**Joint Programmatic/M&E and PSM Laboratory Services[[1]](#footnote-1) and related Supply Chain review**

**Background:**

(*Background on the country and why the review is being requested)*

**Objective(s):**

The objectives of the review are to

1. assess the adequacy of the supply chain management systems and procedures used for HIV, TB, and Malaria laboratory equipment, reagents, and consumables,
2. understand the environment in which laboratory services are provided,
3. estimate the testing coverage and gaps in services, by cross-checking with programmatic results
4. identify the PSM related challenges that could be overcome with an appropriate intervention in order to ensure continuous availability of equipment, quality test kits, reagents and consumables, and
5. support the laboratory services required by the national programmes.

**Scope of Review:**

* To the extent possible, the review should focus on the national laboratory system supporting HIV, TB, and Malaria programs. Where parallel systems are used for the Global Fund grants, these should be described, contrasted with national systems, and justified.
* Geographic area or sampling methodology (how many sites & where; all patients or a sample; period of time being reviewed). Criterions for the selection of the laboratory facilities should be discussed and agreed upon prior to the sampling. It is advisable to select sites that provide laboratory services in areas where a majority of patients receive medical care and treatment and take into account the specificity of the services provided.
* What disease (or grants) are being covered and what specific aspects of the disease programme are being covered.

**Proposed approach**

A two-step approach in the review could be envisaged: the ToR and questionnaire (included in this document) could be separated in two parts: first an **initial desk review** of information available at central level, followed by a discussion of the initial report with the Global Fund Country Team and then tailoring of the **second phase of the review** based on the collected information.

Initial desk review: The LFA may be asked to conduct a review of available information at central level:

* Major grant-supported programmatic activities, and results reported in the past 12 months
* mapping of existing equipment and number of tests per region or per equipment realised in the past year;
* description of quantification of needs, funding sources, procurement, supply system(s);
* description of all active partners supporting the laboratory systems, collecting information on the supported regions, levels of the laboratory network, aspects of the laboratory activities, type of support, year, number of trained professionals and training area, produced documents, etc.;
* reporting systems and what information could be obtained through available periodic reports to the national, local authorities and the different donors;
* description of existing EQA reports, findings and recommendations;
* regulatory framework and guidelines.

**Required background reading**

* Outstanding or due Conditions and/or Management Actions, Global Fund QA Policy for Diagnostics Products, lists of eligible diagnostic products.
* Review existing laboratory assessment reports and laboratory accreditation scores

Based on the initial information collected by the LFA, the Country Team should indicate specific area(s) to focus the second phase of the review on. Specific tables could be prepared for collecting data at facility level to facilitate data collection process and the reporting.

**List of Tasks:**

***[Information for the Country Team: The list below represents a comprehensive assessment. The Country Team should indicate to the LFA whether a full verification is required or whether the LFA should focus on specific areas.]***

**M&E review**

The LFA M&E expert should:

1. Verify data collection, data management and data quality system checking-
	* Availability of standard and appropriate data collection and reporting tools across all levels
	* Availability of standard protocols and guidelines for patient diagnosis, progress assessment and monitoring of treatment outcomes
	* Completeness and accuracy of programmatic data
	* Availability of standard operating procedures for recording, aggregation and reporting of laboratory results
	* Existence of data quality control measures such as cross-checking data against different registers (e.g. laboratory vs treatment registers) and checking reported data against registers.
	* Evidence of data being analysed and used is demonstrated, e.g. display of latest graphs/maps in facilities
2. Confirm human resources capacity
* Responsible staff across all levels trained in data capture and reporting
* Responsible staff have basic understanding of data and ability to analyse and use data in day-to-day management
* Sustainability of human resources ensured (handover systems in place in case of illness or absence of person in charge of data capturing and reporting)
1. Determine the number of people currently on treatment, including per regimen for specific service(s)
2. Determine the number of people tested in a given period (e.g. VCT register) for specific service(s)

**Quality of laboratory services**

The LFA PSM expert should:

