***m-PIMA HIV-1/2 Detect* COMPETENCY ASSESSMENT FORM**

Version: 29 May 2019

This assessment form is designed to assess the level of competency of personnel performing the *m-PIMA HIV-1/2 Detect* test on the *m-PIMA* device. The assessment covers specimen reception, cartridge preparation, device operation, and result communication. It is recommended that all trained Operators who conduct *m-PIMA HIV-1/2 Detect* testing should be assessed immediately after training, six (6) months after training, and then once per year thereafter. The completed assessment form should be kept in the site-level trained Operator personnel file.

**Instructions to the device Operator who is being assessed**

* Review ALL the *m-PIMA HIV-1/2 Detect* standard operating procedures (SOPs), operator manuals, logs, work instructions and workstation tasks as well as any other procedures and documents relating to the *m-PIMA* testing section.
* Under the observation of the Assessor, perform all procedures as described in the above-mentioned documents
* The Assessor will judge your level of competency based on how well you adhere to the procedures defined by the operator manuals and SOPs.
* For areas recorded as unsatisfactory, the Assessor will give you guidance for corrective action.
* In the Operator/Trainee Comments section of the form, note any comments or concerns you have, including procedures that were not clear or were missing from the training materials and SOPs.
* Print your name, date and sign the document
* Indicate whether you are a laboratory-specialized health worker by training. For example, a nurse trained on performing POC testing is not a laboratory-specialized worker, whereas someone who received vocational training in laboratory sciences would be.

**Instructions to the Assessor**

* Observe the Operator as he/she performs each step of a process. The table below defines the procedures as indicated in the operator manuals, SOPs, workstation tasks and work instructions.
* For each step performed correctly, write a tick in the YES column. If any step is performed incorrectly, write a tick in the NO column.
* If there are no more than five (5) “NO” boxes ticked throughout all categories combined, mark the satisfactory box at the end of the form, and sign and date the form.
* If more than five (5) “NO” boxes have been ticked, representing less than 90% of tasks completed correctly, mark the unsatisfactory box. Write in the Corrective Action(s) Suggested box, all actions needed to obtain a satisfactory rating on the form; and explain those actions to the Operator.
* Print your name, date and sign the document
* Ensure the Operator also signs and dates the form, and indicate whether he/she is a laboratory-specialized health worker.
* N/A indicates Not applicable

***m-PIMA HIV-1/2 Detect* COMPETENCY ASSESSMENT FORM**

Operator’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Assessor’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Laboratory-specialized health worker? YES NO If No, specify designation; \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Health Facility Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Assessment: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Observe the Operator as he/she completes the tasks in the table below, and fill in the form as follows:**

* Check the box in the “Yes” column, if the task is done according to the relevant SOP, guideline or operating procedure.
* Check the box in the “No” column, if the Operator deviated from the relevant SOP, guideline or operating procedure, even if partially deviating.
* If you check the “No” box, describe in the “Comments” box how the Operator deviated from the recommended standards.
* Check “N/A” if the task is not applicable or relevant.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1.0 Receiving and Checking a Specimen (if applicable)** |  |  |  |  |
| **Does the Operator…** | **Yes** | **No** | **N/A** | **COMMENTS** |
| 1. Check the specimen package for damage or leakage?
 |  |  |  |  |
| 1. Check that the number of specimens in the package matches the number of POC EID Testing Forms?
 |  |  |  |  |
| 1. Ensure that the ID of each specimen perfectly matches the ID on the respective POC EID Testing Form, and the ID on the specimen transport log (if transferred from spoke site)?
 |  |  |  |  |
| 1. Visually check that each specimen is of sufficient quantity (EDTA-treated specimen tube (e.g. Microvette-200) tube should contain about 200µL to have the desired EDTA final concentration)?
 |  |  |  |  |
| 1. If the ID number on the specimen tube is missing, altered, or doesn’t match the one on the POC EID Testing Form, contacts the requesting facility or unit for further information in identifying the specimen?
 |  |  |  |  |
| 1. If the ID number on the specimen tube is missing, altered or doesn’t match the ID number of the POC testing form; and the identification of the specimen is still impossible after contacting the requesting unit:
	1. Rejects the specimen and notes it in the specimen rejection logbook; and
	2. Asks for a new specimen from the requesting unit using the POC EID Testing Form with a clear mention of the reason? (verify responses by checking and reviewing the rejection logbook)
 |  |  |  |  |
| 1. Arrange specimens in a sequential order in the tube rack labelled “pre-testing” to avoid possible confusion?
 |  |  |  |  |
| **2.0 Cartridge Preparation** |
| **Does the Operator…** | **Yes** | **No** | **N/A** | **COMMENTS** |
| 1. Check the expiration date of the cartridge? Validate expiry by checking the cartridge aluminum pouch with expiry date written boldly on the labelling sticker
 |  |  |  |  |
| 1. Ensure that the cartridge pouch is well sealed, open the cartridge pouch carefully, and check that there is no damage to the cartridge?
 |  |  |  |  |
| 1. Label the cartridge with corresponding specimen ID number using a permanent marker/felt pen?
 |  |  |  |  |
| 1. Handle the cartridge carefully in order to avoid touching the Reactor Chamber at the far end of the cartridge?
 |  |  |  |  |
| 1. If the cartridge is filled directly from a heel prick, does the Operator…
 | **Yes** | **No** | **N/A** | **COMMENTS** |
| 1. Wipe away the first drop of blood and collect the second drop directly into the cartridge’s specimen capillary?
 |  |  |  |  |
| 1. Ensure that the cartridge’s specimen capillary is completely filled, that no air bubbles are introduced, and the specimen is visible in the control window?
 |  |  |  |  |
| 1. Close the cartridge lid firmly immediately after preparation?
 |  |  |  |  |
| 1. Load the cartridge into the device within 10 minutes after opening of the pouch? (open the pouch only when ready to load the specimen into the cartridge)
 |  |  |  |  |
| 1. If the cartridge is filled from an EDTA-treated tube (such as a Microvette tube), does the Operator…
 | **Yes** | **No** | **N/A** | **COMMENTS** |
| 1. Invert the tube at least seven (7) times in order to mix the specimen?
 |  |  |  |  |
| 1. Confirm that the specimen ID on the EDTA-treated tube matches the one on the cartridge?
 |  |  |  |  |
| 1. Collect blood from the EDTA-treated tube using a plain Transfer Capillary tube, and allow the capillary tube to fill approximately half way, while avoiding trapping air bubbles?
 |  |  |  |  |
| 1. Cover the end of the capillary tube with an index finger in order to hold the specimen in the tube while transferring it to the cartridge?
 |  |  |  |  |
| 1. Hold the end of the transfer capillary in angled contact with the specimen capillary of the cartridge while slowly lifting the index finger to release the specimen?
 |  |  |  |  |
| 1. Close the EDTA-treated tube and set it aside in a tube rack labeled "Tested” and keeps the leftover specimen in case an invalid test run is encountered?
 |  |  |  |  |
| 1. Dispose of the transfer capillary in a sharp container?
 |  |  |  |  |
| 1. Close the cartridge lid firmly immediately after preparation?
 |  |  |  |  |
| 1. Load the cartridge into the device within 10 minutes after opening of the pouch? (open the pouch only when specimen is ready)
 |  |  |  |  |
| 1. **Starting and Running the Test**
 |
| **Does the Operator…** | **Yes** | **No** | **N/A** | **COMMENTS** |
| 1. Create a new test by pressing “Run Test” on the device’s software main menu?
 |  |  |  |  |
| 1. Enter operator’s name and specimen ID on the device, and verify twice for a perfect match? The Specimen ID should be the same as the number written on the cartridge and POC EID Testing Form.

