Multicentre Evaluation of the Performance and Operational Characteristics of Point-of-Care (POC) Tests for Early Infant Diagnosis: A Generic Protocol

Conducted by:	
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1.0 PROTOCOL TITLE: **Multicentre Evaluation of the Performance and Operational Characteristics of Point-of-Care (POC) Tests for Early Infant Diagnosis of HIV**

2.0 INVESTIGATORS AND INSTITUTIONAL AFFILIATIONS

Name	Role	Contribution

3.0 LIST OF ABBREVIATIONS

ANC	Antenatal Care
COE	Centre of Excellence
CTL	Central Testing Laboratory
EID	Early Infant Diagnosis
EQA	External Quality Assurance
GCLP	Good Clinical Laboratory Practice
GCP	Good Clinical Practice
MOH	Ministry of Health
NRL	National Reference Laboratory
PCR	Polymerase Chain Reaction
PI	Principal Investigator
POC	Point of Care
POCS	POC Site
QA	Quality Assurance
QC	Quality Control
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
VL	Viral Load
WHO	World Health Organization

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4.0 PROTOCOL SUMMARY

Expensive and technically complex diagnostics for CD4, HIV viral load (VL) and early infant diagnosis (EID) have put appropriate staging, treatment monitoring and infant diagnosis out of reach for many patients in resource-limited settings. The World Health Organization (WHO)/UNAIDS Treatment 2.0 Initiative emphasizes the essential role that cheaper and simplified diagnostic tools, especially point-of-care (POC) technologies, must play in efforts to further expand access to treatment. POC tests, defined as diagnostic testing at or near the site of patient care, brings the test conveniently and immediately near or to the patient. This increases the likelihood that the patient, physician, and care team will receive the results quicker, which allows for immediate clinical management decisions to impact patient care. In resource-limited settings, POC testing has the potential to significantly impact health care delivery and to address the challenges of health disparities.

New POC platforms for CD4, HIV VL and EID are on the horizon and will become available over the next few years. However, many promising new POC tests are currently delayed at the market entry stage due to the burden of variable and lengthy country registration procedures and the requirements for clinical trials in almost every country in which manufacturers wish to market their assays. Partners, manufacturers, and donors also recognize the need for innovative technologies that will help countries achieve sustainable universal access to treatment to capitalize on the preventive benefit of antiretroviral therapy.

This generic protocol aims to provide a standardised approach and procedures for multicentre prospective evaluations of the clinical performance and operational characteristics of POC Tests for EID of HIV for the purpose of obtaining regulatory approval and for programmatic uptake considerations.

A multicentre approach will allow for accurate and reliable evaluation of the performance of the POC device in the population of intended use and will reduce the need for each laboratory or country to perform independent evaluations of the same POC devices. In turn, this will accelerate the availability and widespread implementation of POC testing in resource-limited regions.

5.0 POINT OF CARE TESTS for EID

The UNITAID HIV/AIDS Diagnostics Technology Landscape Report, 2013, provides a detailed overview of each of the POC EID platforms (Figure 1). More than 5 products are in the pipeline.

