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

IAS 2015, Vancouver

Anita SANDS, on behalf of WHO, CDC, USAID

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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

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Comparison of scopes – WHO PQ and USG

- WHO PQ - current scope
  - HIV and HIV-related IVDs
    - RDTs, EIAs, 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

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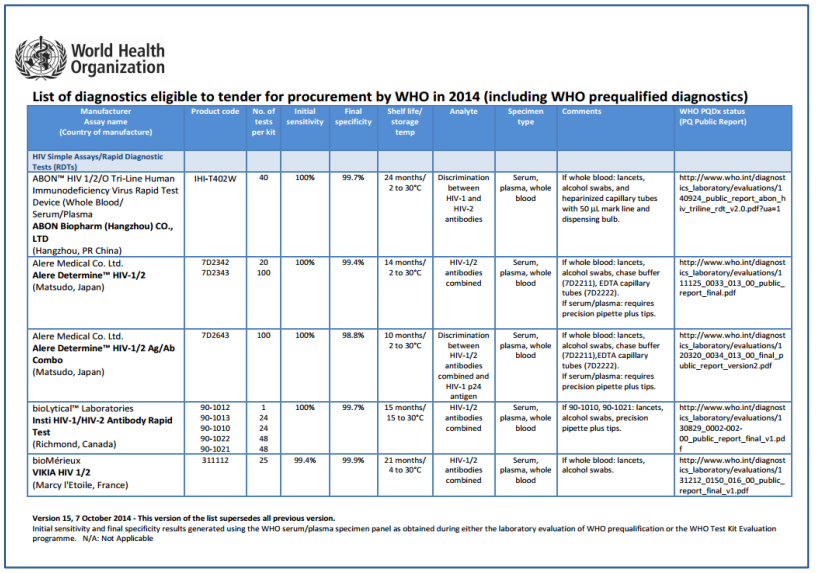
Publication of findings

- WHO
  - PQDx laboratory evaluation reports
  - PQDx public reports
  - List of IVDs eligible for UN procurement, used by Global Fund
    - http://www.who.int/diagnostics_laboratory/procurement/purchase/en/index.html



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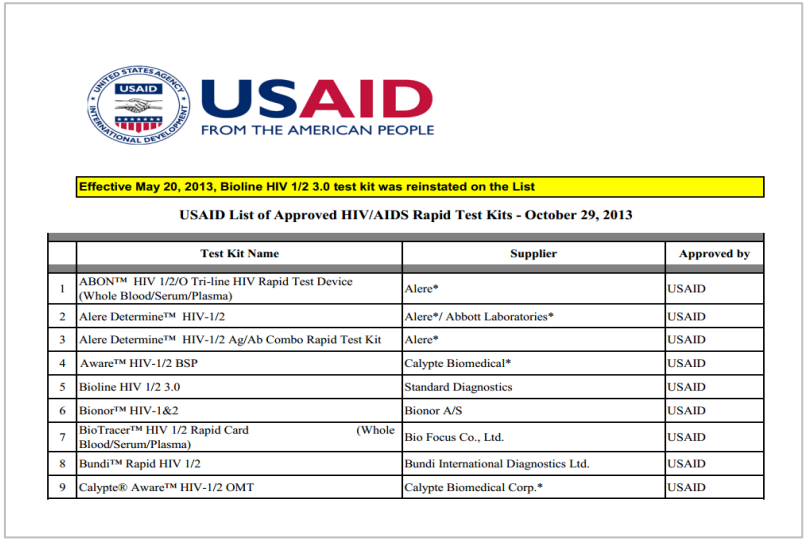
List of diagnostics eligible to tender for procurement by WHO in 2014 (including WHO prequalified diagnostics)

Manufacturer Assay name (Country of manufacture)	Product code	No. of tests per kit	Initial sensitivity	Final specificity	Shelf life/ storage temp	Analyte	Specimen type	Comments	WHO PQDx status (PQ Public Report)
HIV Simple Assays/Rapid Diagnostic Tests (RDTs)									
ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/ Serum/Plasma **ABON Biopharm (Hangzhou) CO., LTD** (Hangzhou, PR China)	IHI-T402W	40	100%	99.7%	24 months/ 2 to 30°C	Discrimination between HIV-1 and HIV-2 antibodies	Serum, plasma, whole blood	If whole blood: lancets, alcohol swabs, and heparinized capillary tubes with 50 µL mark line and dispensing bulb.	http://www.who.int/diagnostics_laboratory/evaluations/140924_public_report_abon_hiv_trilline_rdt_v2.0.pdf?ua=1
Alere Medical Co. Ltd. **Alere Determine™ HIV-1/2** (Matsudo, Japan)	7D2342 7D2343	20 100	100%	99.4%	14 months/ 2 to 30°C	HIV-1/2 antibodies combined	Serum, plasma, whole blood	If whole blood: lancets, alcohol swabs, chase buffer (7D2211), EDTA capillary tubes (7D2222). If serum/plasma: requires precision pipette plus tips.	http://www.who.int/diagnostics_laboratory/evaluations/111125_0033_013_00_public_report_final.pdf
Alere Medical Co. Ltd. **Alere Determine™ HIV-1/2 Ag/Ab Combo** (Matsudo, Japan)	7D2643	100	100%	98.8%	10 months/ 2 to 30°C	Discrimination between HIV-1/2 antibodies combined and HIV-1 p24 antigen	Serum, plasma, whole blood	If whole blood: lancets, alcohol swabs, chase buffer (7D2211),EDTA capillary tubes (7D2222). If serum/plasma: requires precision pipette plus tips.	http://www.who.int/diagnostics_laboratory/evaluations/120320_0034_013_00_final_public_report_version2.pdf
bioLytical™ Laboratories **Insti HIV-1/HIV-2 Antibody Rapid Test** (Richmond, Canada)	90-1012 90-1013 90-1010 90-1022 90-1021	1 24 24 48 48	100%	99.7%	15 months/ 15 to 30°C	HIV-1/2 antibodies combined	Serum, plasma, whole blood	If 90-1010, 90-1021: lancets, alcohol swabs, precision pipette plus tips.	http://www.who.int/diagnostics_laboratory/evaluations/130829_0002-002-00_public_report_final_v1.pdf
bioMérieux **VIKIA HIV 1/2** (Marcy l'Etoile, France)	311112	25	99.4%	99.9%	21 months/ 4 to 30°C	HIV-1/2 antibodies combined	Serum, plasma, whole blood	If whole blood: lancets, alcohol swabs.	http://www.who.int/diagnostics_laboratory/evaluations/131212_0150_016_00_public_report_final_v1.pdf

