Harmonization of HIV IVDs listed as eligible for procurement by WHO and USAID

IAS 2015, Vancouver
Anita SANDS, on behalf of WHO, CDC, USAID
Alignment of recommendations on IVDs

• WHO PQ lists IVDs that meet PQ requirements to be procured by UN agencies, WHO Member States, etc.
• USAID issues recommendations on IVDs to be procured by SCMS and used in PEPFAR-supported countries
• Aim of alignment
  – to align WHO and USG assessments and create one common QA mechanism under a partnership agreement
• Goals of alignment
  – to reduce duplication of effort for each organization and for the manufacturers, leverage each others resources for laboratory evaluation, and to create one list of "approved" products
Comparison of scopes – WHO PQ and USG

- **WHO PQ - current scope**
  - HIV and HIV-related IVDs
    - RDTs, EIA, CD4, qualitative/quantitative NAT
  - HCV and HBsAg IVDs
    - RDTs, EIAs, qualitative/quantitative NAT
  - Malaria RDTs

- **CDC - current scope**
  - HIV-related IVDs
    - RDTs, CD4, qualitative/quantitative NAT
Publication of findings

**WHO**
- PQDx laboratory evaluation reports
- PQDx public reports
- List of IVDs eligible for UN procurement, used by Global Fund

**USG**
- USAID list of approved HIV rapid test kits
- CDC note to the field
Process for joint assessment

• Advisory Panel consists of:
  – WHO PQ
  – USAID
  – CDC
• Decision points
  – AP decides on scheduling for jointly prioritized products
  – AP informed of dossier and inspection nonconformities
  – AP decides on final approval to list
• Through regular teleconference every 2 weeks
Process for joint assessment cont'd

- WHO reviews dossier
  - Scheduling of lab evaluation & site inspection
- WHO conducts site inspection
  - With USG as observer

WHO or CDC conducts laboratory evaluation
- CDC for 3rd generation RDTs, CD4, qualitative/quantitative NAT
- WHO for 4th generation RDTs, EIAs, CD4, qualitative/quantitative NAT
- Two sites are required for prospective CD4 and NAT, if capillary WB
First product for joint assessment

• Joint assessment of AQUIOS CL flow cytometer (Beckman Coulter Life Sciences, USA)
• Dossier assessed by WHO in Q1 2015
• Site inspection by WHO conducted Q1 2015
• Laboratory evaluation conducted in Q1/2 by CDC (Atlanta) and WHO (ITM, Antwerp)
CDC/WHO/NHLS collaboration for EID IVDs

- Evaluation protocol agreed by all partners
- First two products have been requested for delivery at the two evaluating sites
  - Expecting first results in Q4 2015
- Both products are eligible for abbreviated PQ assessment
  - Thus WHO will not require submission of product dossier
- PQ site inspections conducted for both products