Elizabeth Glaser Pediatric AIDS Foundation

Unitaid

CONSUMPTION DATA REPORT AND REQUEST FORM FOR POC EID TEST KITS

Name of the Facility: _____ **Facility Code:** _____ **Region:** _____

Report for Period:

Month Beginning (dd/mm/yy) _____ **Month Ending (dd/mm/yy)** _____

Commodity Name	Unit of Issue (e.g. tests)	Beginning Balance	Quantity Received	Quantity Used for testing	Quantity used for training & verification	Losses (damages, expiries, & unaccounted for)	Losses (errors, invalid, & undetermined)	Adjustments	End of Month Physical Balance	Days out of stock	Quantity Requested for Re-supply

Comments (e.g. explain losses and adjustments):

Completed By: _____ **Tel:** _____ **Designation** _____ **Sign** _____ **Date** _____

Approved By: _____ **Tel:** _____ **Designation** _____ **Sign** _____ **Date** _____

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Error and Specimen Rejection Log

Name of Testing Site: _____ **POC Instrument used:** _____

Health Facility Code/Number: _____ **Instrument Serial Number:** _____

Date	**Requesting facility** (Site where the sample is originating from)	**Sample ID**	**Operator's First Name**	**Instrument Error? (tick if yes)**	**Error code**	**Specimen rejection? (tick if yes)**	**Rejection reason**	**Comments**

Name of Facility:	Month/Year mm/yy

SAFETY and PREVENTIVE MAINTENACE CHECKLIST

Day	1	2	3	4	5	6	7	8	9	1 0	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1. Cleaning of working bench																															
2. Cleaning of Device																															
3. Emptying of Biohazard Trash																															
4. Startup of the Device																															
5. Preparation of work station																															
(including materials/ cartridges)																															
6. Proper shutdown of the Device																															
when done for the day																															
7. Cleaning of working bench																															
8. Proper storage of device & commodities																															
9. Cartridge Stock Monitoring																															
10. Weekly cleaning																															
11. Monthly cleaning																															
12. Equipment not in use																															
Signature/Initial of operator																															
Signature/Initial of supervisor																															

Comments:

COUNTRY				Reporting Period (1st or 2nd half of month)		Cartrid	
Name of Testing Facility	Region	District	Assay cartridge type	From	To	Negatives	Positives

ge Consumption			Cartridge Inventory								
Total number of errors and invalids (fill in details to the right)	OTHERS (used for training or EQA, or unit wasted during sample loading)	Average daily consumption EID/day (work days)	Expired or Damaged	Stolen or Unaccounted for	Number of complete days out of stock of cartridges	Quantity of cartridges IN STOCK at the END of the reporting period	Number of Invalids without error code	Error Code 1 (from errors or invalids)		Error (from erro
								Code	Number of Occurences	Code

Errors and Invalids

r Code 2 rs or invalids)	Error Code 3 (from errors or invalids)		Error Code 4 (from errors or invalids)		Error Code 5 (from errors or invalids)	
Number of Occurences	Code	Number of Occurences	Code	Number of Occurences	Code	Number of Occurences

POC EID Testing Mentorship/Supervision Checklist

To reach our goal of using Point-of-Care (POC) to identify HIV-positive infants for ART initiation, you will provide facility-level mentorship (operator's that need quality improvement) or supervision (routine supportive visit for monitoring) focusing on: (a) Clinical Integration, (b) Technical and Operational Performance, and (3) Linkage to Care. Kindly print data management report for each site prior to site visit to serve as your reference.

Facility name: _____

Name of end-user(s): _____

Contact number of end-user(s): _____

Name and contact number of ART clinician: _____

Date mentorship conducted: _____

Mentor's name & contact number: _____

Device Serial #: _____ Device Location: _____

Activities	
Part 1. Clinical Integration	**Comments/Notes/Corrective Actions**
***Instruction**: Complete this section together with facility stakeholders (in-charge, device users, ART clinicians) in a joint opening meeting. Share data management report and key conclusion based on it. Observe clinic flow and ask relevant stakeholders. Tick the appropriate box when task/s is completed. Write N/A if not applicable.*	
Testing Schedule ☐ Ensure testing is available every day that the health facility is open ☐ Ensure infants needing EID tests can access testing on site ☐ Check and note here the days on which testing is offered _____ **Clinic Flow at the Facility** ☐ Check and note here the clinic days for pediatric ART _____ ☐ Ensure infant receives an EID result before they see a clinician ☐ Ensure an infant that tests positive receives EID results on the same day ☐ If testing volumes are high, ensure patients are prioritized for testing and check if SOP is followed ☐ Make sure ART clinic is prepared to initiate children on ART on same day that the child diagnosed HIV positive ☐ Ensure that client flow, triage, and model of care are followed after the test (check SOP triage section adherence)	
Part 2. Technical and Operational Performance	**Comments/Notes/Corrective Actions**
***Instruction**: Complete this section in the laboratory or other location where the device is located and used. You must observe safety practices, sample collection, and sample analysis and review documentations and overall management of the device.*	
Documents and Records ☐ Check if SOPs are available, in use, and adhered to by the staff ☐ Check if job aids are available and posted in a location visible to staff ☐ Ensure POC EID logbook is properly maintained ☐ Ensure QC/validation log is completed correctly ☐ Ensure error tracking sheet is up-to-date and properly completed	
Competency of Operators/End-users ☐ Ensure staff performing the test receive appropriate training **Sample Collection and Running the Test** ☐ Make sure clients are well informed on the required test, amount of sample needed, method of collecting the sample, waiting time, etc.	

