# SPI-RT FOR LF-LAM: CHECKLIST FOR TESTING SITE QUALITY ASSURANCE

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| **Country:**  | **Department/ Division:** | **Unit/ Team:** |
| **Document Number:**  | **Version Number:**  | **Effective Date:** |
| **Reviewed by (name, signature, and date):** | **Approved by (names, signatures, and dates):**  |
|  |

1. **FACILITY DESCRIPTION**

Complete the checklist below and provide the relevant information in table below.

|  |  |
| --- | --- |
| **Date of Assessment:** | **Assessment Round Number:** |
| **Testing facility name and address:** |
| **Testing site level** | [ ]  National health facility [ ]  Regional/Provincial/Zonal health facility [ ]  District health facility [ ]  Community – outreach/health post [ ]  Other (please specify) |
| **Type of testing site** | [ ]  TB Clinic [ ]  HIV Clinic[ ]  Laboratory [ ]  Treatment center [ ]  Outreach [ ]  Other (please specify) |
| **Affiliation** | [ ]  Government [ ]  Private-for-profit [ ]  Private not for profit [ ]  Faith-based organization [ ]  NGO [ ]  Other (Please specify)  |
| **Setting of patient testing** | [ ]  In-patient [ ]  Out-patient[ ]  Other (please specify) |
| **No. of trained testers at site:** |  |
| **Number of LF-LAM tests performed in the past:** | **Month** | **Quarter** | **Year** |
| **Number of identified TB patients using LF-LAM test in the past:** | **Month** | **Quarter** | **Year** |
| **Number of LF-LAM test Quality Control samples tested in the past:** | **Month** | **Quarter** | **Year** |
| **Names and signatures of site assessor(s):** |  |

1. **SPI-RT FOR LF-LAM TESTING: SITE ASSESSMENT**

For each of the sections listed below, please check “yes”, “partial” or “no”, where applicable. Indicate “yes” only when all elements are satisfactorily present. Provide comments for each “partial” (**some** but not all elements were present, inconsistent implementation or non-adherence to procedures) or “no” response. State “not applicable” in the comments section for those marked with an asterisk (\*) or where otherwise appropriate.

**Scoring Criteria:**

Each element marked is assigned a point value.

Items marked “yes” receive 1 point each.

Items marked “partial” receive 0.5 points each.

Items marked “no” receive 0 points each.

