MTN 026 Laboratory Training Follow Up Visits

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Objectives

- Overview of Lab testing
- Collection of Pelvic Samples
- Collection of Anorectal Specimens
- Specimen Management
- Q&A

Overview of Lab Testing by Visit

	VST 1 SCR	VST 2 ENR	VST 3 Dose	VST 4-6	VST 7-12	VST 13 Final Dose	VST 14-16
UA and Culture	★	★	★	★	★	★	★
Urine GC/CT	X	★	★	★	★	★	★
Urine hCG (♀)	X	X			7		14
CBC/diff/plt	X	★	★	★	★	★	★
AST/ALT/Creatinine	X	★	★	★	★	★	16
HIV-1 and HIV-2 serology	X	X			7		16
Syphilis Serology	X	★	★	★	★	★	★
HSV-1, HSV-2, HBsAg, and HCV Serologies	X						
Coagulation (PT/INR)	X						
Plasma Archive/Storage		X			7		16
Plasma PK (Vsts 3 and 13: pre and 30-60 or 120 mins)			♦	X	7 and 8	♦	X

★ As indicated, ♦ Randomized assigned time points

Overview of Lab Testing by Visit

	VST 1 SCR	VST 2 ENR	VST 3 Dose	VST 4-6	VST 7-12	VST 13 Final Dose	VST 14-16
Vaginal NAAT for GC/CT (♀)	X						
CVL for PD/PK (♀)		X		♦		X	♦
CVF and Biopsies for PK (♀)				♦		X	♦
Pap Test (♀)	★						
Rectal HSV-1/2 detection	★	★	★	★	★	★	★
Rectal NAAT for GC/CT	X	★	★	★	★	★	★
Rectal Fluid for Microflora		X	♦			♦	
Rectal Sponge Mucosal Safety		X	♦			♦	
Rectal Fluid and Biopsies for PK (Vsts 3 and 13: 30-60 or 120 mins)			♦	♦	7 and 8	♦	♦
Rectal Enema for PD/PK		X		♦			♦
Rectal Biopsies for PD (Vsts 3 and 13: 30-60 or 120 mins)		X	♦	♦		♦	♦
Rectal Biopsies for GE, Histology, T Cell Pheno, and Proteomics		X	♦			♦	

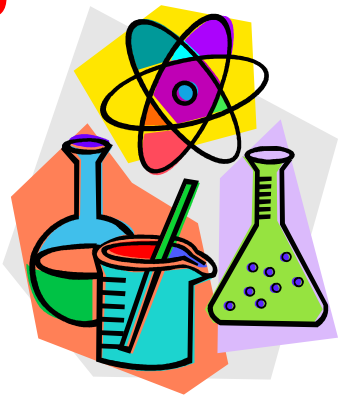
★ As indicated, ♦ Randomized assigned time points

Urine Specimens

- Urine hCG (♀) (Visits 7 and 14)
- Urinalysis and culture (if indicated)
- NAAT for GC/CT (if indicated)

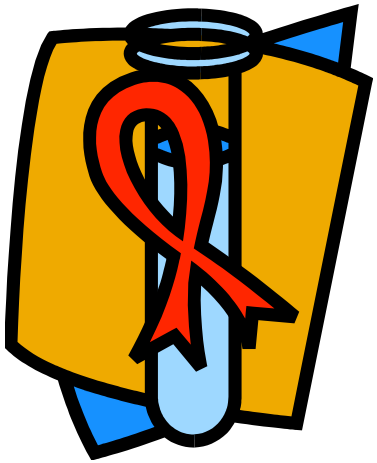
Blood Specimens

- HIV Testing (Visits 7 and 16)
  - In the case of seroconverters, notify MTN LC immediately by submitting a MTN LC HIV Testing Notification and Query Form to mtnvirology@mtnstopshiv.org
- Plasma for storage (Visits 7 and 16)
- Chemistries (Visit 16)
- Syphilis Serology (if indicated)
- CBC with diff and platelets (if indicated)



HIV Testing Notification

www.mtnstopshiv.org



MTN Laboratory Center HIV Testing Notification & Query Form

Study	
PTID	
Site/Contact Person	
Last Update	

Form Closed ☐

Please check one:

☐ Notification (LC response not required)

☐ Query (Waiting for LC Response)

Please copy/paste this table for test results from additional visits.

