POC EID Implementation Site Monitoring Checklist: Hub Testing Site

Facility name:

Name(s) of trained instrument operators/end users:

Date of monitoring visit:

Name(s) of monitors or supervisors:

Observe and ask about the activities in the table below. For each activity, check the appropriate box to indicate if the activity is being done (Yes), partially done (Partial) or not being done (No). If an activity is partially or not done, write a brief explanation and describe the assistance or mentoring provided. If possible, observe at least one instrument operator performing a test. Provide assistance and mentoring as needed or requested. Enter additional information as required, such as the number of POC EID Testing Forms collected.

Part 1. Clinical Integration	**Yes**	**Partial**	**No**	**Comments/Notes**
Adherence to testing algorithms: *(NOTE: Review patient registers, POC EID testing forms, and discuss with facility staff)*				
1.1 All infants who qualify for EID testing have a sample drawn and analyzed on the same day.				
1.2 All EID test results are conveyed to caregivers on the same day as the sample is drawn.				
1.3 All infants who have a positive initial result have a second POC sample run for confirmation on the same day.				
1.4 All infants who have a positive initial POC result are initiated on ART the same day.				
1.5 For all infants who have a positive initial POC test result, but a negative second POC test result (i.e. discordant result), a DBS sample is sent to a reference lab, and contact information is collected from the patient for follow up.				
Patient flow: *(NOTE: Observe the facility and discuss with staff)*				
1.6 There is sufficient waiting room space for caregivers to wait for the results of POC tests.				
1.7 According to health facility staff, over the past two weeks, approximately how much time (in minutes) did caregivers typically wait between sample draw and return of results to the caregiver?	_____minutes			
1.8 The health facility has more than one clinic, ward, or service from which HIV-exposed infants can be referred for POC EID testing (e.g. PMTCT clinic, nutrition ward, pediatric in-patient ward, immunization clinic).				
a. If yes, is the health facility taking actions to increase testing of infants from different entry points (e.g. clinics, wards, services)?				
1.9 The health facility is testing infants on POC EID who are referred from more than one entry point within the same health facility.				
a. If yes, are infants being tested from PMTCT clinics or services?				
b. From nutrition wards or services?				
c. From in-patient wards?				
d. From immunization clinics or services?				
e. Others (please describe): _____				
Part 2. SOPs, Job Aids and Documentation	**Yes**	**Partial**	**No**	**Comments/Notes**
SOPs, job aids, registers, tracking logs, and testing forms: *(NOTE: Observe the facility, discuss with staff, and review error logs and testing forms)*				
2.1 SOPs and job aids are available in the appropriate language.				
2.2 SOPs and job aids are available and visible to staff (e.g. job aids are hung on the wall, training manuals are near the testing platform).				
2.3 SOPs and job aids are used and adhered to by all staff.				
2.4 ANC, PMTCT and ART Initiation registers from the previous three months are properly and completely filled out.				
2.5 An *Error and Specimen Rejection Log* and sections from the				

training manual describing the meaning of error codes are placed next to the instrument.				
2.6 The *Error and Specimen Rejection Log* is up to date and properly filled in.				
2.7 A photo of the *Error and Specimen Rejection* log was taken for analysis by project staff (i.e. to track machine performance).				
2.8 *POC EID Testing Forms* from the previous three months are properly and completely filled out.				
2.9 *POC EID Testing Forms* were collected during the monitoring visit for data entry.				
a. If yes, indicate the number of forms collected:	_____ forms			
Part 3. Operator Training and Performance	**Yes**	**Partial**	**No**	**Comments/Notes**
Training and competency of instrument operators/end-users: *(NOTE: Discuss with facility staff and platform end users)*				
3.1 All staff performing POC testing received initial instrument training from a certified trainer.				
3.2 All staff performing POC testing have passed a competency assessment.				
3.3 All staff performing POC testing have received initial training, or refresher training, from a certified trainer within the last 12 months.				
Observation of operator(s)/end user(s): *(NOTE: If possible observe at least one instrument operator/end user)*				
3.4 The instrument operator is able to explain the correct procedure for device start-up and shut-down (*NOTE: If needed, observe the operator as they start-up and shut down the instrument).*				
3.5 Before the sample is drawn, the POC instrument is switched on and ready.				
3.6 Before the sample is drawn, materials, such as lancets, alcohol wipes, and gauze are available and within reach.				
3.7 Before sample collection and testing, the caregiver is informed about the purpose of the test, the method of collecting the sample, and the waiting time for return of results.				
3.8 The operator correctly: (a) handles and fills the cartridge; (b) checks the sample; and (c) closes the cartridge.				
3.9 Before running the test in the POC instrument, the infant's name is verified.				
3.10 The operator correctly inserts the cartridge into the instrument.				
3.11 The operator correctly enters the User ID and Sample ID into the device.				
3.12 The operator adheres to universal safety precautions for the handling of human blood (e.g. wears gloves and protective clothing, washes hands, disposes of lancets in puncture resistant containers, changes gloves after each specimen).				
Part 4. Instrument Placement and Performance	**Yes**	**Partial**	**No**	**Comments/Notes**
Instrument placement: *(NOTE: Observe the area where the instrument is placed)*				
4.1 The instrument is located in a secure area or room where it cannot be easily damaged or stolen. If needed, the room can be locked, or the instrument is fastened to a table with a lock.				
4.2 There is a thermometer in the room where the POC instrument is located.				
4.3 The room where the instrument is placed is maintained at an appropriate temperature and humidity at all times (e.g. 10 to 40^{o}C for Alere q, 15 to 30^{o}C for Cepheid).				
4.4 The work area around the instrument is clean, well-organized, and set up for efficient operation of POC testing.				
4.5 There is a bio-hazard waste box in the room where the instrument is located. It is being used and not over-filled.				
Instrument performance: *(NOTE: Observe and discuss with facility staff and platform end users)*				
4.6 The instrument is in good physical condition. *(NOTE: Check the instrument, the instrument screen, power cable, power drum, and printer)*				