|  | **Section**  | **Response** | **Comment**  | **Score** |
| --- | --- | --- | --- | --- |
| Yes | Partial | No |
|  | **Testing personnel** |
|  | Have all testers received initial training on LF-LAM testing using the nationally approved training package? |  |  |  |  |  |
|  | Have all testers received refresher training within the past two years? |  |  |  |  |  |
|  | Are there records indicating that all testers have received training before testing patients? |  |  |  |  |  |
|  | Are there records indicating that all testers have been deemed competent before testing patients (within 6 months for new testing personnel LF-LAM testing experience for <2 years) and within one year for established personnel (LF-LAM testing experience for >2 years)]  |  |  |  |  |  |
|  | If available, have all testers been certified through a national certification programme (the certificate is valid for 2 years)? |  |  |  |  |  |
| ***Testing personnel score*** |  |  |
|  | **Testing facility and biosafety** |
|  | Is there a designated area for LF-LAM testing? |  |  |  |  |  |
|  | Is the testing area clean and organized for LF-LAM testing? |  |  |  |  |  |
|  | Is the light adequate to read the LF-LAM test result? |  |  |  |  |  |
|  | Are standard operating procedures and/or job aids in place to implement safety practices? |  |  |  |  |  |
|  | Are standard operating procedures and/or job aids in place on how to dispose of infectious and non-infectious waste? |  |  |  |  |  |
|  | Is personal protective equipment always available to the testers? |  |  |  |  |  |
|  | Do all testers consistently use personal protective equipment? |  |  |  |  |  |
|  |  Is there clean water and soap available for hand washing? |  |  |  |  |  |
|  | Is an appropriate disinfectant available and appropriately labeled to clean/ disinfect the work area and equipment? |  |  |  |  |  |
|  | Are containers for infectious and non-infectious waste emptied regularly in accordance with the standard operating procedures and/or job aids? |  |  |  |  |  |
| ***Testing Facility and Biosafety Score*** |  |  |
|  |
|  | **Guidelines, procedures, and documentation**  |
|  | Are national testing guidelines specific to LF-LAM testing, available at the testing point? |  |  |  |  |  |
|  | Is the national LF-LAM testing algorithm being followed? |  |  |  |  |  |
|  | Is there a process in place for an alternative TB testing algorithm in case of expired test LF-LAM kits or shortages?  |  |  |  |  |  |
|  | Are job aids on client sample collection available and posted at the testing point? |  |  |  |  |  |
|  | Are procedures for LF-LAM test interpretation and timely reporting available and in use?  |  |  |  |  |  |
|  | Are there national guidelines describing how patient identification should be recorded in the LF-LAM testing register? |  |  |  |  |  |
|  | Are patient identifiers recorded in the LF-LAM testing register in accordance with national guidelines? |  |  |  |  |  |
|  | Are all client documents and records securely kept throughout all phases of the testing process? |  |  |  |  |  |
|  | Are all registers or logbooks and other documents kept in a secure location when not in use? |  |  |  |  |  |
|  | Does the facility have a designated, clean, private, and adequate space for sample collection? |  |  |  |  |  |
|  | Are running water and soap available for hand washing before and after urine collection? |  |  |  |  |  |
| ***Guidelines, procedures, and documentation score*** |  |  |
|  |
|  | **Testing, results interpretation, reporting and use** |
|  | Are sample collection supplies (such as urine containers) available? |  |  |  |  |  |
|  | Are testing procedures adequately followed? |  |  |  |  |  |
|  | Does the person in charge routinely review testing records/registers? |  |  |  |  |  |
|  | Are all the elements in the register or logbook recorded or captured correctly (such as client demographics, kit names, lot numbers, expiration dates, tester name and final LF-LAM results)? |  |  |  |  |  |
|  | Are timers available and used routinely for LF-LAM testing? |  |  |  |  |  |
|  | Is the total summary at the end of each page of the register or logbooks completed accurately? |  |  |  |  |  |
|  | Are indeterminate/ equivocal and invalid tests repeated and the results appropriately recorded in the register or logbook? |  |  |  |  |  |
|  | Are invalid test results recorded in the register or logbook and investigated with appropriate corrective actions? |  |  |  |  |  |
| ***Testing, results interpretation, reporting and use Score*** |  |  |
|  |
|  | **Internal quality control (IQC)** |
|  | Are standardized LF-LAM IQC forms or/tools for recording QC data available? |  |  |  |  |  |
|  | Are quality control results properly recorded? |  |  |  |  |  |
|  | Are incorrect or invalid quality control results properly recorded and investigated with appropriate corrective actions? |  |  |  |  |  |
|  | Does the person in charge routinely review quality control records? |  |  |  |  |  |
|  | ***Internal quality control score*** |  |  |
|  |  |  |  |
|  | **External Quality Assessment (EQA)** |
|  | Are LF-LAM test EQA procedures/tools available and in use?  |  |  |  |  |  |
|  | Is the testing point enrolled in an external quality audit or proficiency testing programme? |  |  |  |  |  |
|  | Do all testers at the testing point test the external quality audit or proficiency testing samples? |  |  |  |  |  |
|  | Does the person in charge at the testing point review the external quality audit or proficiency testing results before submitting them to the national reference laboratory or designee? |  |  |  |  |  |
|  | Is an external quality audit or proficiency testing report received from the national reference laboratory and reviewed by testers and/ or the person in charge at the testing point? |  |  |  |  |  |
|  | Does the testing point implement corrective action in case of unsatisfactory results? |  |  |  |  |  |
|  | Does the testing point receive periodic supervisory visits? |  |  |  |  |  |
|  | Is feedback provided during supervisory visits and documented? |  |  |  |  |  |
|  | If testers need to be retrained, are they being retrained during the supervisory visit? |  |  |  |  |  |
|  | ***EQA score*** |  |  |
|  |  |  |  |
|  | **Data collection, Monitoring and Evaluation and Quality Improvement** |
|  | Are LF-LAM testing M & E procedures/tools available and in use? |  |  |  |  |  |
|  | Does the site record/ track the key quality indicators periodically? |  |  |  |  |  |
|  | Are LF-LAM key quality indicators reported? |  |  |  |  |  |
|  | Does the testing facility receive supervisory visit to monitor and evaluate the key Quality indicators? |  |  |  |  |  |
|  | Are results from LF-LAM quality indicators monitoring used to inform quality improvement? |  |  |  |  |  |
|  | Are results from LF-LAM quality indicators monitoring used inform programming/decision making? |  |  |  |  |  |
| ***Data collection, M&E Quality Improvement score*** |  |  |
|  |
|  | **Supplies**  |
|  | Are procedures/tools for LF-LAM stock management /inventory management available? |  |  |  |  |  |
|  | Are supplies routinely monitored and appropriate actions taken in case of shortages?  |  |  |  |  |  |
|  | Has the testing site provided uninterruptable LF-LAM testing in the last year?  |  |  |  |  |  |
|  | Are the test kits kept in a temperature-controlled environment based on the manufacturers’ instructions? |  |  |  |  |  |
|  | Is there sufficient and secure storage space for test kits and other consumables? |  |  |  |  |  |
| ***Supplies score*** |  |  |
|  |
|  | **Ancillary equipment (timer, thermometer)** |
|  | Has all ancillary equipment been calibrated within use dates?  |  |  |  |  |  |
|  | Are LF-LAM test ancillary equipment management procedures in place and in use?  |  |  |  |  |  |
|  | Does the testing site maintain an up-to-date inventory of all ancillary equipment? |  |  |  |  |  |
| ***Ancillary equipment score*** |  |  |
|  |
| ***OVERALL SCORE*** |  |  |
| ***PERCENTAGE SCORE (Add all Sections score divide by maximum possible score x 100%)*** |  |  |