*[NOTE: If SMS printers are in use at spoke sites, the requesting facility number should be entered in front of the Specimen ID so that on the m-PIMA device the complete ID is in the format “123-456789”]* |  |  |  |  |
| 1. Open the door of the device without holding it open with his/her hand?
 |  |  |  |  |
| 1. Insert the loaded cartridge in the device in the direction indicated by the arrows on the front and top of the cartridge?
 |  |  |  |  |
| 1. Use a single finger to push the cartridge to the far end of the cartridge bay?
 |  |  |  |  |
| 1. Close the device door to its fully closed position by sliding the door to the far right?
 |  |  |  |  |
| 1. Remove the cartridge from the bay by completely opening the door to the extreme left to activate the eject mechanism once the test has completed?
 |  |  |  |  |
| 1. Discard the used sealed cartridge as standard biohazard waste according to protocol in place and/or national policy?
 |  |  |  |  |
| 1. Close the device door to its fully closed position by sliding the door to the far right after completing all steps?
 |  |  |  |  |
| **4.0 Interpreting and Reporting Results** |
| **Does the Operator…** | **Yes** | **No** | **N/A** | **COMMENTS** |
| 1. Record the result displayed on the screen onto the POC EID Testing Form?

*[NOTE: In addition, but NOT as a substitute, a printout can also be printed from the device and clipped to the Form or kept at the testing site for recording purposes.]* |  |  |  |  |
| 1. Keep the appropriate copy of the POC EID Testing Form for his/her filing?
 |  |  |  |  |
| 1. If the device has its modem connectivity enabled, transmits results after each test has been completed by selecting all results for export on local network from the “Archive” menu of the device Home screen?
 |  |  |  |  |
| 1. If an error occurred, documents it in the device error and specimen rejection log, and performs a re-test run (using the leftover specimen if an EDTA-treated tube was used, or collecting a new specimen if the specimen was collected directly into the cartridge)?
 |  |  |  |  |
| 1. Enter the results in the relevant clinic register where POC EID results are routinely captured?
 |  |  |  |  |
| 1. Immediately dispatch the results to the requesting unit or facility?

*[NOTE: If SMS printers are used at spoke sites, the hard copy of the POC EID Testing Form bearing the test result still needs to be returned timely to the requesting facility.]* |  |  |  |  |
| **5.0 Device Maintenance and Powering off** |
| **Does the Operator…** | **Yes** | **No** | **N/A** | **COMMENTS** |
| 1. Document daily maintenance activities in an accurate and up-to-date logbook?
 |  |  |  |  |
| 1. Confirm that the device is powered off at the end of each day?
 |  |  |  |  |
| **6.0 Stock Management** |
| **Does the Operator…** | **Yes** | **No** | **N/A** | **COMMENTS** |
| 1. Update the respective inventory stock card when reagents or consumables are used, replaced, or lost, or when invalid tests are encountered?
 |  |  |  |  |

**Operator/trainee’s performance** **□ Satisfactory**  **□ Unsatisfactory**

|  |  |
| --- | --- |
| Assessor’s Additional Comments: | Corrective Action(s) Suggested:  |
| Operator/Trainee’s Comments:  |

Assessor’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Assessor’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Operator’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Operator’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_