questions/Discussion/Break</b>	
4:00 - 4:20	<b>Course Post-Evaluations</b>	Pat Totten PhD and Karen Stephens PhD
4:00 - 4:30	<b>Challenges for POC diagnostics in global health</b> New diagnostic platforms and approaches; persuading marketers, clinicians, and health care providers of the value of diagnostic development	Bernhard Weigl PhD, Center Director
4:30 - 5:00	<b>Panel Discussion with Participants:</b> Enumerate challenges identified. Future courses offered by Center for Point of Care Diagnostics for Global Health.	Bernhard Weigl PhD, Matt Steele PHD MPH, Mike Astion MD PhD, Pat Totten PhD, Karen Stephens PhD

## Faculty

Tim Amukele MD PhD	Senior Fellow, Department of Laboratory Medicine, UW <sup>4</sup>
Michael Astion MD PhD	Professor, Department of Laboratory Medicine, Divisions of Immunology and Biomedical Informatics, UW
Gerard Cangelosi PhD	Associate Member, Seattle Biomedical Research Institute, Seattle, WA
Zehava Chen-Levy, PhD	Senior Lecturer, Department of Laboratory Medicine, Division of Clinical Chemistry, UW
Robert W. Coombs MD PhD	Professor, Departments of Laboratory Medicine, Division of Virology, and of Medicine, Division of Allergy and Infectious Diseases, UW
Chris Crudder PhD	Clinical and Field Research Coordinator, PATH <sup>5</sup> , Seattle, WA
Tala de los Santos MBA MS <sup>3</sup>	Commercialization Officer, PATH, Seattle, WA
Gonzalo Domingo PhD <sup>3</sup>	Research Scientist, PATH, Seattle, WA
David Fredricks MD	Associate Member, Fred Hutchinson Cancer Research Center, Vaccine and Infectious Diseases Institute, Seattle, WA
Matt Golden MD	Assistant Professor, Department of Medicine, Division of Allergy & Infectious Diseases, UW
Tom Hawn MD	Assistant Professor, Department of Medicine, Division of Allergy & Infectious Diseases, UW
King Holmes MD PhD	Wm. H. Foege Chair and Professor, Department of Global Health, Director of Center for AIDS and STD; Department of Medicine, Division of Allergy and Infectious Diseases, UW
Jim Hughes PhD	Professor, Department of Biostatistics, UW
Jane Kuypers PhD	Senior Research Scientist, Department of Laboratory Medicine, UW
Sheila Lukehart PhD	Professor, Department of Medicine, Division of Allergy & Infectious Diseases, UW
Jeanne Marrasso MD	Associate Professor, Department of Medicine, Division of Allergy & Infectious Diseases, UW
Rhoda Ashley Morrow PhD	Professor, Department of Laboratory Medicine, Division of Virology, UW
Syamal Raychaudhuri PhD	CEO, InBios, Seattle, WA
Carole Sibley PhD	Professor, Department of Genome Sciences, UW
Matt Steele PHD, MPH <sup>3</sup>	Clinical and Field Research Coordinator, PATH, Seattle, WA
Karen Stephens PhD <sup>1,3</sup>	Research Professor, Department of Laboratory Medicine, Divisions of Genetics and of Molecular Microbiology, UW
Pat Totten PhD <sup>1,3</sup>	Research Associate Professor, Department of Medicine, Division of Allergy & Infectious Diseases, adjunct Department of Global Health, UW
Wes Van Voorhis MD	Professor, Department of Medicine, Chair of Division of Allergy & Infectious Diseases, UW
Bernhard Weigl PhD <sup>2</sup>	Group Leader, Diagnostics Development Teams, PATH, Seattle, WA

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<sup>1</sup>Directors of POC Diagnostics Course; <sup>2</sup>Director and <sup>3</sup>Leaders of the Center for Point-of-Care Diagnostics for Global Health (GHDx); <sup>4</sup>UW, University of Washington, Seattle, WA, USA; <sup>5</sup>PATH, Programs for Appropriate Technology for Health