**LF-LAM TRAINING OF TRAINERS**

**COMPETENCY ASSESSMENT RECORD**

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| **Country:** | **Department/ Division:** | | **Unit/ Team:** |
| **Document Number:** | **Version Number:** | | **Effective Date:** |
| **Form Reviewed by (name, signature, and date):** | | **Form Approved by (name, signature, and date):** | |
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| **TRAINEE:** | **MASTER TRAINER:** | **DATE:** |
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| **Instruction to the Trainee**   1. The activities required for evaluating a trained LF-LAM tester to become a master trainer are listed in the below checklist. 2. If successful in the assessment, you may train other testers on this procedure. 3. You must be trained and competent on the LF-LAM testing procedure before being assessed as a trainer. 4. You will be evaluated as you guide the trainee(s) through the review of the documentation, and site-specific safety, testing activities relevant for this procedure. 5. You will be observed and evaluated on your ability to demonstrate the procedure for one or more trainee(s) - describing each step and answering any questions. 6. You will be observed and monitored on your ability to evaluate the trainee as they complete the procedure, providing real-time feedback on performance to make sure the procedure is followed accurately. 7. Keep the form until your competency assessment is completed, then provide to the Master Trainer for completion, any supervisory signatures, and subsequent filing with your training/ competency assessment records. | | |
| **Instruction to the Trainer**   1. The activities required for evaluating a trained LF-LAM tester to become a Master Trainer are listed in the below checklist. 2. You must ensure that the tester being assessed to become a Master Trainer is competent on the LF-LAM testing procedure in advance of the training, and fully completes this training. 3. You will observe and evaluate the ability of each trainee as they perform the procedure for their trainee(s) - describing each step and answering any questions. 4. You will observe and evaluate the abilities of the trainee as they guide one or more of their trainee(s) through review and use of all documentation, site-specific safety, and testing activities relevant for this procedure. 5. You will observe and evaluate the abilities of the trainee as they observe their trainee(s) complete the procedure, providing real-time feedback on performance to make sure the procedure is followed accurately. 6. Document completion of each step using the check boxes in the checklist below, then complete the Summary of Direct Observation Assessment fields, and sign and date the form. 7. If you are not the participant’s supervisor, forward the completed checklist forsupervisoryreview, signature, and filing with other staff records. | | |

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| **TRAINING OF TRAINERS COMPETENCY ASSESSMENT CHECKLIST**  Master Trainer to ‘x’ the appropriate box | | | | | |
| Use the checklist below to evaluate the competency of a LF-LAM tester to become a Master Trainer. While observing the the trainee’s ability to demonstrate the procedure, observe and evaluate one or more new LF-LAM testers, and provide explanation when required on the following activities, the Master Trainer marks checkboxes according to level of success for each activity [Yes, Partial, or No- , 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]. | | | | | |
|  | **LF-LAM Standard Operating Procedure (SOP) Review** | **Yes** | **Partially** | **No** | **Comments** |
| a. | Principle of the assay |  |  |  |  |
| b. | Sample type used |  |  |  |  |
| c. | Associated documents, jobaids, and forms/ logs |  |  |  |  |
| d. | Overall summary of the procedure |  |  |  |  |
| **2.** | **Safety** | **Yes** | **Partially** | **No** | **Comments** |
| a. | Overview of biosafety risks and mitigation measures |  |  |  |  |
| b. | Selection of appropriate personal protective equipments (PPE) for the test procedure. |  |  |  |  |
| c. | Adherence to safe work practices and techniques throughout the procedure. |  |  |  |  |
| d. | Cleaning/decontamination of the work area before starting and after completing work. |  |  |  |  |
| e. | Handling of biologic spills according to procedure. |  |  |  |  |
| f. | Discarding the used test materials and waste according to the procedure and testing site policy. |  |  |  |  |
| **3.** | **Pre-Analytical: Sample Collection and Test Preparation** | **Yes** | **Partially** | **No** | **Comments** |
| a. | Sample preparation requirements and the rationale for sample type selection |  |  |  |  |
| c. | Urine collection, handling, transport, and storage (pre-testing and post-testing) conditions |  |  |  |  |
| b. | Ancillary equipment maintenance, calibration, and verification requirements (as relevant to the testing site) |  |  |  |  |
| **4.** | **Analytical: Testing** | **Yes** | **Partially** | **No** | **Comments** |
| a. | Steps of the procedure (using the printed latest version SOP for reference is acceptable) |  |  |  |  |
| b. | Performing the test using fresh urine samples |  |  |  |  |
| c. | Performing the test using frozen urine samples (when applicable) |  |  |  |  |
| d. | Appropriate use of ancillary equipment (including timer) |  |  |  |  |
| **5.** | **Post Analytical: Interpretation and Reporting of Results** | **Yes** | **Partially** | **No** | **Comments** |
| a. | Reading and interpretation of internal quality control results |  |  |  |  |
|  | Reading and interpretation of patient results according to the test reference card |  |  |  |  |
| b. | Documentation of results according to the testing site policies |  |  |  |  |
| c. | Troubleshooting for various scenarios; provides appropriate rationale/ clarifications for each scenario discussed |  |  |  |  |
| d. | Quality assurance activities (routine, new lot/ new shipment, and frequency of competency assessments) |  |  |  |  |
| **6.** | **Equipment operation and routine maintenance** | **Yes** | **Partially** | **No** | **Comments** |
| a. | Use and maintain each piece of ancillary equipment with proper documentation of results: |  |  |  |  |
|  | * Timer |  |  |  |  |
|  | * Precision Pipette (if relevant) |  |  |  |  |
|  | * Centrifuge (if relevant) |  |  |  |  |

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| **Summary of Direct Observation Assessment** | | | | |
| **Overall Observation** | | **Satisfactory** | | **Comments** |
| 1. | SOP review | Yes | No |  |
| 2. | Safety | Yes | No |  |
| 3. | Pre-analytical | Yes | No |  |
| 4. | Analytical | Yes | No |  |
| 5. | Post analytical | Yes | No |  |
| 6. | Equipment operation and routine maintenance | Yes | No |  |

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| **Competency Level** | | **Comments** |
| **Qualifies as a Master Trainer** |  |  |
| **Needs retraining** |  |  |

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| **Section No.** | **Deficiency/Issue observed** | **Correction Actions** | | **Assessor**  **Comments** | **Recommendations** | |
| **Immediate** | **Follow up** | **Actions** | **Timeline / Person responsible** |
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| **Approval** | | |
| **Trainee Comments** | **Trainee signature** | **Date** |
| **Master Trainer Comments** | **Master Trainer signature** | **Date** |
| **Testing Site Supervisor (if different) comments** | **Testing Site Supervisor (if different) signature** | **Date** |