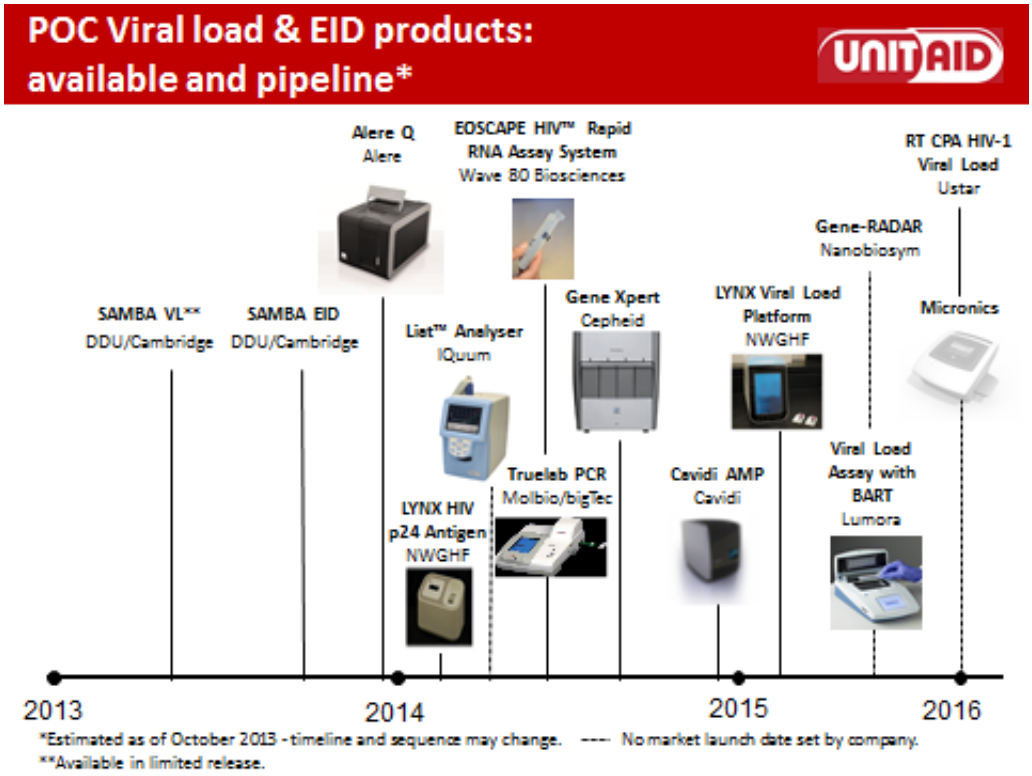

Figure 1: POC EID/VL Technologies in the pipeline as of October 2013.

5.1 Target Product Specifications of POC tests

As POC testing is meant to be performed at or near the point of patient care, in resource-limited settings this means certain operational and performance criteria are essential; tests need to be affordable, sensitive, specific, user-friendly, robust and rapid, and deliverable to those who need them (ASSURED), with no electricity or cold-chain requirements. Most manufacturers have developed their assays to match the performance characteristics of existing reference technologies, as guided by WHO recommendations when available.

In general, accuracy and precision are measured for quantitative tests, while sensitivity and specificity as well as negative/positive predictive values are needed for qualitative tests.

To date, POC EID tests in the pipeline are qualitative (Positive/Negative) and detect proviral DNA and/or viral RNA from whole blood. The WHO Recommendations on the Diagnosis of HIV Infection in Infants and Children strongly recommend that HIV virological assays should have a sensitivity of at least 95% and ideally greater than 98%, and specificity of 98% or more compared to laboratory-based assays. In October 2012, the HIV Monitoring Technologies Workshop Report specified a sensitivity of at least 95% and specificity of at least 98%, but balancing the benefit of increased access, a lower sensitivity and specificity of 90% compared to a laboratory-based reference standard assay may be acceptable for POC EID technologies.

6.0 STUDY JUSTIFICATION

POC technology allows for testing closer to the patient, particularly in resource-limited settings. With the recent commitment of WHO and UNAIDS to put 15 million HIV patients on antiretroviral therapy and to scale up universal access to integrated HIV prevention, treatment, care, and support programmes, the evaluation of the performance and operational characteristics of POC tests for EID is critical in strategic placement of these tests within an existing strengthened laboratory system to provide the greatest access to patients and the most impact to programmes.

This protocol, which outlines a multicentre approach for evaluating POC tests, will help facilitate widespread implementation without the need for several laboratory and country-specific independent evaluations of the same test. This will allow for robust and accurate testing at a central reference laboratory within the region as well as additional testing at POC sites where the test is intended for use. In these settings, the tests will be evaluated under realistic daily testing conditions with region-specific clinical specimens collected by the staff who are intended users of these POC tests.

6.1 Expected Outcomes

The expected outcome of these evaluations of POC Tests for EID is to provide data for regulatory review and approval in countries. The test performance and assessment of operational characteristics will also help inform programme uptake decisions and strategic placement of technologies at different urban or rural settings to reduce loss to follow-up and improve linkage to care.

7.0 OBJECTIVE

The objective of this generic protocol is to provide a framework and process for the multicentre evaluation of POC tests for EID of HIV.

Specific Aim 1: To evaluate the clinical performance of POC for EID of HIV in both central/national laboratory and field/rural settings.

Specific Aim 2: To assess the operational characteristics of POC tests for EID of HIV.

