

# Sample Collection for POC EID

## Supplementary Content 1: Sample Collection and Handling

# Agenda

1

Learning Objectives

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Specimen Management

3

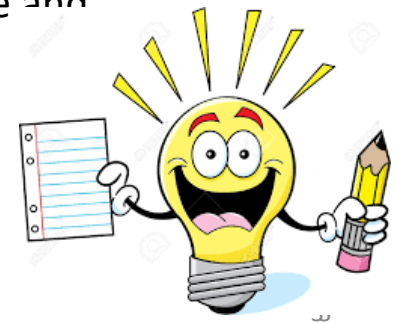
Sample Collection: Capillary Blood

4

Sample handling, storage and transport

At the end of this topic participants should be able to:

- Know and understand the steps of specimen management
- Learn procedures for collecting capillary blood by heel prick
- Collect Dried Blood Spot (DBS) samples for infants
- Discuss proper handling of samples to maintain specimen integrity during storage and transport



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Sample Collection: Capillary Blood

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Sample handling, storage and transport

The quality of the specimen obtained in the pre-analytical phase of testing is crucial to the output of accurate and reliable results

Steps in specimen management:

1. Specimen collection
2. Specimen rejection
3. Specimen handling
4. Specimen referral
5. Specimen storage
6. Specimen transport



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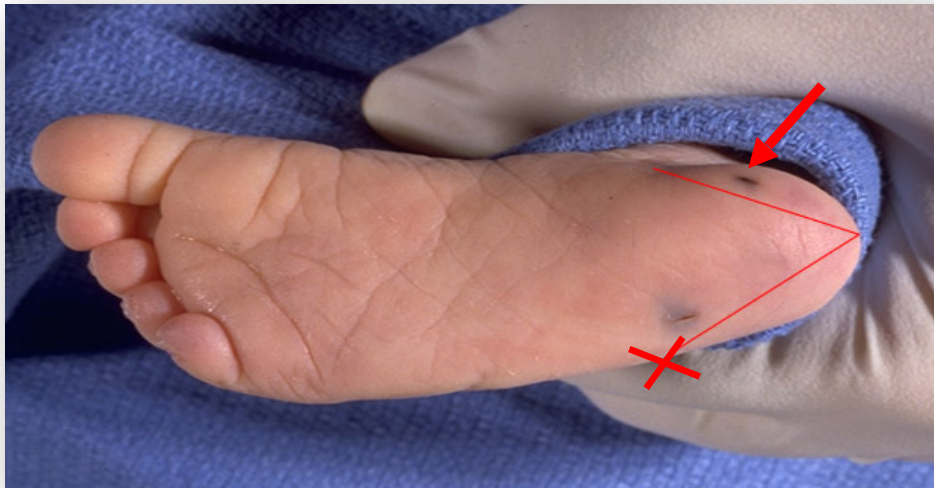
Sample Collection: Capillary Blood

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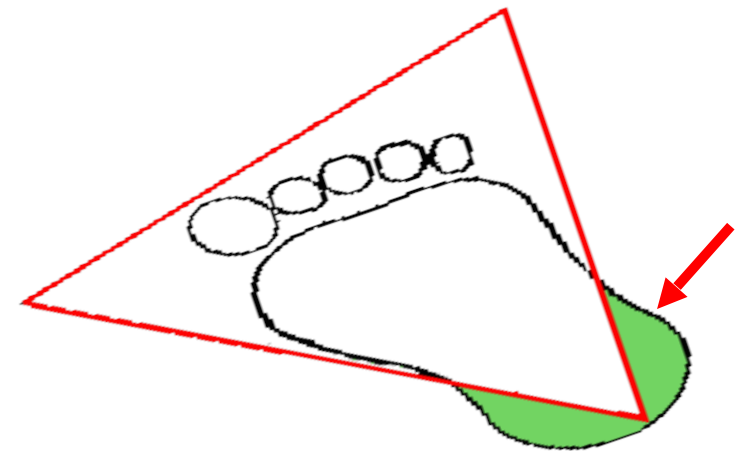
Sample handling, storage and transport

## Best location to collect capillary blood samples

The recommended location for blood collection on a newborn baby or infant (< 4 months) is the edge of the heel. The diagram below indicates in **green** the proper area to use for heel punctures for blood collection.

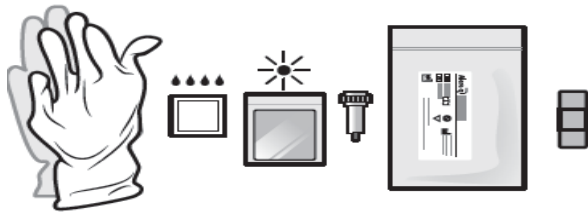


Two heel-sticks have been performed on this baby. One of them has been performed **correctly**. One was performed **improperly**.

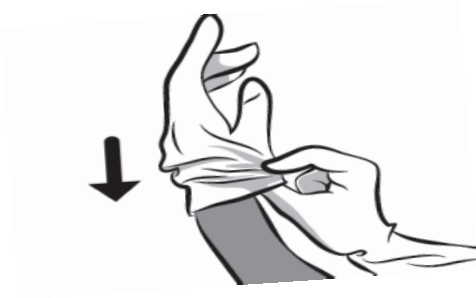


# Sample collection: capillary blood

## A. Collecting Heel-prick capillary blood direct to cartridge



① Prepare workstation: Gather necessary materials to perform the test



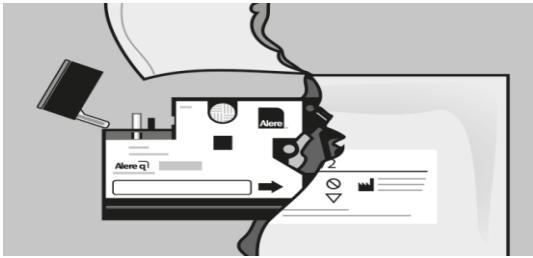
② Always wear a new pair of gloves for every patient!



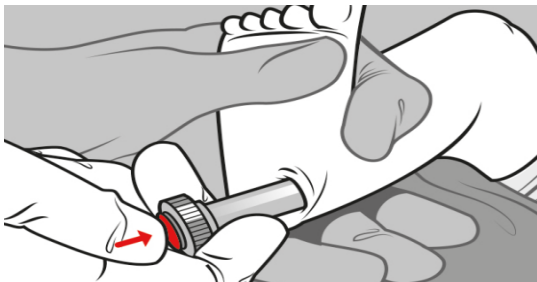
③ Select a site for heel prick. Wipe the heel with an alcohol swab and allow the alcohol to air dry.