1. Verify that laboratory services are available and being used effectively by checking:
	* how the national laboratory system is structured and how this system ensures coverage of the entire range of services required
	* that a national laboratory policy and strategic plan has been designed and is being implemented
	* that laboratory testing being offered is adequate
	* that selection of laboratory equipment has been properly planned and executed
	* that appropriate laboratory equipment *(this list should be established prior to the visit)* is present and used in the country for HIV, TB, and Malaria programs, whether it undergoes routine maintenance, and whether the equipment is functioning properly
	* there is no gap in equipment (needs vs actual equipment present in the country) looking at both the quantity of machines, the machines’ capacity, the estimated number of beneficiaries (see section on cross checks) and/or in the type of laboratory services to be provided according to relevant guidelines and service delivery level
	* that the sample transportation system is efficient and that the results are provided in a timely manner
	* that the equipment is rationally positioned across the country to optimise the service coverage
	* the equipment’s theoretical performance, reported number of tests performed per day, average cost per test
	* where possible, determine the relationship amongst equipment capacity, service need, and available staff (quality and number)
	* that adequate training is provided to laboratory staff
2. Verify that laboratory services are of the required quality by checking:
	* that equipment and related products procured with grant resources conform with the Global Fund’s quality assurance policy for diagnostic products
		+ for equipment and related products not procured with grant resources determine which quality standards are applied
	* that the contract terms related to lab equipment acquisition contain clauses on installation, training and preventive maintenance and that these clauses are enforced at place of reception
	* that the equipment undergoes routine maintenance (including calibration) and that there is evidence of this (contract at central or peripheral level and existence of an up-to-date log book for each equipment)
	* that there are SOPs in-place at all levels that pertain to the equipment and test kits control as per an internal quality assurance scheme
	* the availability of standard guidelines for the provision of laboratory service
	* that the laboratories participate in an internal- and/or external quality assurance programme, as relevant, and is there evidence of this
	* the facility infrastructure and utilities (power, water, environment, physical space, light, waste disposal and drainage) are adequate.
	* QA/QC, EQA measures in place

**Laboratory supply management review *(central level and a sample of facilities)***

1. Verify that the supply chain allows for the right products, in the right quantity, at the right time and for the right price by checking:
	* whether storage and distribution arrangements function effectively with adequate storage facilities, transport means, consistent inventory management and reliable data collection and analysis (information system on laboratory services and commodities)
	* that there are adequate systems and controls in place to minimize the risk of stock-outs or wastage/loss of key diagnostic products
	* that SOPs to support all PSM-related processes exist, are present across all levels, and are used to ensure continuous availability of test kits, reagents and products
	* if problems in procurement and supply chain occur describe the frequency and impact and whether these problems are adequately addressed and prevented
	* whether the selection and procurement of key equipment and related test kits, reagents and consumables took into account the total cost of ownership, the need to keep the pool of machines homogeneous and determine whether it still provides value for money
2. Verify inventory data collection, management and quality system checking
	* The availability of standard and appropriate data collection and reporting tools
	* Completeness and accuracy of inventory data
	* Standard operating procedures for recording, aggregation and reporting are available
	* Data quality control measures such as checking reported data against stock cards and stock registers
		+ Where necessary, the LFA may be requested to check a sample of reported data against stock cards and registers; otherwise, the LFA should verify that control measures are in-place
	* Evidence of data being analysed and used is demonstrated, e.g. ordering in-line with consumption
	* Evidence of over-stocking or stock-outs
	* Compile a list of consumption data for key health products
3. Confirm human resources capacity
	* Responsible staff across all levels are trained in data capture and reporting
	* Responsible staff have a basic understanding of data and ability to analyse and use data in day-to-day management
	* Sustainability of human resources ensured (handover systems in place in case of illness or absence of person in charge of data capturing and reporting)
	* Responsible staff are trained in stock management and the use of specific equipment

Conduct cross checks

* By estimating the number of key tests required for the number of patients managed at the facility and comparing against the number of tests done
* By comparing test kits, reagents and consumables’ consumption data with patient data (e.g. number of suspected malaria cases tested compared to the number of RDTs used)

**Output/Deliverables and timing of deliverables:**

The report should address each of the points listed under the scope of review/list of tasks and include:

1. A clear map of the laboratory services structure and of the laboratory product supply chain with information on the services coverage, including (for the facilities visited) the instruments’ capacity and utilisation. Diagnostic gaps should be highlighted by comparing the current service provision, programmatic targets and available overall diagnostics budget.
2. A detailed description and analysis of PSM related (including LMIS) or laboratory services quality related issues/risks identified. The LFA should comment on the context and root causes of the issues identified, providing background information as necessary and prioritise the list of issues in an executive summary according to their significance.
3. Recommendations for addressing issues identified. Recommendations should be:
* Detailed and actionable
* Specific and contextualised
* Time-bound
* Identifying the main entity responsible for implementation
* Precise and prescriptive

Should the review identify clear evidence of fraud, the LFA should ensure it uses the GF communication protocol to inform the GF Secretariat and the OIG to allow consideration of evidence collection and other issues relevant to a possible criminal investigation.

**Level of Effort**

This task should be undertaken by the LFA PSM Expert and LFA Programmatic /M&E Expert who are accountable for the technical content of this report. They can be supported, as needed, by other LFA team members in the planning and during the verification. The LoE for this task, including report writing, depends on which elements of the ToR and the number and location of service delivery sites are included in the review, as agreed between the Global Fund Country Team and the LFA.

