

Standardization and Harmonization of Laboratory Tests and Equipment: Selected Country Experiences

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Tanzania Experience

- **Assessment of laboratories**
- **Review of Guidelines**
- **Development of the Operational Plan for the National Laboratory System to support HIV/AIDS Care and Treatment**
- **Test Harmonization**
- **Equipment Standardization**
- **Implementation**



Testing at tiered levels

- Health Center
 - Manual, low throughput equipment run by laboratory personnel with minimum certificate level of training.
- District and Regional
 - Medium throughput laboratory equipment run by at a minimum diploma holding laboratory personnel.
- Referral
 - Automated high throughput equipment run by (technicians, technologist and scientists) with at least advanced diploma level of training.



Tiered distribution of lab equipment

Equipment	Referral	Region	District
ELISA	Multiscan Axysm	Multiscan -	
RNA PCR.	Taqman	-	-
DNA PCR	Cobas amplicor	-	-
Flow Cyto	FACS Callibur	FACSCount	FACSCount
Chem	Cobas Integra	Fully	Screen Master Micro Lab 200
Hem	ACT5 DIFF	Pentra 80	Micro 60
OI	BSC II/Inc/Microsc	Incub/Microsc	Incub/Microscopy



Post Maputo

- Meetings with stakeholders
- Training of Biomedical Engineers and technicians
- Database of all equipment procured in country – date of procurement, by whom, reagent procurement support, vendor, manufacturer
- Tender for maintenance contract floated



Cote d'Ivoire Experience Post Maputo



Harmonization of laboratory equipment at PEPFAR supported sites - Cote d'Ivoire

	Reference Labs	Regional & District Labs	Peripheral Labs
Immunology	FACSCalibur FACSCount Guava	FACSCount Guava	FACSCount if >100 CD4 a week
Hematology	Sysmex 200 i, ACT Diff III	KX 21 N, ACT Diff II	Sysmex KX 21 N, CoulterACT Diff II
Biochemistry	Cobas Integra 400	Cobas C 111, Fully	Biolabo Kenza max, Humalyser



Harmonization of lab equipment at PEPFAR supported sites - Level I

	Tests	Instruments	Models
Immunology	CD4	Flow Cytometer	FACSCount
Hematology	WBC Count	Automated mach. 18 parameters	Sysmex KX 21 N, CoulterACT Diff II
Biochemistry	AST ALT Creat., Gluc.	Spectrophometer	Biolabo Kenza max, Humalyser



Harmonization of lab equipment at PEPFAR supported sites - Level II

	Tests	Instruments	Models
Immunology	CD4	Flow Cytometer	FACSCount Guava
Hematology	WBC Count	Automated mach. 18 parameters	KX 21 N, ACT Diff II
Biochemistry	AST ALT Creat., Gluc.	Automated mach. 100 tests/hour	Cobas C 111, Fully



Harmonization of lab equipment at PEPFAR supported sites- Level III

	Tests	Instruments	Models
Immunology	CD4	Flow Cytometer	FacsCalibur FACScount Guava
Hematology	WBC Count	Automated machine (23 parameters)	Sysmex 200i ACT Diff III
Biochemistry	AST ALT Creat., Gluc.	Automated machine (300 tests/hour)	Cobas Integra 400



Ethiopia Experience

Management and Standardization of Laboratory Commodities

- Ethiopian Health and Nutrition Research Institute (EHNRI) oversees Standardization of laboratory commodities across the tiered lab network in Ethiopia
- PEPFAR through SCMS supports procurement of reagents, supplies and equipment
- SCMS/EHNRI/CHAI provide training on laboratory commodity consumption, inventory control and quantification
- SCMS has seconded staff to 6 regions to effectively implement and monitor laboratory commodities inventory control and consumption
- Seconded staff transfer capacity and provide timely information for re-ordering to avoid disruption of services



Standardization of equipment

- EHNRI has established list of equipment for tiered lab levels
- Purchase and use of platforms have been limited to two vendors except for FACSCount
 - Hematology
 - CellDyn 1800
 - Sysmex machines
- Development of local capacity for equipment maintenance at national reference labs
- 5 engineers are trained and provide maintenance to regions
- Required spare parts list is available and parts are ordered through SCMS



Botswana Experience



Botswana: overview of analytical systems

Some standardization, however wide range of platforms:
9 hematology, 10 Chemistry, 4 CD4, and 4 viral load platforms

Hematology	Chemistry	Flowcytometry	Viral load system	EID
<ol style="list-style-type: none"> 1. Sysmex K800 2. Sysmex KX 21N- 3. Sysmex xt 1800i 4. Sysmex xt 2100i 5. Sysmex xt 2200i 6. ACT diff.2 7. Beckman Coulter 8. Humastar 	<ol style="list-style-type: none"> 1. ILAB 300 2. Cobas Integra 400 Plus 3. Pentra 400 Plus 4. Autohumalyser 900 Plus 5. Humalyzer 2000 6. Dr. Lange 7. LP 400 8. LP 800 9. Visual 10. Humalyte ISE for electrolytes 	<ol style="list-style-type: none"> 1. FACSCalibur 2. FACSCount 3. Beckmann Coulter EPICSXL-1 Flowcytometer 4. CyFlow Partec 	<ol style="list-style-type: none"> 1. Nuclisense 2. TaqMan 48 3. Amplicor 4. Exavir- Cavid 	<ol style="list-style-type: none"> 1. Thermocycler 2. Spectrophotometer



Plan for standardization of laboratory equipment in Botswana

- Adopt recommendation and guidelines from the Maputo standardization meeting held January 2008
- SCMS to work with the National Health Lab and the Biomedical Engineering services
- Revision of the existing testing platforms and development of a new platform by facilities (Primary, District and reference lab)
- Development of laboratory products specification database
- Development of a database of equipment in all facilities from proposed standardization plan developed with the Ministry of Health
- Equipment database to provide information on functionality and maintenance
- Future donated equipment requirements include standardization with existing platforms



Proposed harmonization of laboratory equipment

Hematology

1. Sysmex xt 1800i
2. Sysmex xt 2100i
3. Sysmex xt 2200i

Chemistry

ILAB 300

2. Cobas Integra 400 Plus
3. Pentra 400 Plus

Flowcytometry

1. FACSCalibur
2. FACSCount



Proposed harmonization of laboratory equipment

Viral load system

1. Nuclisense
2. TaqMan 48
3. Amplicor

EID

1. Thermocycler
2. Spectrophotometer



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Proposed harmonization of laboratory equipment

Hematology	Chemistry	Flowcytometry	Viral load system	EID
<ol style="list-style-type: none">1. Sysmex xt 1800i2. Sysmex xt 2100i3. Sysmex xt 2200i	<ol style="list-style-type: none">1. ILAB 3002. Cobas Integra 400 Plus3. Pentra 400 Plus	<ol style="list-style-type: none">1.FACSCalibur2. FACSCount	<ol style="list-style-type: none">1. Nuclisense2. TaqMan 483. Amplicor	<ol style="list-style-type: none">1. Thermocycler2.Spectrophotometer

