



MTN 026 Laboratory Training Screening Visit

Pam Kunjara, MT ASCP
MTN Laboratory Center
Magee-Womens Research Institute
Pittsburgh, PA

Objectives

- ◆ Overview of Screening Lab testing
- ◆ HIV Testing Algorithm
- ◆ Q&A





SSP Lab Section

- ◆ This will be your best resource for MTN 026 lab related questions
- ◆ Make sure you have the most current version
 - ◆ Available at www.mtnstopshiv.org

MTN Laboratory Center Contacts

- ◆ Laboratory Center

- ◆ Pam Kunjara 412-641-6393
pkunjara@mwri.magee.edu

- ◆ Johns Hopkins University
Clinical Pharmacology
Analytical Lab (JHU CPAL)

- ◆ Craig Hendrix chendrix@jhmi.edu

- ◆ Mark Marzinke mmarzin1@jhmi.edu



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

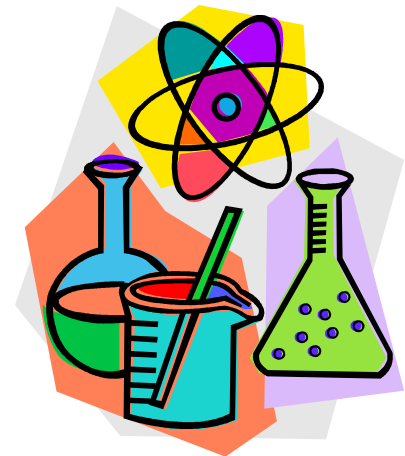


Urine Specimens

- ◆ Urinalysis and culture (if indicated)
- ◆ Urine hCG
- ◆ NAAT for GC/CT
 - ◆ GenProbe Aptima or GeneXpert
 - ◆ Use appropriate collection kit for testing platform.
- ◆ *Separate urine for hCG and Urinalysis.
Refrigerate urine for NAAT.*

Blood Specimens

- ◆ Red top or Green top tube (Na Hep)
 - ◆ Chemistries
 - ◆ ALT
 - ◆ AST
 - ◆ Creatinine
 - ◆ Hepatitis B Surface Antigen
 - ◆ Hepatitis C Antibody
 - ◆ Syphilis Serology
 - ◆ HSV-1 and -2 Testing