*For a more thorough review, the LFA may wish to contract a laboratory expert to support this review; nevertheless, it is expected that the laboratory expert will work closely with the LFA PSM Expert to ensure cohesion in the approach and the recommendations.*

**Questionnaire**

This questionnaire should be viewed as a **guidance tool,** rather than a mandatory tool, which assists in the collection of data needed to develop a robust report.

The questionnaire includes questions to be used for a review at:

1. Central/Intermediate Administrative level; and
2. Facility level

The references used in the development of this questionnaire, include:

1. Assessment Tool for Laboratory Services and Supply Chains (ATLAS)

<http://deliver.jsi.com/dhome/health/lab/labmore/labexpertise>

<http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/AsseToolLab_ATLAS.pdf>

1. WHO Laboratory Assessment Tool

<http://www.who.int/ihr/publications/laboratory_tool/en/>

# Central/Intermediate Administrative Level Questionnaire

## Section I. Organization

How are the laboratories organized? Describe all levels of the program and the relationships between the levels. Attach an organizational chart, if available. (*Include documents that define responsibilities and services provided at each level.*)

How many laboratories does the MOH/this program manage at each level? Are any services out-sourced, for example to private laboratories or faith-based organisations?

Are all laboratory supplies managed (reporting, ordering, distribution, and storage) through one system or through multiple systems (e.g., TB, malaria, HIV and AIDS, essential medical supplies, different donor programs)? List all the systems currently operating in the country, including existing local/regional arrangements.

Is there a laboratory unit/division/committee operating that coordinates laboratory activities in the country?

Is there a national/unified system in place for specimen referral? Or is it disease-specific and/or region-specific?

Is there a central asset management system for managing laboratory equipment?

□ Yes □ Partial □ No

If yes or partial, is each equipment recorded with a paper or electronic equipment form?

□ Yes □ Partial □ No

If yes or partial, does this form include:

Name of the equipment □ Yes □ No

Serial number □ Yes □ No

Name and contact details of manufacturer (or local supplier) □ Yes □ No

Date of receipt □ Yes □ No

Date of first use □ Yes □ No

Location in the laboratory □ Yes □ No

Condition (i.e. new, used) □ Yes □ No

Maintenance activities □ Yes □ No

Damage and repairs □ Yes □ No

The individual primarily responsible for this equipment □ Yes □ No

Does the available data allow estimating the diagnostics contribution and instrument utilization for a sample of key equipment? □ Yes □ No

If yes, please provide the corresponding estimations.

## Section II. Policy

Is there a national policy document for laboratory services – either a single document or per disease program (please specific)?

Does the policy document include the following?

1. Laboratory services packages (test menu) by level?
2. Laboratory test techniques by level?
3. A list of essential equipment by level?

Are there documented standard operating procedures (SOP) for tests performed at each level?

Does the SOP provide a list of essential supplies (reagents and consumables) per test?

Does the SOP provide a list of essential equipment by level?

Are there written guidelines for disposal or destruction of damaged and/or expired laboratory products?

For each category, list the number of different instruments being used for automated laboratory equipment?

1. Haematology
2. Immunohematology
3. Chemistry

Is there a unit responsible for equipment maintenance and service in the country or is it regionally based? Please describe the unit(s).

How are the maintenance, the calibration and the repair organized in the country for equipment under warranty and other?

Are there arrangements in place for provision of spares and maintenance of closed system equipment after their warranty period has ended?

Are there written national laboratory procedures for quality assurance (internal and external)?

## Section III. Quantification

Are all laboratory supplies (reagents and consumables) quantified centrally for all programs?

List programs for which laboratory supplies are quantified, how often the quantification is conducted, is there a committee responsible for the quantification process, and provide a description of the information used to quantify laboratory supply needs. Also include quantification tools used and partners providing technical assistance if available.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Program  | Frequency  | Quantification committee members  | Data Used and source | Quantification tool  | Partner Providing Technical Assistance  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Are there any gaps in the list of products quantified by the programs?

Are there any weaknesses in the methodology used for the quantification and is there a reliable system in place for estimating the actual consumption and adjust the quantification accordingly?

## Section IV. Financing

*Please provide this information by disease program*

What are the sources of existing funding for laboratory services, including infrastructure, supplies (reagents and consumables), and equipment? Indicate the percentage of funding contributed by each source:

a. Government? \_\_\_\_\_\_\_ % of total funding

b. User’s fees/cost recovery? \_\_\_\_\_\_\_ % of total funding

c. Donors (list by donor)? Donor 1:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Donor 2:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Donor 3:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_% of total funding \_\_\_\_\_\_\_\_% of total funding \_\_\_\_\_\_\_\_% of total funding

d. Other? (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_% of total funding

Are funds sufficient to cover the needed supplies and equipment? If not, what is the gap?