8.0 METHODS

8.1 Study Design

This generic protocol will focus on the prospective evaluation of the clinical performance of POC tests for EID of HIV. Table 1, taken from the 2012 HIV Monitoring Technologies Workshop Report,

outlines the framework for the evaluation of a diagnostic test, from Proof of Principle (Phase 1) to feasibility and impact studies (Phase 4). Figure 2 shows where this fits into the Bench to Bedside pathway of diagnostic development.

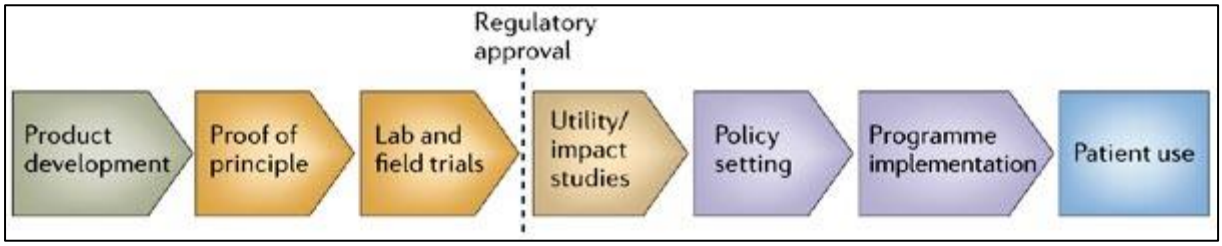

Figure 2: Bench to Bedside pathway of diagnostic development

Table 1: Evaluation of Diagnostic Tests

Phase	Location and users	Sample Type and Size	Study Outcomes	Intended Use of Data
Phase 1: Proof of Principle studies	Typically in a laboratory performed by trained technicians	A panel of archived, well-characterized specimens, N=~ 10-100	Test detects target of interest	By test developers for finalization of product design
Phase 2: Laboratory-based evaluation (can be Retrospective)	In a laboratory performed by a laboratory technician	A panel of archived, well-characterized specimens, N > 100, and a challenge panel for specificity	Analytical performance, (prevalence independent), ease of use	WHO Pre-qualification to inform procurement, MOH
Phase 3: Clinic-based evaluation (Prospective)	In settings of intended use, performed by intended users	Number of samples dependent on the size of the target population in the clinical setting - need sufficient numbers to give a confidence interval of +5% around the point estimate of sensitivity and specificity*	Clinical performance (Prevalence dependent), operational characteristics, e.g. ease of use	Test developer (pre-submission for regulation approval), regulatory authorities, researchers, MOH
Phase 4: Utility studies	Within a health care system, performed by intended users	Clinic samples. N= typically very large	Feasibility, impact on patient outcomes, cost-effectiveness.	MOH for policy development, donors

*"Evaluation of Diagnostic Tests for Infectious Diseases: General Principles," The WHO/TDR Diagnostics Evaluation Expert Panel. *Nature Reviews Microbiology;Evaluating Diagnostics.* September 2006; S21-S33.

8.1.1 Study Participants

The study population for the evaluation of POC Tests for EID will be infants from 6 weeks of age as

per WHO guidelines, or when mothers return for antenatal care (ANC) testing, and continuing up to 18 months of age. Because all POC EID technologies to date require fresh whole blood and sample size can be challenging, previously-identified (restrospective) HIV positive and HIV negative infants will be contacted within two weeks after receiving the initial test results and asked to return for re-draws.

8.1.1.1 Participants Inclusion Criteria

- Infants around 6 weeks of age and less than 18 months old, identified as HIV-positive and HIV-negative by PCR.
- Inclusion criteria should not differentiate between infants on or off prophylaxis so long as data on prophylaxis treatment was recorded.
- Since the target population is infants, consent must be obtained from the parent/guardian after appropriate information is given in writing or verbally.

8.1.1.2. Participants Exclusion Criteria:

- Infants born to HIV-infected mothers who are more than 18 months old and infants who are not born to HIV-1 infected mothers will be excluded.
- Serious medical conditions that might affect the accuracy of normal laboratory analysis.
- Sites should adhere to country-specific limits on the use of lancets for specimen collection for EID tests using lancets..

8.1.2 Sample Size

In order to achieve statistical significance for the comparison of POC qualitative tests for EID, a total of 150-200 positive and 150-200 negative randomly pre-selected samples (or prospective samples) will be tested at each evaluation site. For example, 100 positive and 100 negative samples will be tested at the Central Testing Laboratory (CTL), in addition to 10 positive and 10 negative samples from each of 5 POC sites. Samples collected across the various regions will allow for the evaluation of assay performance using HIV-1, HIV-2 and a reasonable number of subtypes, depending on local prevalence and the manufacturer's claims.

Because the distribution across a population will not be known before testing, an interim analysis will be conducted to ensure there are sufficient samples collected around the critical range(s). If not, more samples will need to be collected to ensure adequate sample size across the entire critical range.

8.1.3 Reference Standard Assays

Reference standard assays used for the evaluation of POC tests for EID are the COBAS AmpliPrep/

COBAS TaqMan (CAP/CTM) HIV-1 Qualitative Test or the Abbott RealTi*m*e Qualitative HIV -1 assay. The reference test should be a laboratory-based assay and not another POC test.

8.2 Study Site Selection

8.2.1 Study Site Collection Criteria

Sites considered for this evaluation need to meet the following criteria:

- Reference laboratories must be competent at performing an EID reference assay as a comparator for assays under evaluation. Reference laboratories are selected based on their proficiency in external quality assurance (EQA) programmes such as NEQAS or CAP in the past 12 to 18 months. Proven proficiency is defined as ≥ 90% score on a minimum of 2 proficiency testing events per 12 months.
- Access to target population and sufficient sample sizes to complete a study in a timely manner (6 -9 months).
- Network of surrounding POCS offering prevailing standard of care.
- Compliance with Good Clinical Practice (GCP)/& Good Clinical Laboratory Practice (GCLP).
- Expertise and experience in conducting diagnostic evaluations.
- Evidence of ongoing accreditation such as ISO 15189 or WHO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) in the Africa Region.
- Able to meet study time lines, including mechanism for timely IRB approval.
- Sufficient staff capacity to complete the study in the given study time and sufficient laboratory technician(s) demonstrating successful competency with reference assays.
- Must work independently – i.e. no involvement from the manufacturer other than initial training on the platform.
- Strong interest to work with new technologies.

8.2.2 Framework for Study

The overall procedure for the performance evaluation of a POC test is as follows:

1. Phase 2, or in-laboratory evaluations, using archived or fresh specimens to assess analytical performance are usually performed by a laboratory that is accredited as a centre of excellence (COE); analytical performance is a characteristic of the test itself and is not dependent on prevalence in a local population. These Phase 2 evaluations do not need to be repeated in every country.
2. Phase 3 or clinic-based evaluations to determine clinical performance are usually performed by a CTL, in collaboration with POC sites;
3. A CTL can also function as the COE if its meets accreditation criteria.

In this study, each evaluation site will be comprised of a CTL, such as a National Reference Laboratory (NRL), and multiple POC sites (POCS) as part of their laboratory network (Figure 3; Table 2).

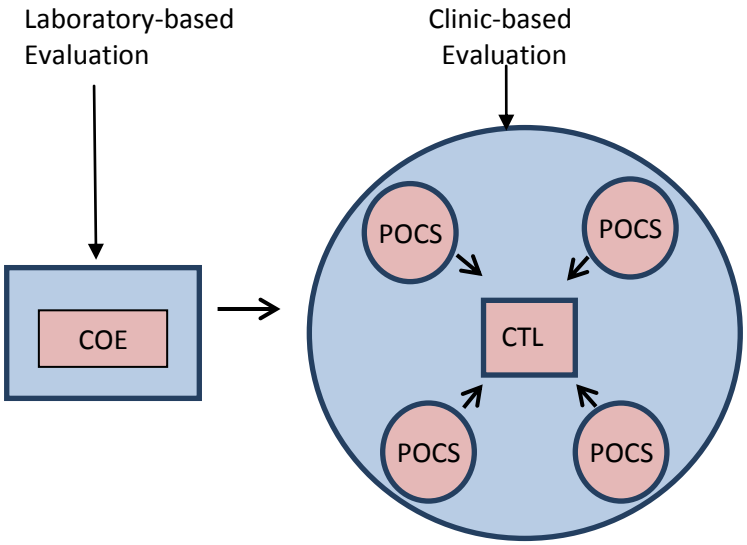

Figure 3: Center of Excellence and Regional POC study site

Table 2: Study site examples

STUDY SITE	ROLE OF STUDY SITE	EXAMPLES
Center of Excellence (COE)	• Phase 2 (optional) • Conduct specificity testing using a challenge panel	CDC laboratory, accredited national reference laboratory or laboratories recognized by WHO/ASLM accreditation programme (SLIPTA)
Central Testing Laboratory (CTL)	• Phase 2, if meets criteria • Phase 3	Accredited national reference laboratory
Point-of-care Sites (POCS)	• Phase 3	POC sites that report to CTL

8.3 Training

Initial training will be provided by staff members or developers of the POC test being evaluated. All training materials will be shared with the regional POCS and collaborators. Only trained and competent staff will participate in the study.

8.4 Patient Recruitment

The parent(s)/guardian of infants between the ages of 6 weeks and 18 months of age will be approached for inclusion in this study.

8.4.1 Ethical Considerations

This study will be conducted with the patient's welfare in mind at all times in accordance with the Helsinki Declaration and other international research ethics standards.

8.4.2 Informed Consent

Inclusion in the study will be completely voluntary, and only after informed consent from the parent(s) or other legal guardian of an infant. The consent procedure includes two documents: the Participant Information and the Informed Consent Forms, both of which should be translated into the local language (**Appendix I and II**).

The Participant Information Sheet will be read in its entirety to the parent(s)/guardian, and he/she will be offered a copy to keep. The expected benefits as well as the risks and inconveniences of the study will be carefully explained to the parent(s)/guardian. After answering any potential questions about the study and if the parent(s)/guardian have agreed to allow her/his child to participate, the signature of the parent(s)/guardian (or thumb print for illiterate parent(s)/guardian) will be obtained on the Informed Consent Form. The parent(s)/guardian will be given a copy of the Participant Information Form to keep.

Benefits for the participant

Participating in the study will not result in any specific benefit for the participants. In the long term, the availability of a POC test will improve patient care.

Risks

Study participants may feel discomfort or have minor bruising when their blood is drawn.

Participant honoraria and incentives

The parent(s)/guardian of an infant enrolled in the study will not receive honoraria or other incentives.

Right to withdraw

The parent(s)/guardian of an infant can withdraw their consent at any time during the study without penalty or alteration of the participant's standard care.

Privacy

All laboratory specimens, reports, data collection instruments, process logs, and administrative forms will be identified by a coded number to maintain participant confidentiality. All records that contain names or other personal identifiers, locator information forms and informed consent forms, will be stored separately from study records, identified by code number and can only be accessed by authorised study personnel. All databases will be password-protected for security of access. Forms, lists, logbooks, appointment books, and any other listings that link participant ID numbers to other identifying information will be stored in a separate, locked file in an area with limited access only by

the data manager and principal investigator or appropriate designee.

A participant's study information will not be released outside of the study without the written permission of the parent(s)/guardian, except as necessary for monitoring by the laboratory chosen for the study, or regulatory authorities. This shared data will be delinked and de-identified to protect participant confidentiality.

8.5 Sampling Procedures

The following procedures will be used for sample collection, labeling and transport.

8.5.1. Sample Collection

Current POC EID technologies require a whole blood sample, which in some platforms is separated into plasma. The tests then use either ultrasensitive p24 antigen lateral flow technology or closed sample preparation amplification and detection chemistry with disposable cartridges to prevent cross-contamination of amplification products.

Appropriate amounts of heel-prick blood will be taken for the POC test and for testing on the reference standard assays. For testing on the POC technology, the heel-prick sample may be collected directly onto a test cartridge or may be processed as required. For testing on the reference assay, heel-prick blood will be collected on dried blood spot (DBS) filter paper. Alternatively, when possible, an EDTA capillary may also be used to collect a heel-prick sample.

8.5.2 Sample Labeling

All samples submitted for the study will be assigned a study code to ensure patient confidentiality. To protect patient confidentiality, information linking the patient ID number with their identity will be held only by the Site Principal Investigator (PI). (**Appendix III, Data Collection Form**).

8.5.3 Sample Transport

Of the whole blood collected from an infant, a portion will be used on the POC test under evaluation and a portion will be transported on DBS filter paper to the CTL for testing on the reference assay, following manufacturer's instructions. Turn-around times should follow the manufacturer's package insert. No other procedures will be required in addition to those normally carried out during patient care, and routine care will not be affected. Figure 4 below shows sample collection at the evaluation sites.

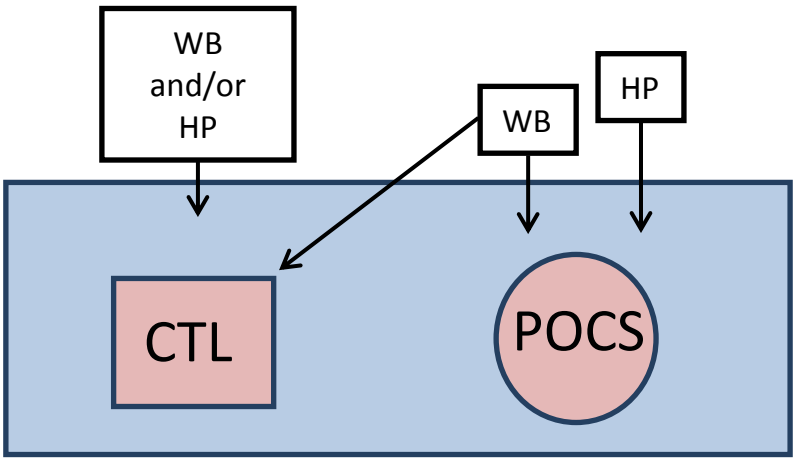

Figure 4: Sample collection at study site (CTL= central testing laboratory, POCS=point-of-care site, HP = Heel-prick; WB= Whole blood)

8.6 Performing the POC Assay

General Guidelines on the Use of Test Kits:

- Note lot number and expiry date: a kit should not be used beyond the expiry date.
- Ensure correct storage conditions: if a desiccant is included in the package, do not use the kit if the desiccant has changed colour.
- If test kits are stored in the refrigerator, they should be brought to room temperature (about 30 minutes) before use. The use of cold test kits may lead to false negative results.
- Discard damaged test kits.
- Use test kits immediately after opening.
- Reagents from one kit should not be used with those of another kit.
- Test should be performed exactly as described in the product insert.

Biosafety Guidelines for Clinic and Laboratory Staff:

- Treat all specimens as potentially infectious.
- Wear protective gloves and laboratory gown while handling specimens.
- Do not eat, drink or smoke in the laboratory.
- Do not wear open-toe footwear in the laboratory.
- Clean up spills with appropriate disinfectants, e.g. 1% bleach.
- Decontaminate all materials with an appropriate disinfectant.
- Dispose of all waste, including sharps and test kits, in a biohazard container.

All POC testing will be performed by trained competent clinic staff following the manufacturer's instructions.

INSERT NAME OF POC EID TEST TO BE EVALUATED AND THE PROCEDURE FOR PERFORMING IT HERE

If the POC test requires a visual interpretation of a line, colour change, or other visual indicator, the result will be read by two independent observers blinded to each other's results and the reference assay results.

8.7 Reporting Results

No POC results will be provided to the parent(s)/guardian of infants participating in the study. Only results from the reference standard test will be provided to the parent(s)/guardian, per national guidelines.

8.8 Assessment of Operational Characteristics

Each operator will assess the following:

- Clarity of kit/device instructions;
- Ease of use of cartridge/kit and/or devices; and
- Ease of interpretation of results, if subjective reading is required.

8.9 Quality Control and Quality Assurance Procedures

All quality control (QC) and quality assurance (QA) procedures and criteria that apply to reference testing should also apply to POC testing. Laboratory standard operating procedures detailing technical procedures involved (e.g. sample collection, processing and storage, assay procedures and how to interpret test results) will also include QC and QA procedures.

Proper maintenance of records, including test requisition forms, questionnaires, specimen logbooks, laboratory workbooks/sheets, technical procedure documents, sample tracking sheets, shipment details, equipment maintenance and calibration records, and personnel and quality improvement plans, will be kept.

On-site supervisors will check and sign off on data sheets at the end of each day.

On-site assessments will be used to strengthen and ensure the quality and reliability of the entire laboratory system on which this protocol depends.

8.10 Biosafety and Biohazard Containment

As transmission of HIV and other blood-borne pathogens can occur through contact with blood, blood products and contaminated needles, appropriate precautions will be used by all staff in the drawing of blood, and in shipping and handling of all specimens. Appropriate biohazard containment and national guidelines will be followed. Study sites must provide biosafety training records for staff participating in the study. POC EID tests use closed sample preparation amplification and detection

chemistry with disposable cartridges to prevent cross-contamination of amplification products. Sample preparation chemistry does not require toxic chaotropic reagents or volatile alcohol and test reagents and consumables are preloaded in the cartridges to minimize or remove pipetting steps.

9.0 DATA COLLECTION AND ANALYSIS

Results of the POC test and the reference standard assay will be entered into the data collection forms (**Appendix III**). Technicians performing the reference standard assay in the laboratory and clinic staff performing the POC test must be blinded to each other's results.

Laboratory and data analysis will be performed at the study sites in collaboration with UNITAID. To assess the performance of a POC test, the following analysis will be performed using the reference standard assay results as comparison:

Qualitative - EID

- **Sensitivity** – The probability (percentage) that patients with the infection, determined by the result of the reference or "gold standard" test, will have a positive result using the test under evaluation.
- **Specificity** – The probability (percentage) that patients without the infection (determined by the result of the reference or "gold standard" test) will have a negative result using the test under evaluation.
- **Positive Predictive Value (PPV)** – The probability that a positive result accurately indicates the presence of infection. Its value depends on the prevalence of the outcome of interest.
- **Negative Predictive Value (NPV)** – The probability that a negative result accurately indicates the absence of infection. Its value depends on the prevalence of the outcome of interest.

The data belongs to the evaluation site, but will be shared with UNITAID and its partners. Confidentiality will be preserved during transmission, use and storage of the data. Technical and administrative stewardship responsibilities of data and documents reside with the site PIs.

10.0 DURATION OF THE STUDY

The total duration of the study is roughly estimated to be 6-9 months from the time of country IRB clearance.

11.0 DISSEMINATION

Dissemination of preliminary real time data will occur amongst other study sites, in collaboration

with study PIs, UNITAID and its partners. A final report of the assessment will be written and distributed among all investigators and sent to companies for review and comments. Results will be submitted to peer-reviewed scientific journals and/or presented at international conferences only upon agreement by all parties, including the company, as long as the product is not yet commercially available. Any request concerning the study data should be presented to the PIs of the study. Any oral or written scientific communication using the study results will need to have consensus from the investigating team based on publication policy developed and agreed upon by the research team investigators.

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APPENDIX 1

Participant Information and Informed Consent Form

Purpose:
We have a new test that would allow us to decide if your baby is infected with HIV. We invite you, _____, to allow your baby to take part in a study to decide if this new test is as good as the one that is now being used in the laboratory.

You have been selected to take part because your baby tested positive for HIV, but has no other serious medical condition.

Procedures:
You will be asked to allow your baby to have a small volume of blood (approximately 5-50 µL or 1-2 teaspoonfuls) taken by heel-prick using a lancet and put into a cartridge, a capillary tube or on filter paper.

All the samples will be used for EID evaluation purposes only, and they will be labeled with a number and not your name or your baby's name, in order to ensure confidentiality.

Benefits:
There will be no direct benefit to your baby from taking part in this study, but his/her participation may allow public health programmes and doctors worldwide to know whether this new EID test is of good quality and gives accurate results.

Risks and discomfort:
The risks involved in this study are minimal. They include the discomfort of drawing a sample of blood, rare bruising and infection at the site of needle stick, and very rarely, fainting. New needles will be used for each patient so there is no risk of transmitting diseases.

Confidentiality:
All information that you provide will be kept confidential, and no mention of your name or any other identifying information, including the baby's name, will appear on the samples or in any publication in connection with this study. Neither your personal information nor the baby's personal information will be stored together with the samples. No persons other than the research staff and the doctors/nurses providing your baby's care will have access to your personal information and the baby's personal information. Only these persons will have the key to link the samples and the information attached to your baby's name.

Freedom to refuse or withdraw:
You may also choose not to allow your baby to participate in this study and you may refuse to allow your baby to participate at any time without penalty or loss of benefits to which you would otherwise be entitled. The decision not to participate in this study will not in any way harm the future relationship between you, your baby and the clinic. You do not have to explain why you do not wish for your baby to participate or why you wish to withdraw.

Contact information:
We, the investigators, encourage you to ask questions regarding the study that you may have at this time. If you have any questions, or if any problems arise in the future, please contact:
(NAME OF RESPONSIBLE INVESTIGATOR AT CLINICAL SITE)

Any individual who has complaints about the way this study was conducted should contact XXX at the National Bioethics Committee, Ministry of Health, (XX) XXX-XXXX.

Dissemination of results:
The results of this study will be made available to public health programmes and others who wish to be informed.

The parents/guardian of the participant will be given a copy of this form to retain for his/her records.

Appendix II

CERTIFICATE of CONSENT

Name of Participant_____

I, _____, hereby agree to allow my baby to participate in an evaluation to find out whether a new EID test is as good as the one that is normally used in the laboratory. I have read and fully understand the Participant Information Form and have had the opportunity to ask questions related to this evaluation.

To participate in this study, I agree to allow my baby to have approximately 50 µL (about 2 teaspoonfuls) of blood taken from him/her using a lancet and deposited into a cartridge, capillary tube or on to filter paper. I understand that this puncture will cause a small amount of temporary discomfort and sometimes bruising at the site of the blood draw.

I understand that the sample will not be used for any other purpose than to perform the same test that my baby would receive under normal circumstances. All information regarding my baby's sample will remain completely confidential and will not be used for any other purpose than the objective of this evaluation.

I understand that I am not obligated to have my baby participate in this study, and I can decide not to have my baby participate at any time. I understand that this study does not place my baby at any greater medical risk than is customary with the test that my baby is receiving, nor does it interfere with the medical care to which he/she is entitled to.

I have read the above document and I understand that I have agreed to allow my baby to participate in this study

Name of Participant_____

Name of Parent/Legal Guardian_____
Address_____ Telephone_____

Signature of Participant (Or Parent/Legal Guardian)_____

Date____/_____/_____

Signature of Principal Investigator:
_____

Signature of Witness:_____
Date ____/____/____
Name in capital letters:_____

Appendix III

Data Collection Form for the Evaluation of POC Tests for HIV

All data for subjects are collected on this form.
This form should be completed at the time of subject enrollment.

Site Facility Name: _____

Subject identification number: _____ Age: ____ Gender: male__/female_

Cartridge ID: _____ **Instrument ID: _____**

Assay performed by: _____

Index assay (test under evaluation) information

Date and time of blood draw for index assay: _____/_____/_____ ___:___

dd / mm / yyyy hh : mm

Type of blood draw : ☐ Heel-prick

Date and time Index assay was initiated: _____/_____/_____ ___:___

dd / mm / yyyy hh : mm

Time index assay result was obtained: ___:___

hh : mm

INDEX EID RESULT: _____ **Error Code Displayed: _____**

Instrument Use & Operability Information

Temperature: _____° C **Humidity: _____**%

How many of the following items were used to collect this sample?

Lancets _____ ; Capillary Tubes _____; Bandages _____

Did anything unexpected or unusual occur *during the sample collection and introduction into the Cartridge*?

☐ No ☐ Yes. Please explain:

Did anything unexpected or unusual occur *while inserting the Cartridge into the Instrument*?

☐ No ☐ Yes. Please explain:

Did anything unexpected or unusual occur *after inserting the Cartridge into the Instrument*?

☐ No ☐ Yes. Please explain.

Supervisor's signature: _____ Date: _____

Data Collection Form for POC CD4 Assay Evaluations

All data for subjects are collected on this form.
This form should be completed at the time of subject enrollment.

Subject identification number: _____ **Site Facility Name:** _____

Assay performed by: _____

Reference assay information

Date and time of blood draw for reference test: _____/_____/_____ ___:___

dd / mm / yyyy hh : mm

Name of reference assay ☐ COBAS AmpliPrep/COBAS TaqMan Qualitative Test

☐ Abbott RealTi*me* Qualitative HIV-1 Assay _____ ☐ Unknown

Date and time reference assay was performed: _____/_____/_____ ___:___

dd / mm / yyyy hh : mm

Reference Assay EID RESULT: _____

Supervisor's signature: _____ Date: _____