Questionnaire for Site assessment of clinical Laboratory capacity

Objectives:

- To assess the capacity of functional laboratory for diagnostic tests, procurement, storage, and inventory control related to VCT, PMTCT and ART services.
- Based on the assessment, implementation plan will be developed to address the issues

1. General information

Date of assessment made	
Person who assessed the site name and position	
Interviewee: Name & Position	
Name of Facility	
District	
Region	

2. Staffing

	Number	Time on Post	Adequacy/	Position
Laboratory technologist				
Laboratory technician				
Laboratory Assistant				
Laboratory Clerk				
Other- specify				

3. Training

	Subject Area	Number	When/Where	Duration	Organization
Past Training					
Planned Training					

4. General Services

	1995 EC	1994 EC	1995 EC	Remarks
Number of out patients tested for all cases				
Number Attended VCT				
Number Tested for HIV				
Number Positive				
Number of pregnant women tested				
Number of pregnant women tested positive				

	1995 EC	1994 EC	1995 EC	Remarks
Number of tests used for quality assurance				
Number RPR tested for syphilis				
Number Positive				
Number tested for TB				
Number Positive				
Other Comments				

5. Laboratory Referral Services

	Yes	No	EHNRI	Reg. Lab	Hosp Lab	Private
Total number of specimen referred to a referral lab						
Total number of patients referred for testing						
# specimen referred for QA in last six months						
# specimen referred for confirmation						
# specimen sent for sensitivity testing						
# specimen sent for culture testing						
# specimen sent for fungus testing						
# specimen sent for liver function						
# specimen sent for sensitivity testing						
# specimen sent for CD4						
# specimen sent for Viral Load						
How far is the referral lab						
How is specimen transported *(by messenger, with facility vehicle, given to patient, in cold box etc.)*						
Reasons for Referral						

6. VCT Protocol

	Always	Sometimes	Remarks
VCT Protocol/algorithm available			
Determine/Capillus/Serocard protocol use			
Determine/Capillus/Unigold protocol use			
Determine only use			
Veronsistika/ELISA			

7. Laboratory Supplies Procurement System

		Remarks
Who selects items to be ordered		
What is selection based on		
Who quantifies amount to be ordered		
What is amount to be ordered based on		
Who initiates lab order		
Who approves order		
Frequency of ordering		
How is order placed (direct, letter, call..)		
Lead Time		
% received from PHARMID		
% received from Private		
What types of things do you get from private		
What delivery method is used for orders (supplier, facility or private vehicle)		
Who is responsible for receiving of ordered supplies		
Are receipts checked against invoice		
Are expiries/damages/shortages checked		
What other receiving forms are used in addition to Model 19		
Do you use stock shortage/damage memo for documenting and reporting discrepancies		

8. Laboratory Waste Management

	Waste bin	Biohazard Bag	Sharps Box	Other Specify
What do you use store sharps (needles, slides…) for disposal				
What do you use store contaminated supplies for disposal				

9. Laboratory Safety

	Incinerate	Burn	Bury	Chemical	Autoclave	No treatment	Other Specify
How do you dispose sharps (needles, slides…?)							
How do you dispose solid contaminated supplies							
How do you dispose liquid waste (blood etc)							

10. Laboratory Operations

	Always	Sometimes	Never	Remarks
Vacutainer used for drawing blood				
Disposable gloves used				
Gowns worn all the time in lab				
All kits and reagents requiring cold storage stored in refrigerators				
Refrigerator/cold room temperature monitored and recorded				
Equipment calibration schedule used				

11. Standard Operating Procedures (SOPs) / Protocol

	Available (yes or no)	Date of preparation	Provided by	Adequate (yes or no)
Is there SOP for ordering, receiving and storage of lab supplies				
Is there SOP of testing procedures				
Is there SOP for specimen management (collection, labeling, handling, disposal, transport…?)				
Is there SOP on confidentiality				
Is there SOP on safety and waste management				
Is there SOP for record management (test orders, result reports, filling etc?)				
Is there SOP for equipment use, repair, maintenance, calibration, care etc)				
Is there SOP on laboratory counseling				
Is there SOP on product inter-facility exchange				

12. Laboratory Tests

	# Tests/month	Method Used	Referred to	Reason for Referral
Hemoglobin				
WBC				
Differential				
Total Lymphocyte				
Blood Typing				
Blood Glucose				
Cholesterol				
AST/ALT (SGPT/SGOT)				
Pregnancy Test				
AFB for TB				
Malaria Smear				