## Sample collection: capillary blood

### A. Collecting Heel-prick capillary blood direct to cartridge



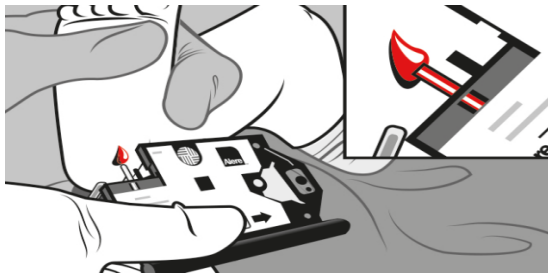
④ Remove a test cartridge from its pouch and completely flip open the cartridge cap. Only open the foil pouch when ready to load sample on the cartridge and process within 10 minutes. Write patient ID on cartridge.



⑤ Perform heel prick: Use sterile lancets to make a skin puncture. It is important to press lancet firmly onto the heel and maintain contact while ejecting the lancet.

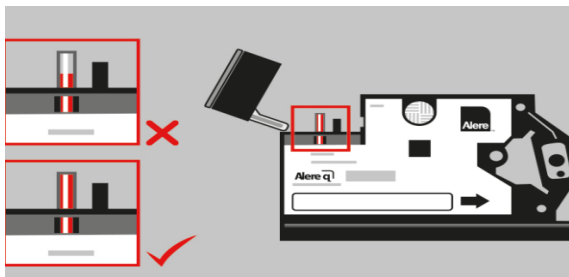
## Sample collection: capillary blood

### A. Collecting Heel-prick capillary blood direct to cartridge



#### ⑥ Collect specimen:

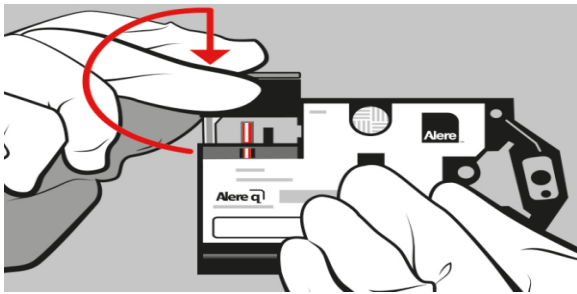
If necessary, massage gently the heel to ensure steady blood flow. Wipe away the first drop of blood with a dry and sterile gauze pad. If necessary, wipe off another drop, until blood flows freely.



⑦ Hold cartridge in a firm grip and ensure visibility of the control window. Position sample capillary directly in contact with the blood drop. The capillary should be filled swiftly and completely. After collection, apply gauze with gentle pressure to stop bleeding.

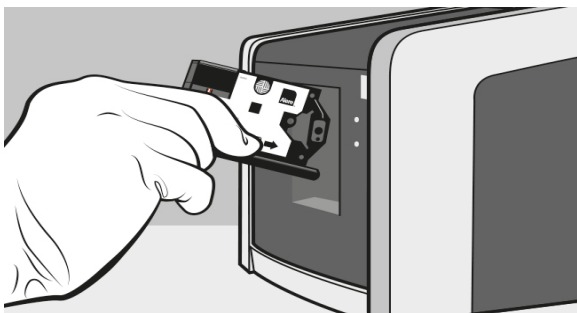
## Sample collection: capillary blood

### A. Collecting Heel-prick capillary blood direct to cartridge



⑧ Stop filling when the sample capillary is full, confirmed by observing the control window.

Completely close the cartridge cap



⑨ Select «Run Test».

The «Insert new cartridge» screen appears.

Open the Alere q door.

Insert loaded cartridge into the Alere q in the direction indicated by the arrow on the cartridge label and manually close the door.



## B. Collecting Heel-prick capillary blood using a microtainer



① Prepare workstation: Gather necessary materials to perform the test. Label microtainer tube with patient ID, date and time of sample collection.



② Always wear a new pair of gloves for every patient!



③ Turn patient's heel upward. Massage patient's heel to increase blood flow.

### B. Collecting Heel-prick capillary blood using a microtainer

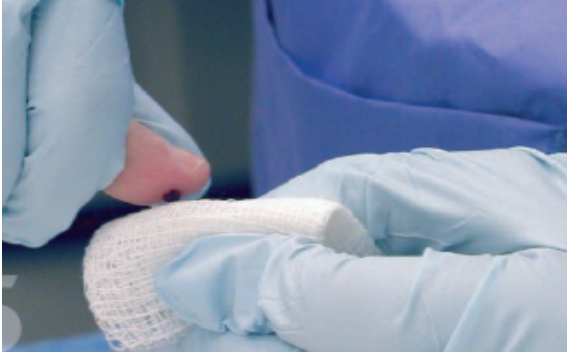


④Scrub the patient's heel with an alcohol swab. Dry with gauze

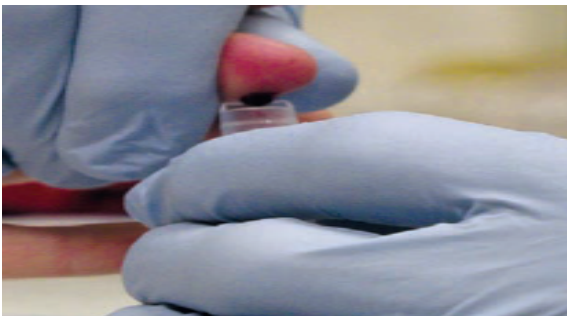


⑤Hold the heel in an upward position and lance the side of the heel with proper auto lancet.