1. **SUMMARY OF AUDITOR’S REPORT FOR SPI- LF-LAM TEST**

The total points scored for each section should be tallied and recorded at the end of the section.

The overall total points obtained by each LF-LAM testing point audited will be weighed to correspond to a specific performance level.

|  |  |  |
| --- | --- | --- |
| **Levels**  | **Score**  | **Description**  |
| **0**  |  | < 40% | No capacity - Needs improvement in all areas and immediate remediation |
| **1** |  | 40–59% | Limited capacity - Needs improvement in specific areas |
| **2** |  | 60–79% | Developed capacity – not eligible for certification  |
| **3** |  | 80–89% | Demonstrated capacity -Eligible for certification |
| **4** |  | ≥ 90%  | Sustainable capacity- Eligible for certification |

|  |  |
| --- | --- |
| **Date of Assessment** |  |
| **Testing facility name:**  |  |
| **Testing site level:**  |  |
| **Type of testing site:**  |  |
| **Names of staff audited** |  |
| **No. of trained testers at site** |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Section** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **Total** |
| **Score Received (A)** |  |  |  |  |  |  |  |  |  | **A=**  |
| **Expected Score (B)** |  |  |  |  |  |  |  |  |  | **B=**  |
| **% Score = (a/ b) x 100=**  | **(\_\_\_\_\_ / \_\_\_\_\_\_) x 100=**  | **\_\_\_\_\_ %** |
| **Performance Level** |  |  |  |  |  |  |
|  | < 40% | 40–59% | 60–79% | 80–89% | ≥ 90% |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section No.** | **Deficiency/Issue observed** | **Correction Actions** | **Assessor/Supervisor’s****Comments** | **Recommendations** |
| **Immediate** | **Follow up** | **Actions** | **Timeline / Person responsible** |
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| Technical supervisor (Name, Signature & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | Assessor/Auditor (Name, Signature & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Facility supervisor (Name, Signature & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |