School of Public Health
UNIVERSITY OF CALIFORNIA, BERKELEY

Forum for Collaborative HIV Research

HIV and HCV Diagnostics and Testing Roundtable
University of California Washington Center – 11th Floor Conference Room
1608 Rhode Island Avenue NW
Washington DC, 20036
Agenda - June 27, 2012

27-Jun-12		
8:00	Breakfast	11th Floor Conference Room
	Morning Session	
8:55	**Welcome and Introductions**	Veronica Miller, Nivedha Panneer and Erik Lontok
9:20	**Roundtable Goals and Objectives**	Bernie Branson and Chong-Gee Teo
9:30	**Current state of HIV and HCV testing recommendations:** HIV testing algorithm High-risk and low-prevalance populations testing HCV testing algorithm and birth-cohort-based testing	**Moderator:** Veronica Miller **Presenters:** Monica Parker Joanne Stekler Geoff Beckett
10:30	**Diagnostic Devices Update and Regulations** Currently-available devices in HCV and HIV testing recommendations CLIA-waiver approvals process	**Presenters:** Chong-Gee Teo Bernie Branson Steve Lovell **Panelists:** Jeff Baker, Chris Bentsen, Elliot Cowan, Gabrielle Heilek, Stephen Lee, and Gerald Schochetman
11:30	Break	
	Emerging Roles of Existing Technologies	
11:45	Home-based HIV testing and viral load tests for diagnosis	**Moderators**: Monica Parker and Joanne Stekler **Discussants**: John Bartlett, George Dawson, Jane Getchell, Gabrielle Heilek, Stephen Lee, Brad Ogilvie, Rick Pesano, and Lorren Sandt
12:15	HCV reflex confirmatory PCR and Core Antigen assay	
12:45	Lunch	11th Floor Conference Room
	Afternoon Session	
13:30	**Strategies promoting diagnosis and linkage to care:** **Current and Best Practices** Florida, Kansas, Massachusetts, Missouri, New York City, New York State, Washington, Veteran's Affairs	**Moderators:** Miriam Alter and John Bartlett **HIV Panel:** Kathryn Thiessen, Dawn Fukuda, Joanne Stekler, David Ross **HCV Panel:** Debbie Barnes, Bruce Burkett, Eric Rude and Colleen Flanigan
15:00	**Strategies promoting diagnosis and linkage to care:** **Recommendations for moving forward** De-exceptionalizing HIV testing Linking HIV and HCV Testing? Future and Unmet Needs of Current Testing Policy	**Moderator:** Veronica Miller **Discussants:** Corinna Dan, Dawn Fukuda, Angelique Griffin, Michele Manos, Monica Parker, Chris Taylor and John Ward
16:00	**Meeting Summary**	John Bartlett and Veronica Miller

Sessions

2) Diagnostic Devices Update

How do point-of-care (POC) tests and laboratory tests fit into current diagnostic algorithms?

What factors are considered when bringing HIV/HCV diagnostics to the US market?

How has the 2008 Guidance Document on CLIA-waivers affected device submissions and approvals?

How is product use and existing device guidelines monitored and modified post-FDA approval?

3) Emerging roles for existing technologies

What types of post-marketing surveillance are envisaged should the HIV home-based test gain FDA approval?

How will linkage to care be addressed with the home-based HIV test?

What is the potential for viral load tests to be used in a diagnostic context?

What is the ideal secondary/confirmatory test to a positive HCV EIA result? How can these be facilitated?

4) Strategies promoting diagnosis and linkage to care: Current and Best Practices

HIV

What are your experiences in implementing the CDC HIV testing algorithm?

What types of HIV tests are conducted by your program?

How will rapid tests conducted by CBOs be confirmed?

What are your experiences with acute HIV testing?

HCV

What types of HCV tests are conducted by your program?

How are HCV test results best communicated to clinicians and patients? Is reporting standardization needed?

What types of surveillance are conducted by your program and how are these funded?

What resources are available for HCV care after a positive test result?

HIV/HCV

Which test technologies increase testing, and which increase linkage to care?

Based on test site, how are patients linked to care after a positive test result?

5) Strategies promoting diagnosis and linkage to care: Recommendations moving forward

As more patients are tested by POC devices, how will this impact surveillance and the delivery of services?

What are the aspects of current HIV and HCV testing practices that are most amenable to linking those testing programs?

Which aspects of HIV and HCV testing (eg. regulations or special requirements) negatively affect your ability to merge HIV and HCV testing operations?

What are the local policies for linking a patient to care after a positive POC–test?

What resources will be available and will be needed for further scale-up of HCV testing and surveillance?