### B. Collecting Heel-prick capillary blood using a microtainer



⑥ Apply slight pressure to start blood flow. Wipe the first drop of blood on a gauze pad and discard pad in appropriate biohazard container



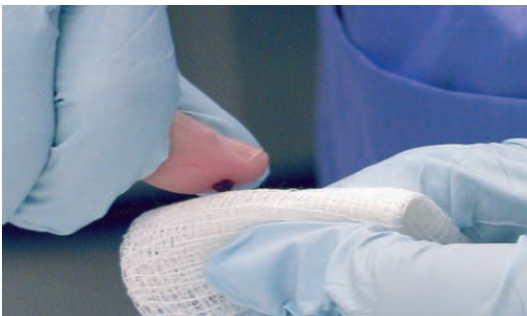
⑦ Keep the heel in the downward position and gently massage it to maintain blood flow. Hold the microtainer at an angle of 30 degrees below the collection site and use the scoop or funnel on the microtainer to fill it to the 250-500 ul level



### B. Collecting Heel-prick capillary blood using a microtainer



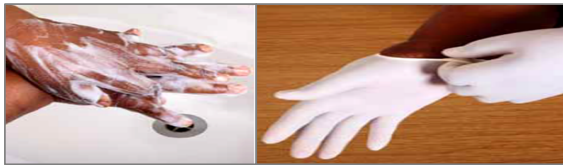
⑧ Cap the microtainer and gently invert it 10 times to prevent clots from forming. Properly discard all used materials and refrigerate the sample until shipment or analysis



⑨ Apply gauze with gentle pressure to stop bleeding

# Sample collection: capillary blood

## C. Collecting Heel-prick capillary blood direct to DBS card



① Get all the materials ready and available within reach

② Always use Universal Safety Precautions: Wash hands and dry thoroughly and put on powder-free gloves

③ Clearly label each card with Infant ID number and date sample collected. Completely fill out and cross-check necessary forms and samples.



## Sample collection: capillary blood

### C. Collecting Heel-prick capillary blood direct to DBS card



Newborn infants 1-4 months (<5kg) - puncture the heel

Infants 4-12 months (>5kg) - puncture the lateral side of big toe

Infants 12-15 months (>10kg) - puncture the 3<sup>rd</sup> or 4<sup>th</sup> finger of the hand the baby uses less



- ④ For Infants, keep the foot down to help the blood flow more easily. Warm site with soft cloth moistened with warm water up to 40C for 3 to 5 minutes or by gentle massage.

## Sample collection: capillary blood

### C. Collecting Heel-prick capillary blood direct to DBS card



⑤ Use alcohol swab to clean the site. Start in the middle and work outward to prevent contaminating the area. Allow the area to dry

Note: Failure to allow alcohol to dry may dilute the specimen



⑥ Hold the heel and firmly place a new sterile lancet off-center on the edge of the heel, toe or finger.

Firmly press the lancet to puncture the fingertip or edge of the heel



## Sample collection: capillary blood

### C. Collecting Heel-prick capillary blood direct to DBS card



⑦ Wipe the first drop of blood. The initial drop contains tissue fluid that may dilute the specimen.

Allow another large blood drop to form before starting collection.



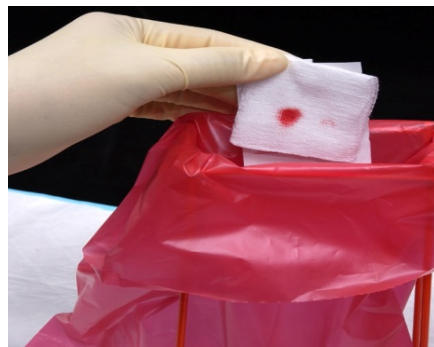
⑧ Fill the entire circle of the DBS card. Allow to soak through and completely fill the circle. Complete all 5 spots (minimum of 3 circles).

## Sample collection: capillary blood

### C. Collecting Heel-prick capillary blood direct to DBS card



⑨ Stop the bleeding by applying gentle pressure. Wipe and clean the area (wipe out excess blood). Leave with no bandage



⑩ Properly dispose of all contaminated supplies.

## Preparing DBS from blood collection tube using calibrated precision pipette

Perform phlebotomy to collect venous blood or Finger/Heel-Prick to collect blood in microtainer tube.

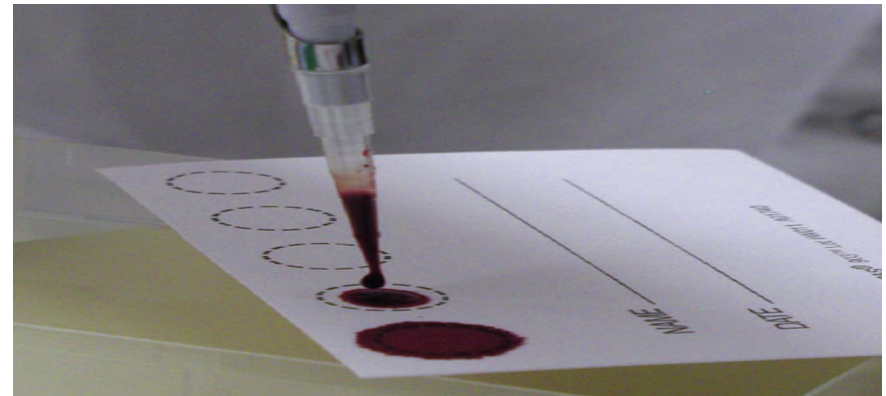
Mix blood sample 10 times by inversion to prevent clot from forming and to equilibrate before performing the test.



Using the precision pipette calibrated to 70ul, fill entire circle of the DBS card.

Allow to soak through and completely fill the circle.

Complete all 5 spots.

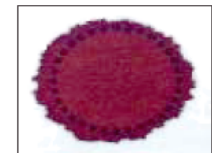


## Validate DBS specimen

Inspect card to ensure you have collected enough blood, and the specimen is valid

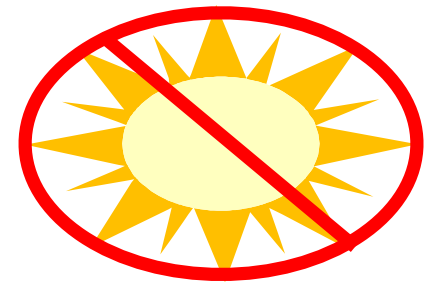
Minimum of 3 completely filled circle is better than 5 insufficient samples

Note: A test result is as good as the sample collected



## Criteria for validating a DBS sample

- The samples should be properly labeled.
- All the 5 circles should be properly filled, or at least 3 spots
- The spots on a DBS sample should not be in contact with anything or any other sample
- The DBS sample should not be heat-fixed; it should be air-dried away from the sun.



