

**Minutes from the 27 September 2023 Lab Meeting at the HPTN Regional Meeting, Cape Town-South Africa**

**Attendees:**

Yaw Agyei, Lebah Lugalia, Vanessa Cummings, Paul Richardson, Dr. Jessica Fogel, Estelle Piwowar-Manning, Dr. Mark Marzinke.

**Sites in Attendance:**

All sites were invited to attend. Those with representation at the meeting are listed below.

- BARC
- WITS/CLS - Cape Town
- WITS/CLS - Johannesburg
- Desmond Tutu Health Foundation
- Desmond Tutu TB Center
- Aurum - Klerksdorp
- UZ CTRC
- Kisumu
- BHHRL - Gaborone
- Johns Hopkins Project Blantyre
- Groote Schuur CRS
- Desmond Tutu Health Center – EMA
- WITS RHI Ward 21
- Malawi – Lilongwe
- MU-JHU Care Ltd/Research Collaboration and Baylor Uganda represented by IDI Core Laboratory
- UVRI-IAVI Uganda
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**Agenda**

- GCLP guidelines.
- Audit action plans and IR.
- Backup labs and concerns with audits.
- Supply chain challenges.
- New POC tests for new protocols.
- Any Other Business (AOB).

## **Discussion Points:**

- **GCLP guidelines**
  - Refresher training is available on the DAIDS training portal online, and there is a shorter version for clinic staff.
  - Most sites prefer face-to-face training over the online version.
  - The meeting agreed that GCLP training doesn't expire, and there is no frequency stated.
  - Sites request that Networks support and provide funding for more on-site training because sites cannot always send people to regional training due to cost issues.
  - Sites request future Zoom trainings that can be broken into time blocks, or a hybrid version.
- **Audits and IRs**
  - CLS feels comfortable discussing and raising concerns about findings with the DCLOT and HPTN LC and confirmed that auditors usually make suggestions on ways to improve their system.
  - Most sites said they feel comfortable discussing findings with auditors and don't always agree with suggestions based on what was observed by the auditor from other labs.
  - Sites agree that the audits are meant to improve their lab procedures, and are not meant to be punitive.
  - Sites feel the audit process has improved over the years, and current auditors are friendly and willing to discuss what labs present as responses to potential citations.
  - Sites are aware that citations are not always final, and they can raise their concerns/objections through their DCLOT contact for further discussions.
  - HPTN LC highlighted the different steps involved in the preparation and review of the AP before it gets sent to the sites for action. Sites are advised to review the pre-audit letters carefully to ensure all the active protocols listed are correct and have PALs on file. Sites are encouraged to review their local resources before coming up with policies to address audit citations. Responses to AP items can be sent in small batches as they're completed, instead of waiting to resolve all citations before responding.
  - Most sites use a suggestion box system as part of their anti-retaliation policy implementation, and some have HR personnel come and talk to lab staff.
  - The meeting discussed the challenges around storage of CD4 samples post evaluation because this was a citation for a lab, and resolved to explore doing separate blood draws for FBC and CD4 if they can procure smaller blood collection tubes. Another option is to seek clarification if going back to TruCount tubes that are set up and stored in a refrigerator will be acceptable.
  - One site mentioned their appreciation of pSmile support regarding new lab setup and instrument validation.
- **Backup labs.**
  - DCLOT is considering additional ad hoc backup labs to be used during reagent shortages/stock outs, but they may need to be audited.

- Sites were not sure how backup labs would respond to being audited.
- **Supply Chain challenges:**
  - Most sites confirmed some improvement with Abbott reagent deliveries since the HPTN -LC got involved and engaged the U.S. office.
  - Sysmex and Beckman Coulter seem to be delaying reagents and supplies for multiple sites because the sites are referred to local vendors that don't always have adequate stock.
  - Malawi sites are facing challenges with Beckman Coulter FBC controls being delivered on time, and have used EQA samples in the past.
  - Sites are also experiencing delays with some Roche reagents due to the dangerous goods category, which determines whether the goods can be shipped on passenger flights or just cargo. The shipment in question was eventually sent by road from South Africa to Malawi.
    - HPTN-LC requested photos of the reagent labels, so this can be investigated further.
  - Roche is using a distribution company called DSV in South Africa, to deliver reagents in the Southern Africa region.
    - Zimbabwe is facing challenges with its Roche 4800 instrument validation due to delays in receiving reagents.
  - Sites request that Networks assist them to order directly from reagent manufacturers, instead of ordering from local vendors.
  - CLS mentioned a shortage of 5 mL EDTA tubes and has resorted to using 6 mL tubes. HPTN -LC advised the meeting to always pay attention to the blood draw volumes when they change the tube sizes and ensure that they are in the blood draw limits in the consent forms. In addition, blood tubes should be filled to the stated capacity so that the blood to anticoagulant ratio is correct.
- **New POC tests:**
  - Chembio HIV/Syphilis kits are available, and the EMA confirmed using it already.
- **AOB**
  - A site mentioned receiving a message from VQA regarding the Roche TaqMan being phased out which the LC was not aware of
  - The LC is aware of plans about the Abbott M2000 and Architect being phased out in the future.
  - Botswana lab raised a concern about difficulties with BD controls for their CD4 instrument (FacsCalibur), and

Zimbabwe suggested trying the Streck controls.

- A recent webinar offered by Bio-Rad and Cardinal Health titled “*The importance of independent Quality Control Materials*” highlighted the importance of using third-party controls because they are manufactured independently of instrument manufacturer, and are better at estimating how a test system is performing.
- LC to review the column on PALs that asks if the backup lab is in use or not (Y/N).