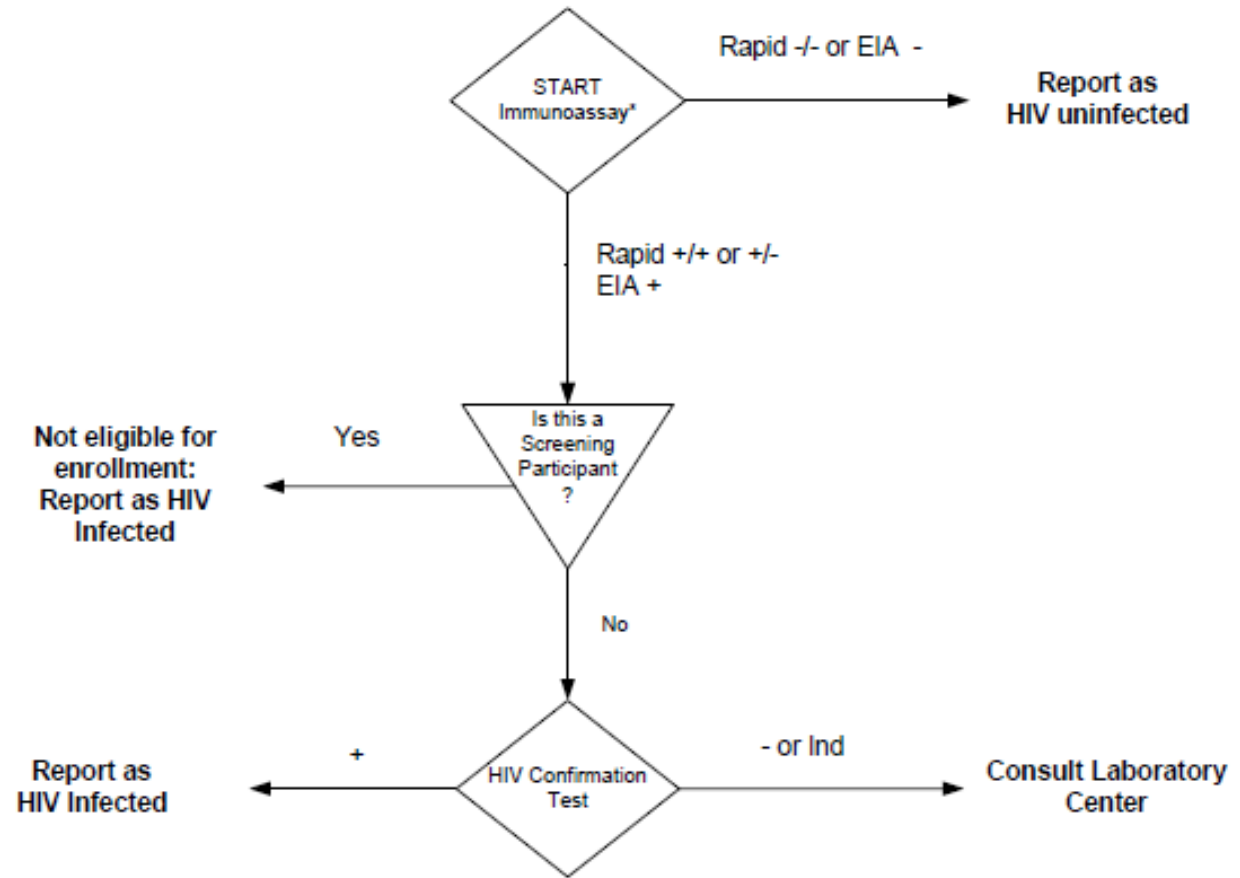
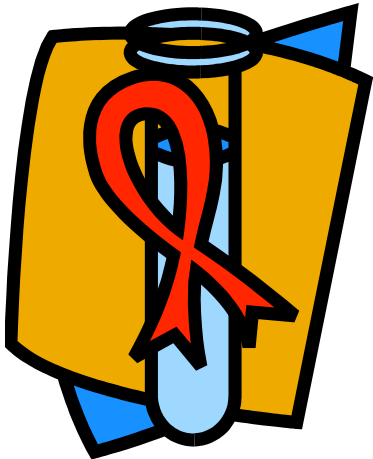


Blood Specimens

- 💧 Whole blood: light blue top tube (Na Citrate)
 - 💧 Coagulation (PT/INR)
- 💧 Whole blood: purple top tube (EDTA)
 - 💧 Complete Blood Count (CBC) with diff and platelets
 - 💧 HIV Testing – follow algorithm (Protocol Appendix II)



HIV Testing Algorithm



*CLIA certified labs may perform 1 rapid test
Ind: Indeterminate test results
EIA: Enzyme Immunoassay



Pelvic Specimens (♀)

- ◇ Pap Test
- ◇ Vaginal NAAT for GC/CT
 - ◇ GenProbe Aptima or GeneXpert

Rectal Specimens

- ❖ HSV-1 and -2 (if indicated)
- ❖ Rectal NAAT for GC/CT
 - ❖ GeneXpert only



Collection of GC/CT Swabs

- ◆ NAAT for GC/CT
 - ◆ *Product gel may cause interference during testing. Please be sure to avoid gel during collection.*
 - ◆ Use appropriate swab for testing platform.
 - ◆ Swab lateral wall of the vagina (♀), rotating 360°
 - ◆ Insert swab into rectum, rotating 360°
 - ◆ After collection place the swab in the transport tube, break off shaft and cap. Store according to collection kit recommendations.
 - ◆ The results are sent to the clinic and are reported on a CRF.



Specimen Management

- ◆ All specimens must be tracked according to site Chain of Custody.
- ◆ CRFs are required for specimens reported to SCHARP.

Any Questions?

