Feedback from the HIV/HCV diagnostics and testing roundtable

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Steering committee

- **Co-chairs**
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  - Dr. Joanne Stekler (UW)
  - Dr. Erik Lontok (Forum)

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Current state of HIV and HCV diagnostics and testing

- 2010 HIV Testing Algorithm
  - Increased sensitivity and specificity to detect HIV-1 infection.
  - Efficiently detects HIV-2 and acute HIV infections.
- HCV Testing Algorithms
  - *Current Algorithm*
    - ⊙ Distinguishes between active and resolved infections
  - *Draft Algorithm*
    - ⊙ Emphasizes identification of acute infection.

Roundtable Topics

I. Discuss regulatory issues involving the CLIA-approvals process

II. Discuss emerging roles for existing technologies in HIV and HCV diagnostic algorithms

III. Identify best practices for implementation of the different technologies in various settings and in different populations

I. Discuss regulatory issues involving the CLIA-approvals process

- CLIA-Waiver Approvals Process
  - Risk analysis studies
  - Accuracy studies
  - Limit of detection
    - ⊙ Does the updated CLIA waiver guidance document represent the least burdensome approach for manufacturers for device approval while ensuring accurate, reliable and simple point-of-care diagnostics?

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- Emerging Roles of Existing Diagnostics
  - Home-based HIV Testing
    - How effective will the OraQuick In-Home HIV Test be in linking people to care upon a preliminary positive result?
  - HIV and HCV Viral Load Assays
    - What role can public health play in gathering the necessary data for such validation studies? Roundtable participants also encouraged additional discussions with the FDA on potential alternate validation studies.

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- Draft HCV Testing Algorithm
  - Central Role of NAAT
  - RIBA
    - Do public health systems have a responsibility to inform patients of their past, resolved HCV infections?

- Massachusetts Department of Public Health
  - Adoption of 2010 HIV Testing Algorithm
  - Linking HIV and HCV Testing and Prevention Services
  - Abstracts 129, 130
- University of Washington & Public Health — Seattle King County HIV/STD Program
  - NAAT Program
  - Care and ART Promotion Program
  - Abstracts 44, 45, 79

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- New York City Department of Health and Mental Hygiene
  - Check Hep C
  - Abstracts 32, 69, 71, 147
- New York State Department of Health
  - HCV Rapid test demonstration project
  - Abstracts 31, 116, 143