before sample collection and testing ☐ Ensure client name is verified in health passport ☐ Confirm device is switched on and ready before sample collection ☐ Ensure materials are available within reach before sample collection ☐ Ensure sample collection and cartridge handling, filling, sample check, and closing are done correctly ☐ Ensure that the first drop of blood is wiped away with sterile gauze before collecting a sample using the test cartridge or capillary tube/micro tube ☐ Ensure that enough blood is collected for the sample (control window completely filled with blood) or at least 200ul using micro tube ☐ If the blood sample is collected using micro tube and it needs to be transported to testing site, ensure that samples are handled and transported appropriately ☐ Ensure that the completely filled cartridge is inserted into the device correctly and immediately after being loaded with blood ☐ Ensure user's ID and sample ID are entered correctly in the device	
Device Maintenance ☐ Ensure start-up and shut-down procedure are observed ☐ Check the device's physical condition (device, device screen, power cable, power drum, and printer) and confirm that it is free from dust. ☐ Check the location of POC testing and confirm compliance to temperature and device requirement ☐ Check device operational condition (is the device working or not?) ☐ **Yes**, the device is working ☐ **No**, the device is not working If the device is not working, note in the comment box when it broke down, the duration of breakdown, the reason for breakdown, and what was done to fix it. Follow-up with supplier, if needed. ☐ Check if the maintenance checklist is up-to-date and discuss with staff if they performed the appropriate actions to maintain device functionality	
Keeping the Area Clean, Organized, and Safe ☐ Ensure workstation is maintained clean, organized, and set-up for efficient operation ☐ Check storage of reagents and confirm compliance to temperature (ambient 2-30° C) and reagent requirements ☐ Ensure adherence to universal safety precautions? E.g., Wear gloves ☐ Check that the bio-hazard waste bin is available and in use	
Reagents and Supplies ☐ Check if there are adequate POC supplies (cartridges, sample collection kits, and thermal papers) and restock as necessary ☐ Maintain inventory of POC commodities ☐ Check expiration dates of stocks on hand	
Test Volume Monitoring & Data Collection ☐ Collect number of tests run by end-users (check logbook and device archives) ☐ Collect total number of tests done in the facility (from POC logbook) and export data from device archives	
Test Error Code and Rate Monitoring ☐ Ensure error codes are clearly recorded ☐ Ensure number of repeat tests done due to error is clearly recorded ☐ Check error rate and error trend by error codes. If a number of errors	

happens consecutively, collect service export data and send to supplier technical person (for timely error code resolution and device swap out)

Test Results Management

- ☐ Ensure test results are clearly recorded and up-to-date in the logbook
- ☐ Ensure test results are returned to the patient on the same day
- ☐ If the result is "detectable" ensure that a repeat test is performed according to the POC testing algorithm or SOPs
- ☐ If the result is confirmed as, "detectable," ensure that the HIV-positive infant is initiated on ART on the same day (See Part 3: Linkage to care)

Result Verification/EQA (*if applicable during time of visit)*

- ☐ Ensure QC run passed in order to validate the test result
- ☐ Ensure that DBS samples were collected and sent to referral lab as scheduled (duplicate testing in lieu of EQA PT panels)
- ☐ Check and follow up on previous DBS results if they have not yet been returned to the facility
- ☐ If EQA PT panels are available, ensure that the PT samples are labeled correctly and run as part of routine testing. EQA PT results should be recorded and submitted as per the NPHL's EQA PT instructions

Connectivity Management

- ☐ Check if the device sends results successfully. If not, check network strength. If network strength is ok, check if server is online. If server is ok, check device configuration. If device connection is ok, check SIM credits. If all are ok and it is still not sending, record observations in the comment box and export data if necessary.

Part 3. Linkage to Care | **Comments/Notes/Corrective Actions**

Instruction*: Complete this section from the ART clinic or where the infant master cards/files are stored. Bring the POC EID logbook with you and use it to verify the documentation and if HIV-positive infants are on ART*

- ☐ Ensure there is a referral linkage established within the facility that goes both to and from other child care services and inter-facility referral linkages
- ☐ Cross check POC EID logbook and ART register/patient file to confirm the HIV-positive children initiated on ART (record verification findings in the space below)
- ☐ Check and follow-up on facility interventions to increase identification of HIV-exposed children from various entry points to optimally use the device (use comment box to describe intervention/s)

Verification (for HIV-positive infants only beginning after last mentorship to date)

- Are infants diagnosed HIV-positive initiated on ART? ☐s, all of them Yes ☐me of them No ☐
- Tick the corresponding number of infants recorded in the POC EID logbook (row 2), if the same infants are recorded at ART register/patient file (row 3), and number of days passed between EID result and ART initiation (row 4). Write on the back if table below is not enough (if HIV-positive infants are more than 10).

Row 1 (Px #)	1	2	3	4	5	6	7	8	9	10
Row 2 (lab)										
Row 3 (ART)										
Row 4 (TAT)										

- If any did not have EID result recorded accurately, why? Describe corrective actions to be taken (if applicable).

- If any had >1 day between EID result and ART initiation, why? Describe corrective actions to be taken (if applicable).

Part 4. Recommendations	
Instruction: *Complete this section together with facility stakeholders (in-charge, device users, and ART clinicians) in a joint closing meeting. Share overall observations, corrective actions and specific recommendations. Leave a copy of this summary of key findings for the facility for their records and for any follow up to be addressed in agreed timelines. Use back page if the space is not enough.*	
Additional Notes/ Overall Recommendations:	
Specific Recommendations and Follow up:	
Device Users/Operators:	**ART Clinicians:**

Mentorship/Supervision verified by:

_____	_____
Mentor/Supervisor's Name and Signature	Facility In-Charge Name and Signature
_____	_____
Date	Date