

**Recommendation on Clinical Laboratory Testing  
Harmonization and Standardization Meeting  
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# Introduction

- Effort seeks to strengthen laboratory capacity in resource-limited settings
- Provide access to high quality, rapid, and affordable diagnostic tests for care, treatment, prevention and surveillance of HIV/AIDS, tuberculosis (TB) and malaria.
- Accurate and reliable clinical laboratory testing is an important component of a public health approach to disease management in resource-limited settings



# Objectives

- To review and agree on a list of tests needed at each level of an integrated tiered laboratory network, and classify the supplies as Crucial, Important, or Needed
- To develop a consensus to guide the standardization of laboratory equipment, reagents, and supplies at each level of an integrated tiered laboratory network
- To develop a consensus on key considerations to guide maintenance and service contracts for equipment at various levels of an integrated tiered laboratory network.



# Tiered Laboratory Network

A tiered laboratory network is an integrated system of laboratories organized in alignment with the public health delivery network in a country

- Level I-Primary: Health post and health center laboratories that primarily serve outpatients.
- Level II- District: Laboratories in intermediate referral facilities (e.g., district hospitals).
- Level III-Regional/Provincial: Laboratories in a regional/provincial referral hospital that may be part of a regional or provincial health bureau.
- Level IV-National/Multicountry Reference Laboratory: The national/multicountry public health reference laboratory for one or more countries.



# Acquisition and Standardization of Laboratory Equipment

- Infrastructure (power, generator, water, temperature, space)
- Environmental conditions
- Laboratory workload; staff skills and training
- Vendor support, reliability and availability (in-country or region)
- Availability, stability and temperature sensitivity of reagents, controls and calibrators
- Availability of local service, technical and training support
- Simplicity of operation; ease of maintenance and calibration
- Track record of performance (domestic and/or international)
- Analytical performance/technical quality (sensitivity, specificity, reliability, level of detection)
- Test menu (consider scalability for various volumes)
- Open or closed test/reagent system
- System costs (includes equipment, service, reagents, and supplies); cost per reported test
- Specimen types
- Throughput
- Turnaround time
- QC and QA required
- Availability of EQA and inter-laboratory comparisons
- Data management capability; interface capability
- Safety
- Availability of back-up methods
- Supply chain management capability



# recommendations regarding donated equipment

**workgroups agreed to use the *WHO Guidelines on the Donation of Medical Equipment*. In addition to the WHO guidelines, the following recommendations were made for donated laboratory equipment.**

- Donated equipment should be accepted only if part of the laboratory strategic plan.
- Donors should be involved in national laboratory planning.
- Countries should have clear policies at the central level with a list of acceptable reagents and equipment.
- Donors should send equipment specifications prior to delivery.
- Donated laboratory equipment should have at least 80% useful life remaining at time of donation.
- Donated equipment should follow normal supply management processes to assure adequate reagents and supplies; service, maintenance and training systems must be available.
- Vendors should be pre-qualified where possible within the country by the national laboratory system.
- Equipment retirement procedures need to be developed and followed for donated and other equipment.



# Equipment Maintenance and Service Contracts

These challenges may be addressed by:

- Addressing infrastructure needs
- Developing partnerships between laboratories and manufacturers
- Cross-training personnel on equipment service
- Encouraging manufacturers to establish local representation
- Insisting that manufacturers have available loaners
- Ensuring that laboratories have back up equipment or techniques
- Providing continuing education for laboratory staff
- Developing an integrated laboratory network



# Equipment Maintenance and Service Contracts:

## Service Contracts (after-sale maintenance contracts)

- Service contracts should be negotiated at time of equipment procurement.
- Reagent rental agreements with bundled service and reagents should be considered.
- Contracts could be for a minimum of 3 years, renewable with no cost increase annually.
- Service contracts should include at a minimum:
  - Response time (ideally within 48 hours).
  - Number of preventative maintenance visits (as required by the manufacturer).
  - Training of local service engineers and users.
  - Availability of routine/emergency service.
  - Costs incurred outside of the contract.
- Penalties should exist in the contracts for failure to meet the conditions of the agreements.
- A periodic contract review process to determine compliance should be in place.
- Local service providers should be certified by the manufacturer.
- Contracts should provide for backup support (loaners) within 72 hours and access to spare parts.
- Contracts should include a contingency plan for returning equipment for service if repairs cannot be done in-country.
- In-country support should be guaranteed in the contracts.



# Equipment Maintenance and Service Contracts:

## Service Delivery

- Qualified service technicians should exist locally for the number of equipment.
- Structured formal training programs should exist to train and qualify local engineers.
- Engineers should install, train, service and help users with problem solving (in order to accomplish this, they should speak local language).
- Regular schedules of preventative maintenance should be established and followed by laboratory users and service providers.
- Laboratory sites should obtain and retain documentation of services performed by service providers.
- Hotlines for real time support should be available.
- Engineers should arrive with proper equipment and spare parts.
- Engineers should have access to loaner equipment to swap out if on-site repairs are not possible.
- Troubleshooting and service tips should be shared with users.
- Local service providers should have good relationships with manufacturers.
- Vendors should provide periodic information on recalls and updates.
- Laboratories should actively monitor equipment including service and maintenance as part of the QA program.
- Laboratories should report any adverse events to the manufacturers, documenting downtime and service problems.