	# Tests/month	Method Used	Referred to	Reason for Referral
Syphilis				
Gram Stain for bacteria				
HIV Rapid Test				
CD4 Count				
PCR				
Viral Load				
Comments				

13. Laboratory Equipment

	Specification Model/Type	# Working	# Not working	Repair Plan	Source
Microscope Binocular					
Sterilizer					
Centrifuge					
Counting Chamber					
Autolab					
Colorimeter					
Spectrophotometer					
Coulter counter					
ELISA unit					
CD4 Machine					
PCR					
Viral Load Machine					
Refrigerator					
Freezer -20					
Freezer -80					
Cold Box					
Ice Pack					
Water Distiller					
Safety cabinet					

14. Laboratory Reagents/Chemicals

	Qty/Amt Available	Expiry Date	Monthly Use	# of Stock-out in last 6 months	Source
Anti A, B, C, D.					
Ziel Neelson					
Carbol fuchsin					
Methylene Blue					
Hydrochloric acid					
Wright's Stain					
Drabkin's Reagent					
Geimsa Stain					

	Qty/Amt Available	Expiry Date	Monthly Use	# of Stock-out in last 6 months	Source
Gram stain					
Normal Saline					
Pot. Hydroxide					
Alcohol 70%					
Distilled Water					
Immersion Oil					
RPR/VDRL					
Determine test kits					
Capillus test kits					
Oraquick test kits					
Unigold test kits					
Veronsistika plus O for ELISA					
Chlorine disinfectant					
Others					

15. Laboratory Reagents/Consumables

	Qty Available	Expiry Date	Monthly Use	# of Stock-out in last 6 months	Source
Cover Slips					
Microscope slides					
Microscope Objectives 10					
Microscope Objectives 40					
Microscope Objectives 100					
Test tubes					
Centrifuge tubes					
Pipettes					
Micropipettes					
Capillary tubes					
RBC pipettes					
WBC pipettes					
Syringe/Needle Disposable					
Vacutainer					
Biohazard Bag					
Sharps box					
Gloves					
Apron					
Goggle					
Waste bin					
First aid kit					
Fire extinguisher					

16. Infrastructure / / Utilities

	Available	Number	Adequacy/ Condition	Proposed Change/Addition	Resources available For change
Free Standing Laboratory structure					
Counter separating client/testing area					
Room for HIV/AIDS testing					
Room for reagent prep./staining					
Separate laboratory officer office					
Room for confidential counseling					
Separate part/room for expired/unusable product					
Working table for staining					
Working table for instrumentation					
Working table for recording etc					
Safety Cabinet or hood					
Window for ventilation					
Concrete floor					
Temperature monitor					
Filing cabinet, lockable					
Storage Cabinet, lockable					
Shelves					
Pallets for cartons					
Running water with sink					
Power supply with outlets					
Gas Supply					
Standby generator					
Space for expansion					
Others					

17. Laboratory State

	Good	Fair	Poor	Action required	Remarks
Cleanliness					
Organization					
Security					
Leakage					
Dust					
Congestion					
Accessibility					
Storage of heat sensitive products					
Handling of dangerous materials					
Equipment handling and upkeep					
Records handling and upkeep					
Error control					

18. Record Keeping/Lab information system (LIS) Tools

	Used	Up to date	Accurate	Remarks
Patient Registration/Log Book				
Standard Supply Order Form				
Non-Standard Order Form				
Bin/Stock Card				
Daily Test Record Form				
Result Reporting Form				
Test Order Form				
Specimen Referral Form				
Monthly Report Form				
Stock Status Reporting Form				
Expiry/Loss/Damage Report Form				
Stock Exchange Form				
Computer				
Telephone				
Printer				
Internet				
Reference Book (please list)				
Other				

19. Laboratory Request Form, Laboratory Register, Laboratory Report

Observe and question	Indicator		
Are the approved laboratory request forms used for every patient?	Approved laboratory request forms are used for every patient	Yes	No
Are laboratory request forms submitted with complete information?	Laboratory information are submit with complete information	Yes	No
Is the laboratory register present, and all columns completed properly?	Laboratory register is present Laboratory register is properly complete and legible	Yes Yes	No No
Are patient records in laboratory register consistent?	If no, how many patients have missing records	Yes	No
When is result information entered into the laboratory register?	Results entered into the register daily	Yes	No
Are laboratory results recorded on the request form?	Laboratory results are recorded directly onto the form	Yes	No
How soon are the results reported to the treatment center or physician?	Same Next day	Yes Yes	No No
Recording keeping duration, Manual		Yes	No
Electronic		Yes	No
Explain any problem or deficiencies			