## Criteria for rejecting a DBS sample

- Insufficient quantity of blood
- The spots are discolored, contaminated or diluted.
- Blood spots appear coagulated.
- Blood spots appear layered, abraded or scratched.
- Blood spots presents serum rings
- Dirty DBS
- DBS/ filter paper not properly dried.
- Poor labeling or no label

### Invalid specimen:



1. Specimen quantity insufficient for testing.



2. Specimen appears scratched or abraded.



3. Specimen not dry before mailing.



4. Specimen appears supersaturated.



5. Specimen appears diluted, discolored or contaminated.

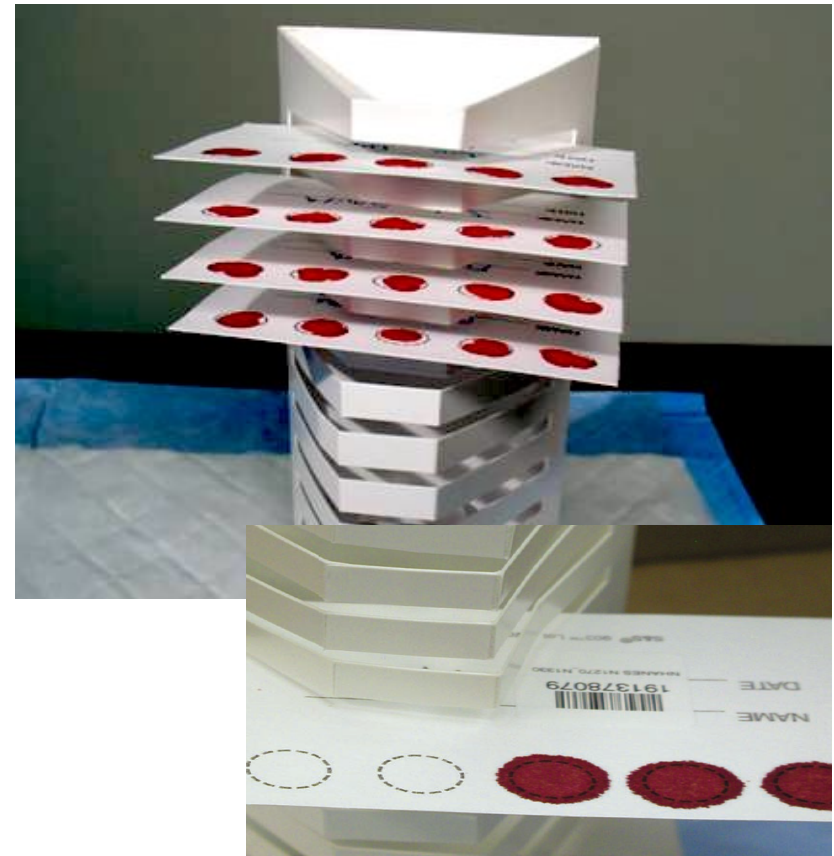
## Drying the DBS cards

11 Place filter paper horizontally with the spots at the exterior on a clean drying rack to AIR DRY for at least 4 hours or overnight

Do not heat-dry DBS samples

Keep away from direct sunlight, dust, and bugs

Do not allow blood spots to come into contact with any surface or with each other.

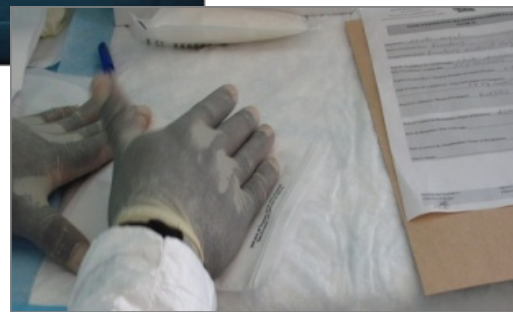


## Packaging DBS samples



12 Pack each DBS card with desiccants and humidity indicator cards into a small Ziploc bag

Press out the air completely and seal.



## Packaging and handling DBS samples



- 13 Place bag into envelope

Add lab requisition form and specimen delivery check list

- 14 Keep packaged DBS (in sealable ziploc bags) in a dry, cool and airy area of the lab free from dust, heat, insects and sun (preferably in a drawer) until transported to reference laboratory



**Avoid leaving in vehicle, as sun and heat will deteriorate DBS**



15 Clearly label outside of the envelope

Fill up any Sample referral logs ( HF staff & courier/ transporter)

Transport to designated reference laboratory for processing

Register all the samples you send to the reference Lab in your integrated Lab register



**Avoid leaving in vehicle, as sun and heat will deteriorate DBS**

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Sample handling, storage and transport

## Sample Handling

A summary of the sample handling recommendations for EID testing as per assay device requirements:

### GeneXpert: Sample storage and transport Requirements

#### Whole blood Sample in EDTA microtainer tube

Temperature and storage time

+31 to +35°C → 8 hours (EID only)

+15 to +30°C → 24 hours (EID)

+2 to +8°C → 72 hours ( EID)

#### DBS Sample (EID)

Temperature and storage time

+2 to +25°C → 12 weeks

+31 to +35°C → 8 weeks

### Alere q EID: Sample storage

If testing is not possible right after collection, capillary blood can be stored at 18-28 °C for up to 24 hours after draw and before testing.

### Cartridge Storage

Should be stored between 4 -30°C

Questions?



Thank You!

## Acknowledgments

The development of the POC EID Training Package was made possible thanks to Unitaid's support.



Unitaid accelerates access to innovation so that critical health products can reach the people who need them.



# Data Management for POC EID

Supplementary Content 2: Use of logbooks for record keeping

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Learning Objectives

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Importance of documentation and keeping record

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Use of Logbooks

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M&E Indicators

At the end of this topic participants will be able to:

- Understand the importance of correct recording and documentation
- Learn how to completely fill in the logbooks and forms that will be used within the POC EID program
- Understand the role of M&E and schedule for routine data collection



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M&E Indicators

- Documentation plays a crucial role in any test and treatment program setting
- Documentation is the only to assure the quality of care provided to clients is not only maintained, but can be consistently improved
- Documentation is necessary to identify problems within the health facility itself and overall health care system; accurate records are needed to find effective solutions to current problems and prevent others from happening in the future
- Another way to look at documentation is to echo the old philosophical question: “If a health care worker renders services and there is no documentation to support it, did it happen?”

**No documentation = No work done!**

## Why is good record keeping important?

- Well kept records are the primary source of information for providing effective, high-quality health care services; good recordkeeping underpins the entire testing and treatment program.
- Managing and improving any health care program relies on this information, without it the program cannot function. Good recordkeeping means that information is available where and when it is needed.
- Consistent, high-quality recordkeeping allows programs to trust the information that is available.
- If a program can easily access and trust information then it can be used to make more informed decisions and to take appropriate actions to solve problems and improve the quality of services provided.

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M&E Indicators

[Before the start of the training, insert here a copy of the POC EID testing logbook or register that will be used at the facility. During the training, discuss each field of the logbook and how it should be completed]

When discussing each of the next slides, clearly indicate who should complete each record, when the record should be completed, and what format the data should be in.

[Before the start of the training, insert here a copy of the lab request form that will used at the facility (if applicable). During the training, discuss each field of the lab form and how it should be completed]

[Before the start of the training, insert here a copy of the logbook that will be used to track rejected tests/ errors that will used with the POC device. During the training, discuss each field of the logbook and how it should be completed]

# Safety and Preventive Maintenance Checklist

Name of Facility:  Month/Year

SAFETY and PREVENTIVE MAINTENANCE CHECKLIST																															
Day	1	2	3	4	5	6	7	8	9	10	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:																															

[Before training, update this slide with different image if an alternative checklist will be used for safety and preventive maintenance – this image is of the generic checklist provided in the POC EID Training Toolkit]

[Before the start of the training, insert images of the forms that will be used for consumption tracking and/or inventory management for POC EID products.]

[Before the start of the training, insert images of any additional records/logbooks/forms that will be used during POC EID testing. Insert as many slides as needed to cover all record keeping sources.]

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M&E Indicators

- M&E is a process that helps improve program performance and achieve results
- The M&E process involves collecting and analyzing data in order to make informed decisions about program performance, management and resource allocation
- M&E can be conducted at the facility, region or national level
- All M&E relies on complete, accurate data

### Goal of POC EID

To expedite clinical decision-making by reducing test turn-around time for EID, thereby enabling earlier treatment initiation for HIV-positive infants

#### Impact

- Improve quality of life for HIV-positive infants
- Increase survival rate of children diagnosed with HIV

#### Outcomes

- Increase access to high-quality POC EID testing
- Accurately identify HIV-positive Infants
- Decrease time to treatment initiation for HIV-positive infants

- Number of POC EID tests performed and results returned to caregivers
- Number of HIV-positive infants identified through the use of POC EID
- Proportion of caregivers receiving EID test results on the same day as the test
- Proportion of HIV-positive infants initiated on ART within 2 months of testing
- Turnaround time from EID sample collection to ART initiation
- Error rates, rate of device utilization, and operator performance metrics as captured through testing data automatically recorded by the POC device
- Device functionality including frequency and reasons for inability to use the device (e.g. stock outs, breakdowns, etc.)

[Before the start of the training, add any additional M&E indicators that will be included in the national M&E program]

## M&E Data collection plan

[Before the start of the training, include here a list of data sources that will be used for routine M&E and the frequency of M&E data collection (eg. monthly, quarterly, semi-annually). Examples of data sources include: POC EID register, patient records, mentorship reports, service and maintenance logs, onboard device data etc.]

Questions?



Thank You!

## Acknowledgments

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# Quality Assurance for POC Testing

Supplementary Content 3: QA, Mentorship and Operator Certification for POC EID Testing

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Quality Assurance (QA) framework and QA for EID POC Testing

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Use of SPI -POCT checklist or equivalent to certify POC EID Sites

4

Use of supervision/mentorship checklist

5

Use of connectivity to monitor performance

6

Q&A

At the end of this topic participants will be able to:

- Understand the country's QA framework
- Explain QA approaches for POC EID
- Understand and learn how to use the SPI-POCT checklist to assess facility performance
- Understand and learn how to use the mentorship/supervision checklist during field visits
- Understand how connectivity can be used to monitor program performance



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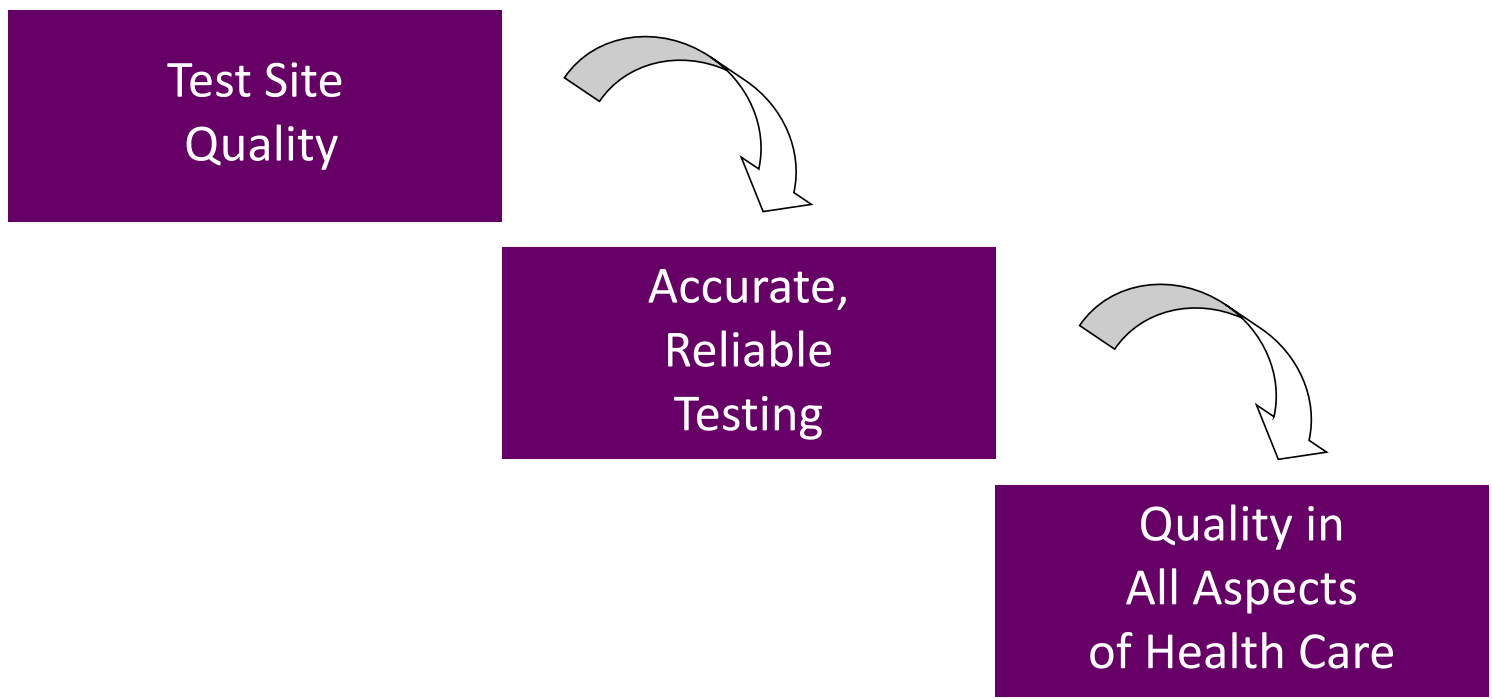
Use of supervision/mentorship checklist

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Use of connectivity to monitor performance

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Q&A



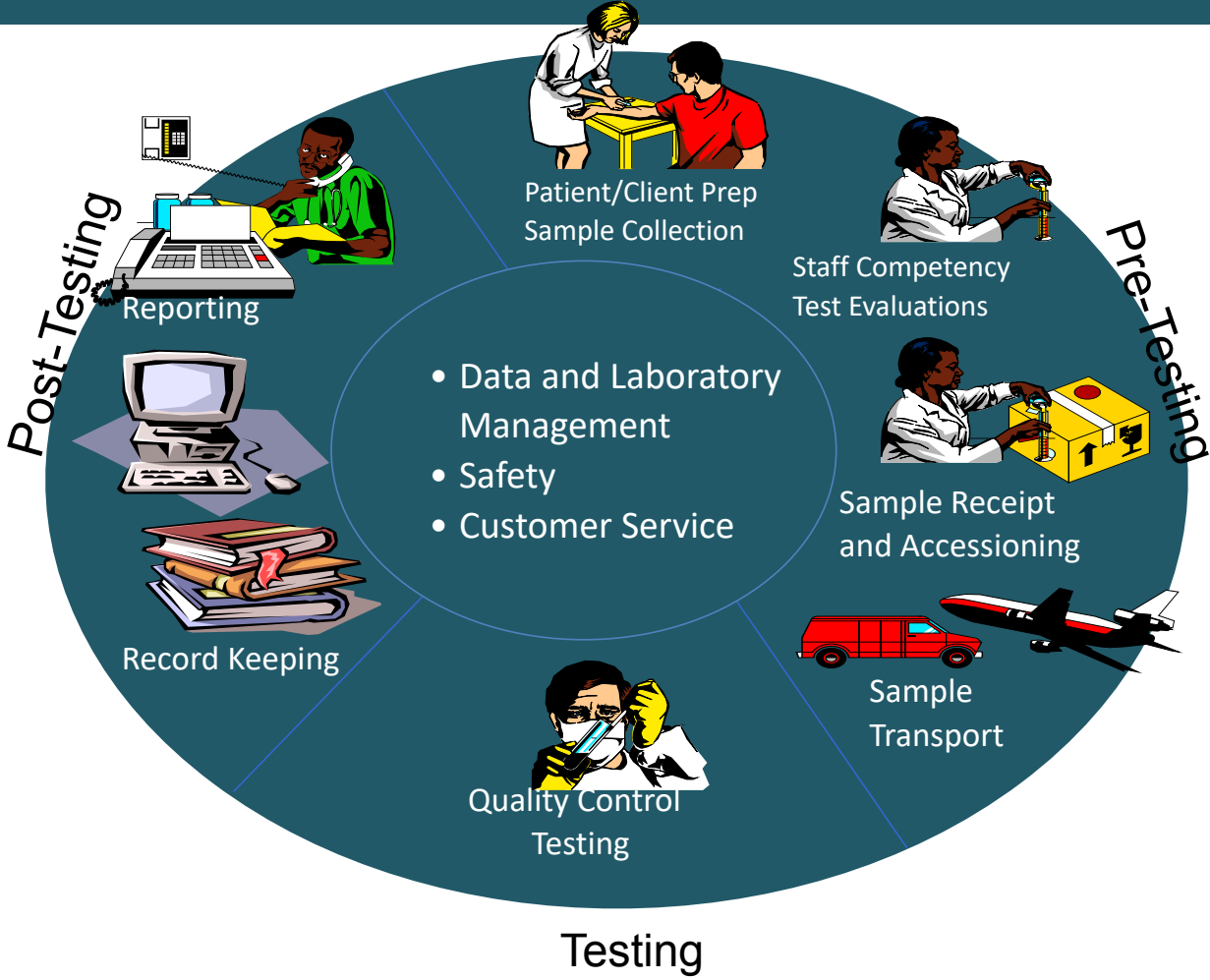
# The Laboratory Quality System

The organizational structure, responsibilities, processes, procedures, and resources for implementing quality management of the laboratory or testing site.

In other words...all activities contribute to the quality of testing, directly or indirectly!



# Quality Assurance should be implemented in all phases of Testing



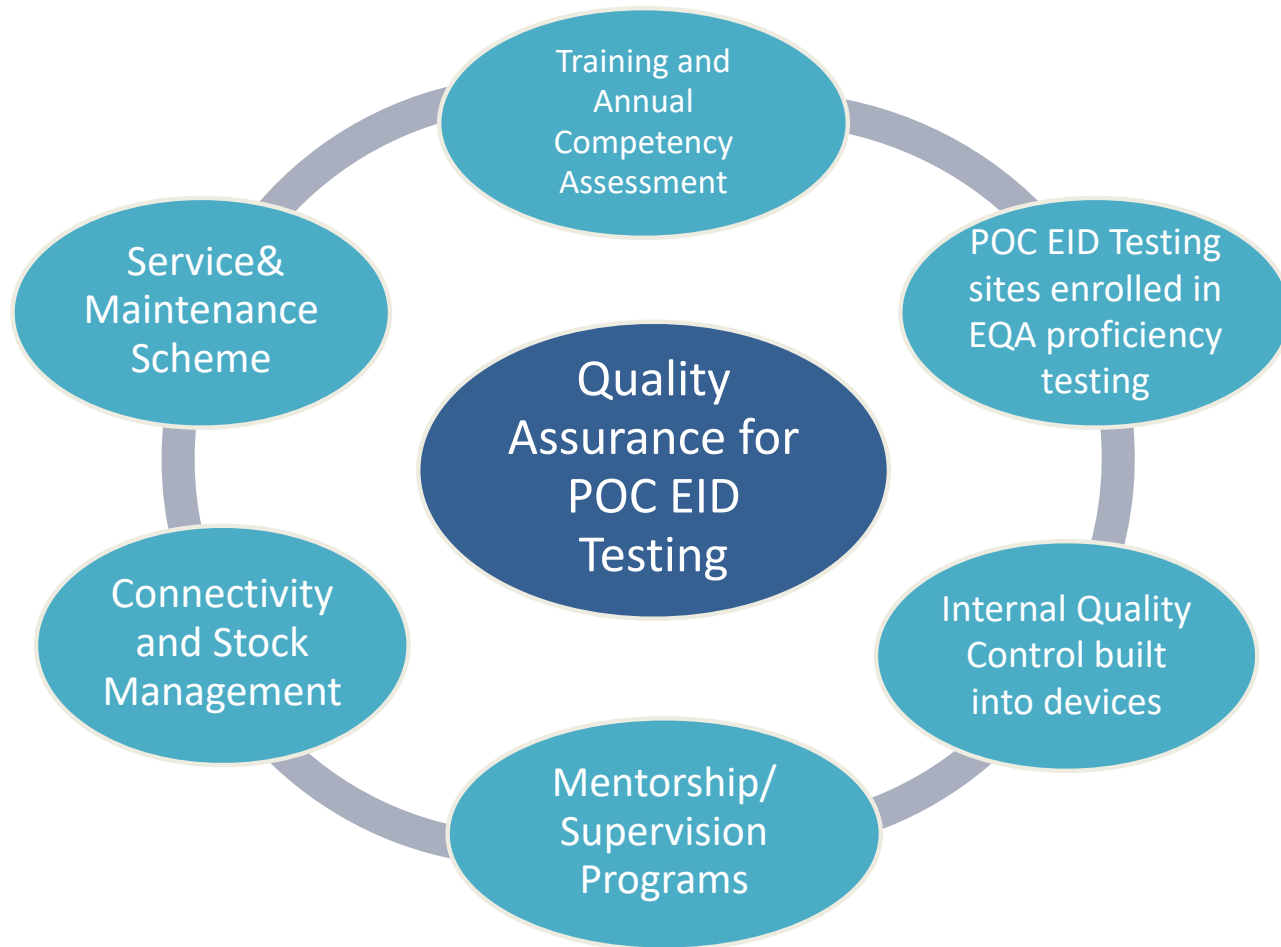
Every country should have a national QA framework that applies to testing across all programs and platforms

2

[Before the start of the training, insert here a diagram of the National QA Framework]

Similarly, POC EID testing should follow the same QA operational framework and, at a minimum, should include these components

2



## Proposed interventions to ensure successful routine EQA

1. Central level supervisors should coordinate the External Quality Assurance exercise (e.g. National Public Health Lab)
2. Enroll POC EID sites in EQA scheme available for the country (e.g. QASI, CDC, national QAP)
3. All EQA panels should be distributed to POC sites as per EQA panel distribution SOP following the handling and transport standard requirements
4. Central level supervisors should specify with the testing lab preferred timelines for the results
5. Central level supervisors should follow up on the results from the testing sites
6. Central level supervisors should communicate performance to respective POC EID sites and conduct corrective actions when necessary.
7. To be repeated every 6 months (2 cycles per year as defined by EQA scheme provider)

What needs to be in place:

- Communication in advance to prepare the sites
- Supervisor/mentor review in advance to assess POC site performance based on data transmitted through connectivity to the POC dashboard to identify and plan for any corrective actions (if connectivity is established)
- Supervisor to travel to all the POC EID sites, bringing EQA-PT panels from National Reference Lab; mentorship and supervision can be done alongside EQA-PT panel delivery.
- Logistics for supervisor field visit

[Before the start of the training, insert here the national policy for managing discordant EID results]

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Q&A

## The Stepwise Process for Improving the Quality of POC Testing (SPI-POCT) checklist is a simple and easy to use tool assess POCT testing quality

3

The SPI-POCT checklist assesses 9 aspects of POC testing to generate a facility score:

1. Integration of POCT service for patient care
2. Personnel training, competency and certification
3. Physical facilities
4. Safety
5. Pre-testing phase
6. Testing phase
7. Post-testing phase
8. Supplies, reagents and equipment
9. Monitoring quality

[Link to The SPI-POCT Checklist on the POC EID Toolkit](#)

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Q&A

The goal of periodic site supervision and mentorship is to identify issues early and to provide corrective and preventive actions

4

### Assessment report

- Generated from POC Database on testing & error trends or equivalent report
- To be used during site supervision

### Supervision

- Carried out by trained Lab Tech/Lab coordinator using the POC supervision and mentorship checklist
- Every quarter or every 6 months (depends on the agreed # of cycle)

### Mentorship


- Carried out by trained Lab Tech on a need basis
- Based on the supervision/data report findings and Test performance result

## Mentorship and supportive supervision provide opportunities for observation, assessment, reflection and joint problem solving

Mentorship by experienced individuals to less experienced individuals is an essential element of medical and nursing education; clinicians learn best by doing, while being supported by a more experienced colleague.

- Mentoring is a critical bridge for the training gap that exists between traditional didactic training and practice in the clinical setting
- Mentoring occurs at site level, thus ensuring that POC operators learn how to adopt SOPs and systems to their own patient population in the clinic setting

Supportive supervision improves the quality of service delivery through observation, discussion and direct problem-solving, mentoring and learning from the topics that are discussed then planning the way forward with POC operators and clinic staff.