Is there a separate budgetary line item for laboratory services, one for supplies and one for equipment?

## Section V. Procurement

Describe the procurement process, using a process map for the national level. (*Specify any differences by program and/or donor.*)

What is the average procurement lead time for each program and/or donor specified above?

In general, are adequate amounts of all laboratory supplies received? (*Specify any program differences.*)

What other partners procure laboratory supplies?

Are there any local distributors for major supplies (including control) for haematology, biochemistry, immunology, and microbiology?

## Section VI. Storage and Distribution

Describe the current system for storing laboratory supplies (reagents and consumables) and equipment at all levels:

Is there an established distribution system for laboratory supplies and equipment for all levels?

Describe the current system for distributing laboratory supplies (reagents and consumables) and equipment to all levels:

Is the existing storage and distribution capacity adequate (including cold chain)

* to handle the required quantities of laboratory supplies at the national (or intermediate, if no national) level and
* to handle the expanded program goals for the next three years?

Are supplies collected by lower levels or actively distributed? In the latter, is the available fleet of vehicles adequate in number and quality to meet the distribution schedule at the following levels?

## Section VII. Inventory Control System

Do laboratories at all levels have a set minimum and a maximum stock levels for a pre-established list of reagents and consumables based on the services to be provided according to the policy document ?

Who determines resupply quantities to fill orders (is it a push or a pull system)?

Are damaged/expired products physically separated from inventory and removed from stock records?

## Section VIII. Laboratory Services and Supplies Management Information Systems

*Where differences exist by disease program, please provide the information by disease program.*

Are there standard national forms available and used to collect and report information on laboratory services? Specify the form names.

Are there standard national forms available and used to collect and report information on laboratory stocks? Specify the form names.

Do the forms include the following data:

Name of product? □ Yes □ No

Unit of measure? □ Yes □ No

Supplier? □ Yes □ No

Lot number? □ Yes □ No

Date of receipt? □ Yes □ No

Appropriate storage? □ Yes □ No

Expiration date? □ Yes □ No

Expected shelf life? □ Yes □ No

Stock on hand? □ Yes □ No

Consumption? □ Yes □ No

Losses and adjustments? □ Yes □ No

Quantity ordered or requested? □ Yes □ No

Are stock balances at all levels and the services (quantity and type of services) monitored regularly so that procurement decisions and actions can be made on time to avoid stock-outs or overstocks? (*Specify any program differences AND Check the latest aggregated data at central and intermediate levels or the last 3 summary reports.*)

Describe the reporting systems (for both services and supplies) in detail, including the reporting level, the information reported, and the reporting frequency (monthly, bimonthly, and quarterly).

Approximately what percentage of districts and what percentage of laboratories submit these reports each reporting period, according to the schedule? \_\_\_\_\_\_\_\_\_\_\_ % of districts \_\_\_\_\_\_\_\_\_\_\_ % of laboratories

Are laboratory registers and results log books for recording test results standardized nationally?

Is this system integrated with the MOH health management information system?

## Section IX. Supervision

Is scheduled laboratory supervision conducted at the following levels? If so, how often?

1. National reference laboratories?
2. Provincial or regional laboratories?
3. District laboratories?
4. HC laboratories?
5. Private sector laboratories?

Do the activities routinely conducted during the supervisory visit include the monitoring of the performance of the supply chain for laboratory reagents and consumables?

Is there a standard supervision checklist or protocol? If yes, please provide a copy.

## Section X. General Questions

What are the major areas of concern for laboratory services and supply chain at the national level?

How can these areas of concern be addressed nationally?

# Facility Level Questionnaire

*(If there is a central and/or regional store, the relevant questions from Sections V, VI, and VII should be used.)*

General Information

|  |  |
| --- | --- |
| 1. Unique identifier:  |  |
| 2. Name of facility:  |  |
| 3. GIS coordinates (latitude, longitude) |  |
| 4. Region:  |  |
| 5. District:  |  |
| 6. Level of the facility:  | □Regional hospital□District hospital  | □HC □Other\_\_\_\_\_\_\_\_\_\_\_\_  |
| 7. Type of facility:  | □Government □Private not-for-profit □Other (*specify*)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |
| 8. Coverage |  |

## Section I. National Guidelines and Protocols

Are national guidelines and protocols for laboratory testing procedures available in this laboratory?

Are written guidelines for specimen referral available in this laboratory?

Are written guidelines for laboratory waste management available in this laboratory?

Are written guidelines for disposal or destruction of damaged and/or expired products available in this laboratory?

Are written guidelines for storage of laboratory products available in this laboratory?

