

Desmond Tutu Health Foundation/ Groote Schuur CRS/ J52 Old main Building

Laboratory Non-Conformance/ Corrective Action and Preventative Action Form

Date problem/ event occurred: 8-9 January 2024

Nature of problem:

During the external audit conducted by PPD on the 8-9 January 2024 the laboratory was cited for not having a policy in place for addressing all EQA requirements according to the DAIDS GCLP guidelines

Root cause investigation:

Under the section External Quality Assurance in the Quality Management Plan the laboratory's policy did not mention how to handle EQA samples.

Corrective Action taken:

The Quality Management Plan was updated the procedure for handling and storage of EQA samples. Laboratory staff were informed about the changes to the QMP and signed the acknowledgement page that they understood the changes.

Monitoring of effectiveness:

Effectiveness of adding the procedure to the QMP will be done by monitoring if any deviations from the policy occurs which could cause incorrect results.

Preventative Action taken:

Periodic review of QMP to ensure appropriate updates and revisions are made and staff are trained and competent to perform all laboratory procedures.

Prepared By: Melina Carr // Date: 10 April 2025

Reviewed By: Xolile Mhlanga Date: 10 April 2025