20. Lab Quality control/Quality assurance

	Yes	No	Frequency	Responsible	Destination
Is internal quality carried out for all laboratory procedures					
Is external quality assurance done for HIV testing					
External QA done by sending samples to referral lab					
External QA done by ref. lab sending samples for testing					
Records of QA kept					
Is internal quality carried out for TB tests					
Is external quality assurance done for TB testing					
Are QA mechanism applied for other lab tests					
Hematology					
Serology (ELISA based tests)					
Serology (agglutination test –slide or tube agglutination test)					
AFB Smear microscopy					
Gram staining					
Are records kept for all QA tests					
Who is your supervisor					
When was last supervision					
What is your relations with EHNRI					

21. Quality assurance procedure and programs

Is information gathered about laboratory turn-around times for specimens (time from receipt of specimens to issue of the report)?	Yes	No
Does the laboratory use any system for internal controls?	Yes	No
Are internal controls included in each test run?	Yes	No
If Yes, is the performance of these internal controls recorded and monitored over time?	Yes Yes	No No
Does the laboratory participate in any external quality control assurance or proficiency schemes?	Yes	No
If Yes, what programs?	Yes	No
Bacteriology Unknown sample?	Yes	No
HHIV/Hepatitis panels	Yes Yes	No No
Antimicrobial susceptibility	Yes	No
AFB Smear microscopy	Yes	No
Other (specify)	Yes	No

Does your laboratory keep records of deliveries of reagents and materials?	Yes	No
Does your laboratory have a system for regularly monitoring of quantities of reagents and materials so that there is warning if stocks become low?	Yes	No
Does the laboratory have problems obtaining and maintaining most supplies of essential reagents and materials?	Yes	Yes
If Yes, what is the most important reason for not mainti9aning an adequate stock of reagents and supplies?		
Information about how to obtain materials	Yes	No
Long delay ordering and delivery of materials	Yes	No
Lack of funds	Yes	No
Inconsistent demand for test from physicians	Yes	No
Is the functioning of ALL electrical or mechanical equipment routinely monitored and recorded (e.g. microscope calibration, checking temperatures of refrigerators or incubators, calibration of pipettes or handling devices autoclave function etc)?	Yes	No
Are calibration, maintenance and service records kept?	Yes	No

22. Laboratory training Needs

	Target	Training priories	Recommended training venue	Recommended partner
Quality Assurance (QA)	Quality assurance officer	QA system theory, development and administration	APHL member Laboratory/on-site QA training at EHNRI or elsewhere	EHHIRI/APHL/CDC
	Laboratory Director or supervisor	Implementation	In-country workshop	CDC/EHNRI
Rapid HIV Testing	All laboratory technicians	QA/QC, Procedure, interpretation	In-country workshop	EHNRI/CDC
HIV serology				
CD4, Hematology				
Clinical chemistry				
Viral load				
STD other than HIV				
Tuberculosis				
Opportunistic infections				
Any other observation/recommendation/training requirement				

23. Monitoring & Evaluation

	Yes	No	Frequency	Responsible	Destination
Inventory list of equipment and supplies					
Inventory of equipment and supplies made					
Temp of cold storage monitored					
Expiry of test kits and reagents monitored					
Expired/Damaged items disposed					
Disposed items list/cost reported					
Monthly report on tests performed and results made					
Supervisory visit received					
Supervisory feed back received					
Is internal quality carried out for capillus HIV tests					
Is external quality assurance done for HIV testing					
External QA done by sending samples to referral lab					
External QA done by ref. lab sending samples for testing					
Records of QA kept					
Is internal quality carried out for TB tests					
Is external quality assurance done for TB testing					
Are QA mechanism applied for other lab tests					
Hematology					
Serology (ELISA based tests)					
Serology (agglutination test –slide or tube agglutination test)					
Are records kept for all QA tests					
Who is your supervisor					
When was last supervision					
What is your relations with EHNRI					

24. List person of participants in the assessment

1. Lab supervisor/lab personnel who assisted and provide the information requested			
Name	Position	Date	Signature
2 Person who completed the questionnaires			
Name	Position	Date	Signature

_____ _____ _____ _____

Name Position Signature Date

3. Lab supervisor/lab personnel who assisted and provide the information:

_____ _____ _____ _____

Name Position Signature Date