Are written guidelines for the service and maintenance (including calibration) of equipment used in this laboratory available?

Are there SOPs for the laboratory logistics system available in this laboratory?

## Section II. Laboratory Personnel

When did this laboratory receive the last supervisory visit?

What programs were covered during the supervision? (Check all that apply.)

□ Malaria

□ STI

□ HIV and AIDS

□ TB

□ None

□ Other (specify): ………………………

What activities were conducted during the supervisory visit?

□ Infrastructure inspected

□ Equipment inspected

□ Reinforcement of universal safety precautions

□ Record keeping of performed tests checked

□ Equipment maintenance records checked

□ Cold chain records checked

□ Stock cards, stock ledger, and/or reports checked

□ Quality control records checked

□ On-the-job training/coaching

□ Provide feedback to staff

□ Receive feedback from staff

□ Other (specify): ………………………

Did the laboratory get written feedback from the visit? Y/N

## Section III. Equipment Availability and Maintenance

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name and Model of Machine  | Equipment Working  | Service Contract  | Machine Log book Up-to-date  | Maintenance Schedule Available  | Local Agent Available  | User Manual Available  | Handling of Repairs  |
| **Chemistry**  |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call local agent □ Other……  |
| **Haematology** |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call local agent □ Other……  |
| **CD4** |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call local agent □ Other……  |
| **Viral load** |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call local agent □ Other……  |
| **GeneXpert®** |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call local agent □ Other……  |

|  |
| --- |
| **General Laboratory Equipment Available** |
| Name and Model of Machine  | Equipment Working  | Service Contract  | Machine Log book Up-to-date  | Maintenance Schedule Available  | Local Agent Available  | User Manual Available  | Handling of Repairs  |
| **Microscopes**  |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call technician□ Call manufacturer□ Call local agent □ Other……  |
| **Balances**  |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call technician□ Call manufacturer□ Call local agent □ Other……  |
| **Centrifuges**  |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call technician□ Call manufacturer□ Call local agent □ Other……  |
| **Micropipettes**  |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call technician□ Call manufacturer□ Call local agent □ Other……  |
| **Autoclaves**  |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call technician□ Call manufacturer□ Call local agent □ Other……  |
| **Safety Cabinets**  |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call technician□ Call manufacturer□ Call local agent □ Other……  |
| **Refrigerators**  |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call technician□ Call manufacturer□ Call local agent □ Other……  |
| **Freezers**  |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call technician□ Call manufacturer□ Call local agent □ Other……  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name and Model of Machine  | Equipment Working  | Service Contract  | Machine Log book Up-to-date  | Maintenance Schedule Available  | Local Agent Available  | User Manual Available  | Handling of Repairs  |
| **Rockers**  |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call technician□ Call manufacturer□ Call local agent □ Other……  |
| **Shakers**  |
|  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Yes □ No  | □ Call supplier □ Call technician□ Call manufacturer□ Call local agent □ Other……  |

Does the facility have a notable equipment gap?

If so, please indicate which equipment in the column on the left and the reason why in the column on the right.

## Section IV. Laboratory Testing Services

|  |
| --- |
| **Tests Performed at Laboratory**  |
| **Laboratory Test**  | **Technique**  | **Test Currently Available**  | **Reason for Not Testing**  |
| Rapid HIV (screening)  | □ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Other (*specify*): ..............  | □ Yes □ No  | □ Test not requested at this level/in this facility□No reagents □Equipment not functioning □ No equipment□ Staff not trained□ Equipment not functioning□ No reagents |
| Rapid HIV (confirmatory)  | □ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Other (*specify*): ..............  | □ Yes □ No  | □ Test not requested at this level/in this facility□No reagents □Equipment not functioning □ No equipment□ Staff not trained□ Equipment not functioning□ No reagents |
| Rapid HIV (tie breaker)  | □ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Other (*specify*): ..............  | □ Yes □ No  | □ Test not requested at this level/in this facility□No reagents □Equipment not functioning □ No equipment□ Staff not trained□ Equipment not functioning□ No reagents |
| CD4  | □ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Other (*specify*): ..............  | □ Yes □ No  | □ Test not requested at this level/in this facility□No reagents □Equipment not functioning □ No equipment□ Staff not trained□ Equipment not functioning□ No reagents |
| Viral load/EID | □ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Other (*specify*): ..............  | □ Yes □ No  | □ Test not requested at this level/in this facility□No reagents □Equipment not functioning □ No equipment□ Staff not trained□ Equipment not functioning□ No reagents |
| Malaria  | □ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Other (*specify*): ..............  | □ Yes □ No  | □ Test not requested at this level/in this facility□No reagents □Equipment not functioning □ No equipment□ Staff not trained□ Equipment not functioning□ No reagents |
| Sputum for acid-fast bacillus  | □ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Other (*specify*): ..............  | □ Yes □ No  | □ Test not requested at this level/in this facility□No reagents □Equipment not functioning □ No equipment□ Staff not trained□ Equipment not functioning□ No reagents |
| Stool microscopy  | □ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Other (*specify*): ..............  | □ Yes □ No  | □ Test not requested at this level/in this facility□No reagents □Equipment not functioning □ No equipment□ Staff not trained□ Equipment not functioning□ No reagents |
| Urine microscopy  | □ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Other (*specify*): ..............  | □ Yes □ No  | □ Test not requested at this level/in this facility□No reagents □Equipment not functioning □ No equipment□ Staff not trained□ Equipment not functioning□ No reagents |
| Syphilis screening  | □ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Other (*specify*): ..............  | □ Yes □ No  | □ Test not requested at this level/in this facility□No reagents □Equipment not functioning □ No equipment□ Staff not trained□ Equipment not functioning□ No reagents |
| Full blood count  | □ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Other (*specify*): ..............  | □ Yes □ No  | □ Test not requested at this level/in this facility□No reagents □Equipment not functioning □ No equipment□ Staff not trained□ Equipment not functioning□ No reagents |

