

MTN 020

Lab Samples and Testing Summary



Overview of Laboratory Sample and Testing Requirements

Routine on-site testing.

Possible local off-site testing (hCG, rapid HIV).

Special testing to be performed at MTN NL. LDMS generated labels; shipping aliquots/slides when instructed by MTN



Overview of Laboratory Sample and Testing Requirements

Urine:

Pregnancy testing:

Quidel QuickVue Urine or
Combo hCG test kit

GC/CT:

BD ProbeTec
(not clean-catch,
first 15-60 mLs of urine)

Culture:

If indicated, per local standard of care.



Blood:

Rapid HIV: Two tests, at least one FDA approved.

Syphilis Testing: RPR, MHA-TP or TPHA, titer

CBC/FBC

Chemistry (AST, ALT, Creatinine)

Plasma archive: Process/freeze w/in 4 hours if kept at room temperature, if sample is refrigerated freeze w/in 24 hours. Store at $\leq 70^{\circ}\text{C}$.

Routine Visits: minimum 4 mL; in 1-2 mL aliquots

Follow-up Positive HIV tests:
minimum 6 mL; in 1 mL aliquots

Post-seroconversion: minimum
6 mL; in 1 mL aliquots

Notify MTN if less than minimum obtained. Can recall participant if mandatory archive is not stored or is $< 50\%$ of minimum.



Leftover Specimens:

Leftover specimens may be temporarily stored for site QA purposes and problem resolution. This process must be described in an SOP or policy onsite which indicates how long the samples will be stored. Local guidelines and regulations must be followed in these situations.





Vaginal/Cervical:

Vaginal pH: strips from Machery-Nagel, Baker or S/P Cardinal Health unless approved by MTN

Wet Prep for Candidiasis and BV if indicated

Rapid Test for Trichomoniasis (Genzyme Rapid Trichomonas)

Vaginal Gram Stain: Two slides (ship one to MTN NL, archive other)

Pap Test: Per local standard of care.

Vaginal Swab Archive: PK and Biomarkers: Self collected swabs. Samples to lab w/in 8 hours, cryovial; store at $\leq -70^{\circ}\text{C}$

Endocervical Swab Archive: Biomarkers: Swab in a cryovial w/PBS.
Samples to lab w/in 8 hours; store at $\leq -70^{\circ}\text{C}$

Herpes Lesion: If indicated, per local standard of care

Positive Rapid HIV Tests:

Additional testing/samples required only after positive rapid HIV test (collected at same visit):

Western Blot (Genetic Systems)

HIV RNA PCR

CD4+ T Cell Count

Plasma archive



Depending on a participant electing to remain with MTN 020 and/or enroll in MTN 015, the required testing will change.

They will no longer have HIV serology, CBC/FBC, chemistries, plasma/vaginal fluid sampling but will have CD4, HIV RNA PCR and plasma aliquots added at specified visits.

Questions:

Off-site testing.

Urine for cultures (when visit requires GC/CT testing)

“Left-over” specimens