QUERY DATE:					
	Screening Immunoassay 1	**Screening Immunoassay 2**	**Confirmatory Assay**	**HIV RNA**	**Other Test**
Visit Code					
Testing Date					
Kit Name					
Kit Lot/Exp (optional)					
Result					

SITE COMMENTS/QUERY:

LC RESPONSE:

Participant Final Outcome

☐ HIV NEGATIVE

☐ HIV POSITIVE

☐ OTHER (Please describe further)

Blood Specimens

- Plasma for PK
  - Collect 10mL EDTA blood at each time point.
  - For visits 3 and 13, a pre-dose draw along with a randomized time point at 30-60 mins or 120 mins after dosing will be obtained. Be sure to identify time point by circling it on the LDMS TS.

☐	Blood – *Plasma PK Post-dose* **(BLD)** **Collection Time:**_____:_____ Hour : Min	**EDT** (purple top)	**PL1**	**N/A**	Store in 1.0 ml aliquots and freeze within 8 hours of collection. Enter **PK** into Other Spec ID field of LDMS. **PK Time Point (circle one):** 30-60 min or 120 min

  - At visits 4-8 and 14-16 only one time point is required.

Pelvic Samples (♀)
(Visits r4-6, 13, r14-16)

- CVF swab for PK
  - Collect within one hour of PK blood draw.
  - Weigh dacron swab/collection kit before and after collection using same analytical scale measuring to 0.1mg. Record weights onto LDMS TS.
  - Swab may be pre-cut and held with forceps or cut post collection. For details see SSP.
  - Keep refrigerated and freeze within 2 hours.

- Cervicovaginal Lavage for PD/PK

Pelvic Samples (♀)
(Visits r4-6, 13, r14-16)

- Cervical biopsies for PK
  - Weigh two (2) labeled cryovial using an analytical scale with a sensitivity of 0.1mg. Document the pre-weight on the LDMS TS.
  - Collect two (2) biopsies and place one in bottom of each pre-weighed cryovial.
  - Obtain the post-weight for each cryovial containing a biopsy using the same analytical scale and document on the LDMS TS.
  - Immediately freeze in liquid nitrogen or a dry ice alcohol bath. Document frozen time.
  - Store frozen biopsies at ≤-70°C.

Rectal Specimens

- Rectal Swabs
  - Microflora (Visits 3 and 13)
  - PK (Visits 3, r4-6, 7, 8, 13, and r14-16)
  - NAAT for GC/CT (if indicated)
  - HSV-1 and -2 (if indicated)
- Rectal Sponge for M Safety(Visits 3 and 13)
- Rectal Enema for PD (Visits r4-6 and r14-16)
- Rectal Biopsies in order of importance
  - PK (Visits 3, r4-6, 7, 8, 13, and r14-16)
  - Gene Expression (Visits 3 and 13)
  - Histology (Visits 3 and 13)
  - PD (Visits 3, r4-6, 13, and r14-16)
  - T Cell Phenotyping (Visits 3 and 13)
  - Proteomics (Visits 3 and 13)

Collection of Rectal Specimens

- Rectal swab for PK
  - Collect within 1 hour of PK blood draw
  - Weigh dacron swab/collection kit before and after collection using same analytical scale measuring to 0.1mg. Record weights onto LDMS TS.
  - Swab may be pre-cut and held with forceps or cut post collection. For details see SSP.
  - Keep refrigerated and freeze within 2 hours.

Collection of Rectal Specimens

- Rectal Biopsies for PK
  - Weigh five (5) labeled cryovial using an analytical scale with a sensitivity of 0.1mg. Document the pre-weight on the LDMS TS.
  - Collect five (5) biopsies and place one in bottom of each pre-weighed cryovial.
  - Obtain the post-weight for each cryovial containing a biopsy using the same analytical scale and document on the LDMS TS.
  - Immediately freeze in liquid nitrogen or a dry ice alcohol bath. Document frozen time.
  - Store frozen biopsies at ≤-70°C.

Specimen Management

- All specimens must be tracked according to site Chain of Custody.
- CRFs are required for specimens reported to SCHARP.
- Specimens to be shipped to the Laboratory Center must be accompanied by an LDMS tracking sheet and entered into LDMS.

Any Questions?