|  |  |  |  |
| --- | --- | --- | --- |
| **Laboratory Test**  | **Technique**  | **Test Currently Available**  | **Reason for Not Testing**  |
| Electrolytes  | □ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Other (*specify*): ..............  | □ Yes □ No  | □ Test not requested at this level/in this facility□No reagents □Equipment not functioning □ No equipment□ Staff not trained□ Equipment not functioning□ No reagents |
| Chemistry  | □ Automated □ Manual  | □ Yes □ No  | □ Test not requested at this level/in this facility□No reagents □Equipment not functioning □ No equipment□ Staff not trained□ Equipment not functioning□ No reagents |

**Specimen referral**

Does the laboratory routinely refer specimens for tests that are NOT performed in this laboratory to other laboratories?

□ Yes

□ No

Where does the laboratory refer these specimens? (Note name of the referral laboratory.)

□ National Reference laboratory

□ Central hospital laboratory

□ Provincial hospital laboratory

□ District hospital laboratory

□ HC laboratory

□ Indicate name of referral laboratory: …………………………….

What type of specimens does this laboratory routinely refer? (Check all that apply.)

□ Blood

□ Sputum

□ Urine

□ Stool

□ Swabs

□ Biopsy

□ Other…………………………….

What type of tests does this laboratory routinely refer? (Check all that apply.)

□ EID polymerase chain reaction (PCR)

□ TB culture

□ CD4

□ Viral load

□ Histology

□ Chemistry

□ Haematology

How long does it take for this laboratory to receive the results for the routinely referred specimens?

□ One day

□ Two days to a week

□ More than a week but less than two weeks

□ Two weeks or greater

Does this laboratory sometimes refer specimens for tests that it should be providing?

□ No (If no, end here)

□ Yes

What are the reasons for referral of these specimens?

□ No reagents

□ No staff

□ Broken equipment

□ Other

Is there a specimen referral register in this laboratory? (Ask to see the register and note the information recorded.)

How are the test results of the specimens referred communicated to this laboratory?

□ Facility transport

□ Post

□ Courier

□ Fax/Phone

□ Email

□ SMS/texting

Does this laboratory keep a record of the test results of referred specimens?

Are patients notified when results are received from the referral laboratory?

If NO, how do patients receive the test results of referred specimens?

How long does it take the laboratory to receive the results for ad hoc sample referrals?

□ One day

□ Two days to one week

□ More than a week

Does the laboratory have supplies for collecting specimens for referral?

How does the laboratory obtain supplies for specimen collection?

□ Provided through central medical/laboratory stores

□ Other, please specify:…………………………

Does this laboratory receive specimens from other laboratories or health facilities?

Is there a register for specimens received from other laboratories or health facilities?

How do facilities that refer specimens to this laboratory receive their results?

□ Referring laboratory collects

□ This laboratory sends result to referring facility

What is the average turnaround time for sending results on referred specimens?

□ One day

□ Two days to a week

□ More than a week but less than two weeks

□ Two weeks

## Section V. Quality Assurance

For equipment, test kits, reagents and consumables procured with grant funds, do they conform to the Global Fund’s quality assurance policy for diagnostic products?

For equipment, test kits, reagents and consumables procured with other resources, is there a quality assurance policy for diagnostic products that the need to conform to? If yes, please specify.

Are there written quality assurance policies and procedures available in this laboratory?

Is the laboratory accredited?

Is the laboratory working towards accreditation i.e. enrolled in SLMTA (Strengthening Laboratory Management Towards Accreditation) program.

