

MTN Manual of Operational Procedures (MOP)

APPENDIX II: HIV-Testing Quality Assessment Policy

Prepared by	Date Adopted	Supersedes Procedure #
Adapted from HPTN Policy		N/A

Review Date	Revision Date	Signature

Distributed to	# of Copies	Distributed to	# of Copies

1 SCOPE

- At the discretion of the MTN LC, baseline and seroconversion plasma/serum samples from all seroconverting adult participants will be retested by the MTN LC, using FDA-licensed tests (that is, HIV antibody, HIV DNA PCR or HIV RNA, if necessary). If not otherwise specified in the protocol, specimens will be retested at the end of the study. In the event of an unexpected result (that is, positive baseline sample or negative endpoint sample in a seroconverter), retesting of additional aliquots or time points may be performed as determined by the MTN LC.
- In case of testing issues, unusual HIV testing results or at the discretion of the MTN LC, the MTN LC can request sites to perform additional testing locally or ship samples to the MTN LC for additional testing.

2 PURPOSE

HIV testing quality assurance procedures are performed to ensure the accuracy of local HIV testing in MTN clinical trials.

3 RESPONSIBILITIES

The Statistical Data Management Center (SDMC) is responsible for the following:

- Generating participant identification numbers (PTIDs) for retesting
- Providing retest PTIDs to the sites
- Providing PTIDs and HIV test results from participant case report forms (CRFs) to the MTN LC

The MTN LC is responsible for the following:

- Working with sites to ship samples to the MTN LC for retesting
- Conducting the retesting
- Providing the SDMC with results resulting from the retesting as needed

4 PROCEDURES

4.1 Generating and Distributing Retest PTIDs

The SDMC generates shipping lists containing PTIDs and associated specimen collection dates for retesting, following the guidelines, specified under the SCOPE section above, and sends the list to the MTN LC and to the site(s) along with instructions to pull and ship specimens to the MTN LC.

4.2 Retesting Specimens

Retesting is conducted as follows:

- The site pulls and ships specimens to the MTN LC, using the PTIDs and collection dates.
- The MTN LC conducts the retesting and informs the SDMC when retesting has been completed.
- The SDMC provides the MTN LC with a retest list containing retest PTIDs, collection dates and the HIV test results performed at the site's local laboratory and documented by the site's on study CRFs.
- The MTN LC matches the HIV retest results to the site's local laboratory results and identifies any discrepancies. The MTN LC and SDMC will follow up on discrepancies, as appropriate.