Mentoring overlaps with supportive supervision whereby the testing and clinic flow is assessed and concerns are addressed through the use of collaborative problem solving

# The POC EID Mentorship/Supervision Checklist can be used to guide site visits and identify areas for intervention and improvement

Suggested mentorship/supervision visit schedule: Monthly for the 1<sup>st</sup> 3 months, and then 6 monthly  
Lower performing sites can be visited more frequently

## POC EID Testing Mentorship/Supervision Checklist

*To reach our goal of using Point-of-Care 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:** \_\_\_\_\_

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Learning Objectives

2

Quality Assurance (QA) framework and QA for POC EID Testing

3

Use of SPI -POCT checklist or equivalent to certify POC EID Sites

4

Use of supervision/mentorship checklist

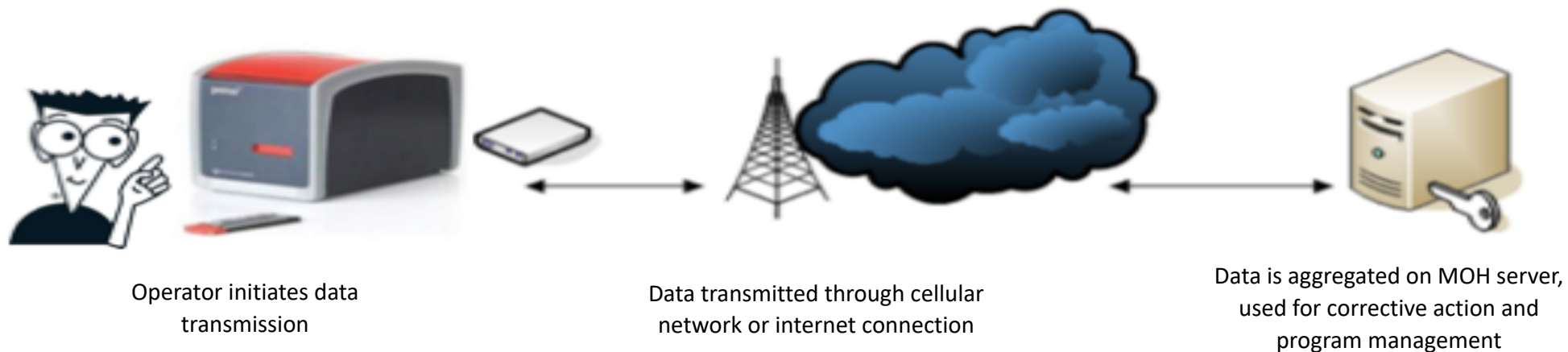
5

Use of connectivity to monitor performance

6

Q&A

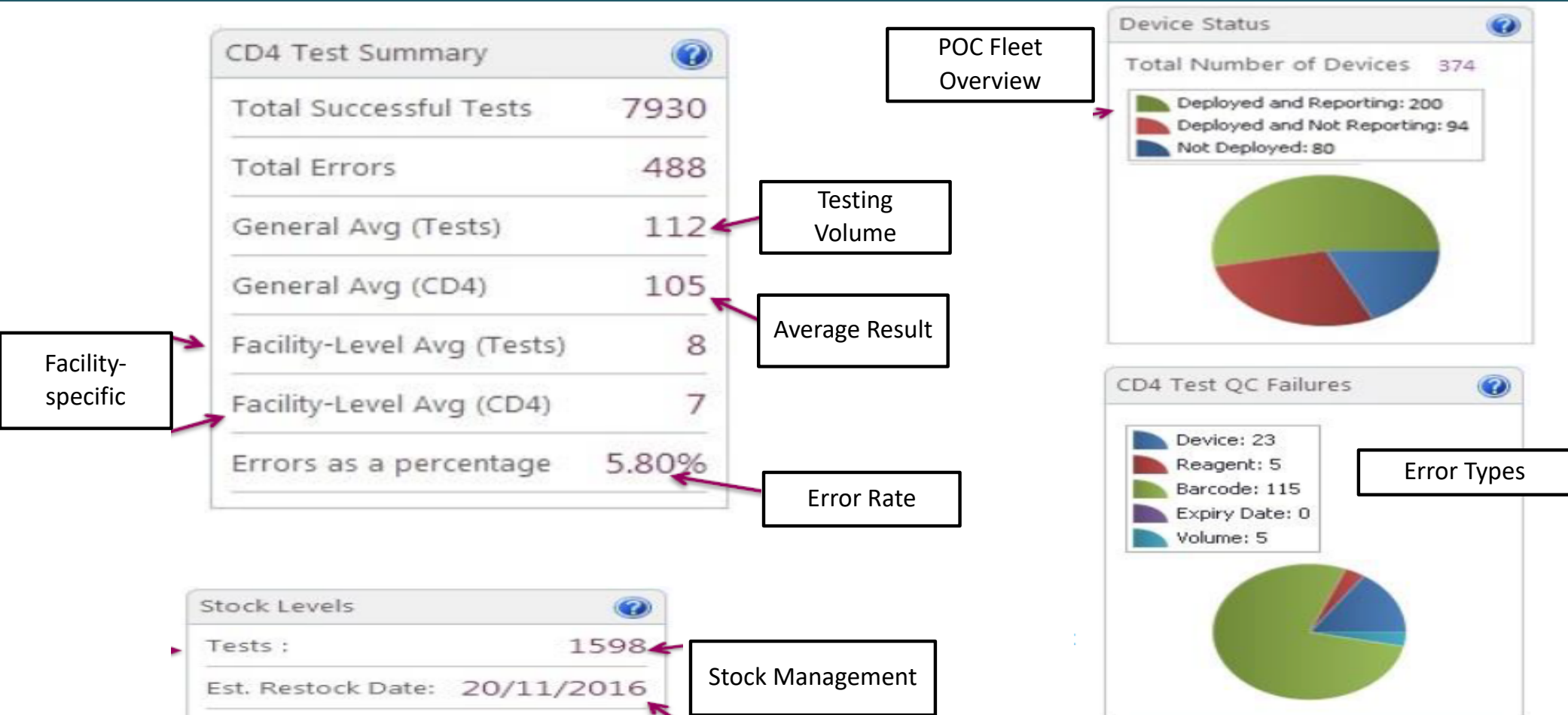
POC devices can be monitored remotely through wireless connectivity that transmits testing data to a central server



#### Examples of data captured by POC devices:

- Error messages
- Error rates by facility/operator
- Inventory tracking
- Test results
- EQA results
- Testing volumes
- Device breakdown tracking

A program manager can monitor many aspects of POC testing using wirelessly transmitted testing data



# Agenda

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Q&A

Questions?



Thank You!

## Acknowledgments

The development of the POC EID Training Package was made possible thanks to Unitaid's support.



Unitaid accelerates access to innovation so that critical health products can reach the people who need them.