Does the laboratory undertake the following internal quality control procedures (*check all physically*):

Daily record refrigerator temperature charts □ Yes □ No

Daily record freezer temperature charts □ Yes □ No

Include commercially prepared controls whenever a batch of tests is run (list instruments for which this applies)? □ Yes □ No

Does the laboratory have guidelines for handling cold chain products that have been exposed to higher temperatures? (For example, by sitting outside for a while or after a relatively long power outage.)

□ Yes

□ No

□ Don’t know/not sure

Are consumables and reagents inspected upon receipt?

If yes or partial, are there protocols for acceptance/rejection of consumables and reagents?

Are consumables and reagents appropriately stored (temperature, humidity, etc.)?

Is the date of opening clearly written on the reagents/kits?

Are new reagents (new product, new lot, including home-made reagents) validated against old reagents or reference materials before use?

Are disposable supplies (e.g. tips, plastic pipettes, gloves) reused?

□ Never

□ Sometimes

□ Regularly

□ Non applicable

Are expired reagents used?

□ Never

□ Sometimes

□ Regularly

□ Non applicable

If sometimes or regularly, is quality control performed on these expired reagents?

If sometimes or regularly, does quality control testing demonstrate that the quality of reagents is still acceptable?

Does the laboratory prepare in house controls for quality control testing?

Does the laboratory participate in any external quality assurance scheme?

If yes, which scheme?

How often in a year?

With which program?

## Section VI. Storage

Inspect the storage area of the laboratory

Are there written guidelines for storing laboratory supplies according to their specifications (flammable, caustic, etc.; e.g., Are Material Safety Data Sheets available)?

Are flammable and hazardous chemicals stored in specialized storage areas?

Are reagents stored according to first-to-expire, first-out practice in the laboratory?

For the following set of questions, if no damaged or expired products are evident, ask the stock keeper to explain the accepted practice for such products. Verify the practice to the extent possible.

* Does the laboratory separate damaged and/or expired supplies from good products?
* Does the laboratory make it a practice to follow guidelines for the disposal and/or destruction of damaged and/or expired laboratory supplies?
* Are cold chain items always stored at appropriate temperatures? If not, list cold chain items and how they were found.

Have there been any problems with the storage of laboratory supplies?

If yes, list the three major problems with storing laboratory supplies? (Start with the highest priority.)

a. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

b. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

c. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Section VII. a. Inventory Management

Does the laboratory have a set minimum and maximum stock levels for reagents and consumables?

How often is the stock level of reagents and supplies reviewed?

□ Each time an issue is made

□ Monthly

□ Every two months

□ Quarterly

□ Other

□ Never

How often is a physical inventory of reagents and consumable supplies conducted in the laboratory?

□ Monthly

□ Every two months

□ Quarterly

□ Other

□ Never

## Section VII. b. Logistics Management of Laboratory Supplies

What forms does the laboratory use to keep track of reagents and consumables in stock?

□ Stock cards

□ Store Ledgers

□ Other (*specify*): ……….

□ None

What forms does the laboratory use for ordering supplies?

□ Order book

□ Delivery note

□ Requisition and Issue voucher

□ Other (specify): ……….

What forms does the laboratory use for receiving supplies?

□ Delivery note

□ Requisition and issue voucher

□ Other (*specify*): ……….

Who determines how much to order?

□ Laboratory

□ Higher level authorities

Which data elements are used to calculate how much to order?

□ Average monthly consumption

□ Number of tests performed

□ Stock remaining in the laboratory

□ Set maximum stock level for reagents

□ Other (specify): ……….

□ Don’t know/not sure

Where does this facility send its order for resupply? (Check all that apply.)

□ National reference laboratory

□ National medical stores

□ Regional medical stores

□ District medical stores

□ Private supplier/open market

□ Other (*specify*): ……….

How often are orders placed?

□ Monthly

□ Quarterly

□ Every six months

□ Other (*specify*): ……….

How many emergency orders have been placed in the last year?

Number: ……….

Under normal circumstances, how long does it take from the time an order is placed to the time the supplies are received and available for use?

□ \_\_\_\_\_\_\_\_\_\_\_ days

□ \_\_\_\_\_\_\_\_\_\_\_ months

□ Don’t know/not sure

What were the reasons for the delay in receiving the supplies?

□ Supplies unavailable in country

□ No funding

□ Supplier failed to supply

□ Wrong product supplied

□ Other (*specify*): ……….

□ Don’t know/not sure

Does the laboratory have standard pre-printed test requests and reporting forms?

Does this laboratory send reports on the following: (Read list and check all positive responses)

□ Stock on hand

□ Consumption

□ Lab tests performed

□ Surveillance reports

□ Other (*specify*): …………

How often are these reports sent? (Check all that apply.)