4.7 Over the past month, how many hours was the instrument not operational (i.e. broken, not able to run POC tests)? *(NOTE: If not operational for any amount of time, explain why in the comments box.)*	_____ hours			
Part 5. Inventory and Waste Management	**Yes**	**Partial**	**No**	**Comments/Notes**
Reagents and Supplies: *(NOTE: Observe and discuss with facility staff)*				
5.1 All supplies needed to perform POC testing are available at the facility (e.g. cartridges, gloves, lancets, alcohol wipes, gauze, and thermal paper).				
5.2 The area where POC testing supplies are stored is clean and well organized.				
5.3 There is a thermometer in the area where testing cartridges (i.e. reagents) are stored.				
5.4 Testing cartridges (i.e. reagents) are stored at the required temperature of 2 to 30° degrees Celsius.				
5.5 Stock cards for POC supplies are used and kept up to date. (*NOTE: For each individual product, stock cards should indicate the quantity of stock received, on hand, and lost/expired as well as adjustments, such as transfers of stock to another facility*).				
5.6 In the last 90 days, there have been stock outs of supplies needed to perform POC testing. (*NOTE: If yes, the reason for stock outs in the comments box.)*				
a. If yes, which products were not available?				
b. Approximately how long did the stock out last (in days)?	_____ days			
5.7 A physical count of POC EID cartridges was completed within the last four (4) weeks.				
a. If yes: what was the date of last physical count:	DD MM YY			
b. How many cartridges were reported on that date:	_____ cartridges			
5.8 If there is any concern about inventory management, and time permits, conduct a physical inventory of POC supplies and cross check the quantities available against those written in the stock cards. Do the quantities match those indicated in the stock cards?				
Waste management: *(NOTE: Observe and discuss with facility staff)*				
5.9 Cepheid cartridges are used at this location.				
a. If yes, Cepheid EID and Viral Load cartridges are disposed of using a high-temperature incinerator (>1000 °C).				
Part 6. Linkage to Care	**Yes**	**Partial**	**No**	**Comments/Notes**
6.1 Infants diagnosed as HIV-positive on POC instruments are referred the same day to child services *within the health facility* for linkage to care.				
6.2 Infants diagnosed as HIV-positive on POC instruments are referred the same day to child services *at another health facility* for linkage to care.				
6.3 In the previous three (3) months, all infants diagnosed as HIV-positive were successfully linked to ART services *(NOTE: If possible, cross check positive cases in POC EID Testing Forms or logbooks against the facility's ART register)*				
Part 7. Receiving samples from spoke sites (for hub sites only)	**Yes**	**Partial**	**No**	**Comments/Notes**
7.1 There is a log book for sample reception from spoke sites.				
a. If yes, the log book is properly filled out.				
7.2 Samples are received from spokes sites within 24 hours of sample collection (if kept at room temperature) or within 72 hours of collection (if kept at 4 degrees C).				
7.3 Samples are transported in appropriate conditions (e.g. in cool box if kept at 4 degrees C)				
7.4 All samples arrive with EID request forms appropriately filled out and with linked sample.				
7.5 Samples from spokes sites are tested as soon as they arrive.				
a. If samples are not tested immediately, how many hours typically elapse between the time when samples are delivered to the hub site and when they are tested?	_____hours			

Part 8. Mentoring, Training, and Information Sharing

- *List the topics covered and the recipients of mentoring, training and information sharing.*
- *List recommendations or plans for future training, mentoring or information sharing.*

Part 9. Suggestions for Improving POC EID Implementation

- *Additional notes, recommendations, or follow-up needed to improve the quality of POC EID services.*