# Equipment Maintenance and Service Contracts

## Reagent/Supply Delivery

- Defined forecasting and inventory management systems should be operational in each laboratory.
- Reagent rental and standing orders for reagent delivery should be options.
- Central coordinating bodies should perform regular reviews and verify sustainable supply chain management systems.
- Lot assurance should be provided by suppliers.
- Pack size should meet facility and transportation requirements.
- Cold chain requirements should be met in transport and storage at each site.
- Effective clearance procedures and duty waivers should be available.
- National policy should exist for minimum expiry dates on reagents.
- Feedback from users on reagent/supply delivery systems should be obtained.
- Reliable distributors/agents should exist in-country.
- Replacement policy for unusable or expired products should be defined in contracts.
- Quality assessment of products to be used in-country must be performed.
- Quality should drive procurement more than cost.
- Sole sourcing should occur only if unavoidable.
- Global pricing may be useful to reduce high local costs.
- A centralized, transparent procurement system is desirable.
- Streamlined purchasing and payment processes should be in place to avoid stock-outs.



SUMMARY OF WORKGROUP RECOMMENDATIONS FOR TESTS PERFORMED AT EACH LEVEL OF A LABORATORY NETWORK\*

Laboratory tests for diagnosis and monitoring (1)	Primary Care Level (2)		District Level (3)		Regional/Provincial Level (4)		National/ Multicountry Level (5)
	Send out (6)	On-site	Send out (6)	On-site	Send out (6)	On-site	On-site
<b><i>HIV antibody testing</i></b>							
Lab ELISA	X			X		X	X
Rapid point of care 1		X		X		X	X
Rapid point of care 2		X		X		X	X
Rapid point of care 3		X		X		X	X
<b><i>HIV virological diagnostic testing</i></b>							
RNA	X		X			X	X
DNA	X		X			X	X
Ultrasensitive p24 antigen	X		X		X		X
<b><i>HIV viral load measurement</i></b>	X		X			X	X
<b><i>Hematology assays</i></b>							
Hemoglobinometer such as HemoCue		X		X		X	X
WHO color scale		X					
Full blood count and differential	X			X		X	X
<b><i>CD4</i></b>							
Absolute count	X			X		X	X
% desirable if available	X			X		X	X
<b><i>HIV resistance testing (7)</i></b>			X		X		X (8)
<b><i>Pregnancy testing</i></b>							
Urine rapid test		X		X		X	X
<b><i>Chemistry assays</i></b>							
Liver function tests		X (if power)		X		X	X
Whole blood glucose (glucometer)		X		X		X	X
Serum glucose				X		X	X
Serum electrolytes	X			X		X	X
Renal function tests		X (if power)		X		X	X
Lipids				X		X	X
Amylase				X		X	X
Lactate				X		X	X



Laboratory tests for diagnosis and monitoring(1)	Primary Care Level (2)		District Level (3)		Regional/Provincial Level (4)		National/ Multicountry Level (5)
	Send out (6)	On-site	Send out (6)	On-site	Send out (6)	On-site	On-site
<b>Urine analysis</b>							
Urine dipstick		X		X		X	X
Urine dipstick with microscopy				X		X	X
<b>Tuberculosis tests</b>							
<b>Microscopy</b>							
Light		X		X		X	X
Fluorescence		X (if high vol)		X		X	X
<b>Culture and ID</b>							
Solid medium	X		X			X	X
Liquid medium	X		X			X	X
<b>Drug susceptibility test</b>							
First-line			X			X	X
Second-line			X		X		X
<b>Malaria tests</b>							
Rapid test for malaria		X		X		X	X
Microscopy for malaria (thick/thin)		X		X		X	X
<b>Microbiology tests</b>							
Gram's stain				X		X	X
Microbiology culture and ID			X			X	X
Blood culture			X			X	X
Microbiology susceptibilities			X			X	X
Wet mounts/preps		X		X		X	
<b>Syphilis tests</b>							
Syphilis rapid diagnostic test		X		X		X	X
Syphilis serological (RPR, FTA, TPPA/ TPHA)				X		X	X
<b>Hepatitis tests</b>							
Hepatitis B by EIA				X		X	X
Hepatitis C by EIA				X (if high prev)		X	X
<b>Cerebrospinal fluid (CSF) tests</b>							
CSF microscopy including cell count, India Ink, Gram's stain and AFB				X		X	X
CSF glucose			X			X	X
Cryptococcal antigen (serum or CSF)				X		X	X



**THANKS**