***Cepheid Xpert HIV-1 qual* COMPETENCY ASSESSMENT FORM**

Version: 29 May 2019

This assessment form is designed to assess the level of competency of personnel performing the *Xpert HIV-1 qual* test on the Cepheid GeneXpert instrument. The assessment covers specimen reception, cartridge preparation, instrument operation, and result communication. It is recommended that all Operators who conduct *Xpert HIV-1 qual* 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 employee’s personnel file.

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

* Review ALL the *Xpert HIV-1 qual* standard operating procedures (SOPs), operator manuals, logs, work instructions and workstation tasks as well as any other procedures and documents relating to the GeneXpert 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 upon 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 Employee/Trainee Comments section of the form, note any comments or concerns you have, including procedures that were not clear or were missing from the operator manuals or 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 employee 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 and 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.

**Xpert HIV-1 qual COMPETENCY ASSESSMENT FORM**

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

Laboratory-specialized health worker? YES NO If No, specify your 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 employee 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** |  |  |  |  |
| **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?
 |  |  |  |  |
| 1. Assign laboratory numbers to the POC EID Testing Forms and POC EID logbook (if internal lab numbers are used)?
 |  |  |  |  |
| 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 by checking that cartridge storage box if expiry date is boldly written once opened)
 |  |  |  |  |
| 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 by holding the cartridge from the sides to avoid touching the Reactor Chamber at the back of the cartridge and avoid shaking the cartridge?
 |  |  |  |  |
| 1. Open the cartridge lid and, using the transfer pipette (big) provided, add into the specimen chamber 750µl (3rd mark on pipette) of the Specimen Reagent also provided in the kit?
 |  |  |  |  |
| 1. Load the Specimen Reagent and the specimen into the cartridge within 10 minutes following opening of the pouch, while ensuring that the cartridge is at ambient temperature?
 |  |  |  |  |
| 1. Mix the specimen by inverting the EDTA-treated (e.g. Microvette) tube at least seven times?
 |  |  |  |  |
| 1. Confirm that the Specimen ID on the tube matches the one on the cartridge before opening the EDTA-treated tube?
 |  |  |  |  |
| 1. Open the Microvette tube containing the blood specimen and collect, using the transfer micropipette (small) provided, 100µl of blood from the Microvette tube by filling the micropipette up to its swan neck, while avoiding trapping air bubbles?
 |  |  |  |  |
| 1. Transfer immediately the 100µl of specimen into the specimen chamber of the cartridge?
 |  |  |  |  |
| 1. Dispose of the transfer micropipette in a sharp container?
 |  |  |  |  |
| 1. Close the Microvette 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. Close the cartridge lid firmly immediately after preparation and without delay run the test on the device (no later than 30 min after the cartridge is loaded with the specimen?
 |  |  |  |  |
| 1. **Starting and running the test**
 |
| **Does the Operator…** | **Yes** | **No** | **N/A** | **COMMENTS** |
| 1. Correctly create a new test on the instrument’s software menu, and scan the cartridge?
 |  |  |  |  |
| Enter patient and specimen IDs 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 on POC EID Testing Form.  |  |  |  |  |
| 1. Confirm that the Assay Protocol automatically selected based on the cartridge barcode matches the intended test, and does not change the module selected (done automatically)?
 |  |  |  |  |
| 1. Click on the “start test” button and insert the loaded cartridge in the module with a green light flashing?
 |  |  |  |  |
| 1. Close the instrument door properly after the cartridge has been introduced in the GeneXpert?
 |  |  |  |  |
| 1. Remove the cartridge from the bay by opening the door once the test has completed?
 |  |  |  |  |
| 1. Discard the used sealed cartridge as special biohazard waste according to the Cepheid guidance provided (high temperature incineration) and according to national policy?
 |  |  |  |  |
| 1. Close the instrument door properly after completing all aspects of the test?
 |  |  |  |  |
| **4.0 Interpreting and reporting of Results** |
| **Does the Operator …** | **Yes** | **No** | **N/A** | **COMMENTS** |
| 1. Record the result displayed on the screen onto the POC EID Testing Form/result return form?
 |  |  |  |  |
| 1. Keep the appropriate copy of the POC EID Testing Form (if used) for record keeping at the lab?
 |  |  |  |  |
| 1. Enter the results in the relevant Lab register where POC EID results are routinely captured?
 |  |  |  |  |
| 1. Immediately dispatch results to the requesting unit or facility using the POC EID Testing Form?
 |  |  |  |  |
| 1. If SMS printers are used at spoke sites, does the Operator…
 |  |  |  |  |
| * 1. Return the paper copy of the POC EID Testing Form/result return form bearing the test result to the requesting facility?
 |  |  |  |  |
| * 1. Ensure immediate electronic transmission of the result by the computer?
 |  |  |  |  |
| 1. If an error or an invalid event occurred, does the Operator…
 |  |  |  |  |
| * 1. Document the error or invalid event, including its associated code if any, in the instrument error and specimen rejection log?
 |  |  |  |  |
| * 1. Perform a re-test using the leftover specimen before deciding whether to request another specimen?
 |  |  |  |  |
| * 1. If the repeat test produces a second error or invalid result, collects or requests another specimen from the requesting facility or unit using the POC Testing EID Form?
 |  |  |  |  |
| **5.0 Instrument maintenance and Powering off** |
| **Does the Operator…** | **Yes** | **No** | **N/A** | **COMMENTS** |
| 1. Perform and document maintenance activities on the GeneXpert device in an accurate and up-to-date logbook as per manufacturer’s instruction for the…
 |  |  |  |  |
| 1. Daily scheduled maintenance?
 |  |  |  |  |
| 1. Weekly scheduled maintenance?
 |  |  |  |  |
| 1. Monthly scheduled maintenance?
 |  |  |  |  |
| 1. Confirm that the system is shut down correctly at the end of each day by exiting the software using the User menu while no cartridges are left in the device modules, by turning off the device, shutting down the computer, and finally by covering the device with its plastic protector?
 |  |  |  |  |
| **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 suggested:  |
| Operator/Trainee’s Comments:  |

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

Operator Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Operator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_