Version 15, 7 October 2014 - This version of the list supersedes all previous version.
Initial sensitivity and final specificity results generated using the WHO serum/plasma specimen panel as obtained during either the laboratory evaluation of WHO prequalification or the WHO Test Kit Evaluation programme. N/A: Not Applicable

- USG
  - USAID list of approved HIV rapid test kits
    - http://www.usaid.gov/sites/default/files/documents/1864/usaid_approved_test_kit_list.pdf
  - CDC note to the field



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Effective May 20, 2013, Bioline HIV 1/2 3.0 test kit was reinstated on the List

USAID List of Approved HIV/AIDS Rapid Test Kits - October 29, 2013

	Test Kit Name	Supplier	Approved by
1	ABON™ HIV 1/2/O Tri-line HIV Rapid Test Device (Whole Blood/Serum/Plasma)	Alere*	USAID
2	Alere Determine™ HIV-1/2	Alere*/ Abbott Laboratories*	USAID
3	Alere Determine™ HIV-1/2 Ag/Ab Combo Rapid Test Kit	Alere*	USAID
4	Aware™ HIV-1/2 BSP	Calypte Biomedical*	USAID
5	Bioline HIV 1/2 3.0	Standard Diagnostics	USAID
6	Bionor™ HIV-1&2	Bionor A/S	USAID
7	BioTracer™ HIV 1/2 Rapid Card (Whole Blood/Serum/Plasma)	Bio Focus Co., Ltd.	USAID
8	Bundi™ Rapid HIV 1/2	Bundi International Diagnostics Ltd.	USAID
9	Calypte® Aware™ HIV-1/2 OMT	Calypte Biomedical Corp.*	USAID

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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

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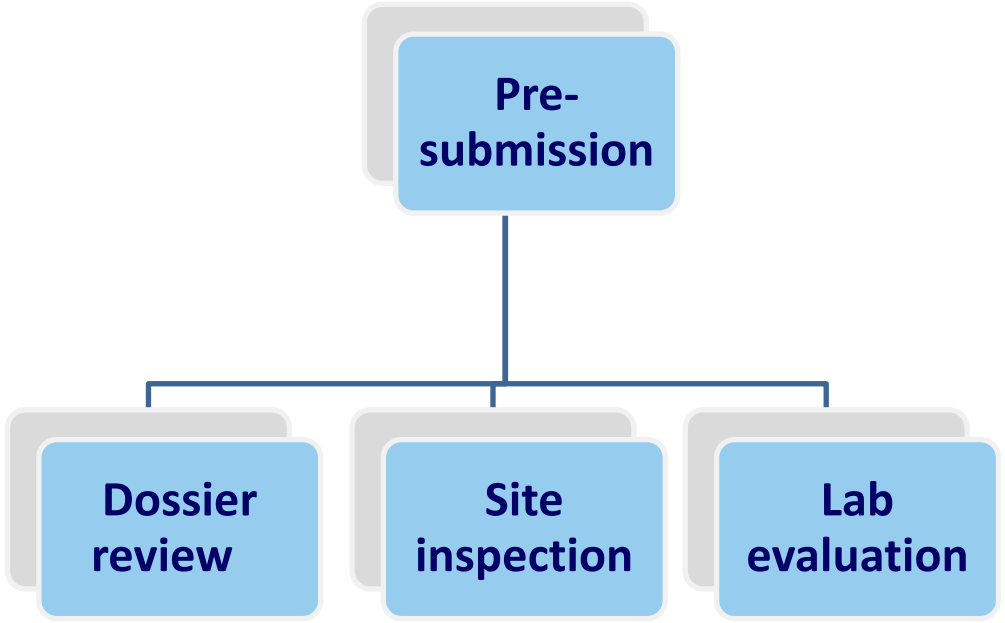
Process for joint assessment cont'd

- 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)

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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

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