□ Monthly

□ Every two months

□ Quarterly

□ Other (*specify*): …………

Where are these reports sent?

□ To the central laboratory

□ To the regional laboratory

□ To the district laboratory

□ Other (*specify*): …………

How are the reports sent?

□ Facility transport

□ Post

□ Courier

□ Fax/phone

□ Email

□ SMS text

□ Other (*specify*): …………

Is the LMIS used for other health products integrated with the laboratory management information system?

□ Yes

□ No

□ Don’t know/not sure

## Section VII. c. Transport

Do all of the laboratory supplies come from the same source?

Is the distribution of laboratory supplies integrated across all programs?

Explain which program’s products (e.g., HIV and AIDS, TB, malaria, etc.) are distributed together and which are distributed separately.

How do lab supplies usually arrive at the laboratory? Specify any differences for vertical programs (e.g., HIV and AIDS, TB).

□ Laboratory picks them up

□ Higher level (e.g., district, regional) delivers them

□ National medical store delivers them

□ Private supplier delivers them

□ Other (specify): ………..

Does the laboratory have access to a vehicle?

Does the laboratory use the vehicle to pick up supplies?

What is the frequency of supply? Is it regular or upon request from the laboratory?

What is the supply lead time (period of time between order and delivery)?

What are the major problems you have experienced related to transport in the last year?

a. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

b. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

c. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Section VII. d. Availability of a list of Sample Reagents and Infection Control Commodities

|  |  |  |
| --- | --- | --- |
| **Sample Reagents**  | **Stockout on Day of the Visit**  | **Stockout in the Last 30 Days (Not Including Day of Visit)**  |
| Field stain A  | □ Yes □ No  | □ Yes □ No  |
| Field stain B  | □ Yes □ No  | □ Yes □ No  |
| Gram stain  | □ Yes □ No  | □ Yes □ No  |
| ZN stain  | □ Yes □ No  | □ Yes □ No  |
| Sodium chloride  | □ Yes □ No  | □ Yes □ No  |
| RPR antigen  | □ Yes □ No  | □ Yes □ No  |
| Immersion oil  | □ Yes □ No  | □ Yes □ No  |
| Uristix  | □ Yes □ No  | □ Yes □ No  |
| Methanol  | □ Yes □ No  | □ Yes □ No  |
| Xylene  | □ Yes □ No  | □ Yes □ No  |
| HIV screening test kit  | □ Yes □ No  | □ Yes □ No  |
| HIV confirmatory test kit  | □ Yes □ No  | □ Yes □ No  |
| HIV tie-breaker test kit  | □ Yes □ No  | □ Yes □ No  |
| Viral load test kit | □ Yes □ No  | □ Yes □ No  |
| CD4 test kit | □ Yes □ No  | □ Yes □ No  |
| GenXpert cartridge | □ Yes □ No  | □ Yes □ No  |
| Blood group/type antisera  | □ Yes □ No  | □ Yes □ No  |
| Acetic acid, glacial  | □ Yes □ No  | □ Yes □ No  |
| Formalin, solution  | □ Yes □ No  | □ Yes □ No  |
| Ether  | □ Yes □ No  | □ Yes □ No  |
| India ink  | □ Yes □ No  | □ Yes □ No  |
| Potassium hydroxide, reagent  | □ Yes □ No  | □ Yes □ No  |
| Pregnancy test kit  | □ Yes □ No  | □ Yes □ No  |
| **Infection Control**  |
| Gloves latex disposable  | □ Yes □ No  | □ Yes □ No  |
| Goggles  | □ Yes □ No  | □ Yes □ No  |
| Masks  | □ Yes □ No  | □ Yes □ No  |
| Biohazard bags  | □ Yes □ No  | □ Yes □ No  |
| Disinfectants  | □ Yes □ No  | □ Yes □ No  |
| Sharps boxes  | □ Yes □ No  | □ Yes □ No  |

## Section VIII. Waste Management

Does the laboratory have waste management guidelines in place?

Does the laboratory separate infectious waste from general trash?

Is infectious waste contained in clearly marked bags or receptacles such as a red bag or a container marked with a biohazard symbol?

Does the laboratory have a functioning incinerator or other nationally acceptable waste management method (e.g., a protected pit) to correctly dispose of all hazardous materials (e.g., needles, toxic materials)?

Are there guidelines for the removal/disposal of obsolete laboratory equipment available in this laboratory?

Is there any obsolete equipment currently being stored in the laboratory?

Does the laboratory have adequate packaging materials for the transportation of infectious materials from the laboratory?

Does the laboratory have guidelines on the management of spillages available in laboratory?

1. Laboratories for programmatic diagnosis and monitoring for HIV, TB, and Malaria programs [↑](#footnote-ref-1)