Objectives

- Overview of Screening Lab testing
- HIV Testing Algorithm
- Q&A
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](http://www.mtnstopshiv.org)
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<table>
<thead>
<tr>
<th></th>
<th>VST 1 SCR</th>
<th>VST 2 ENR</th>
<th>VST 3 Dose</th>
<th>VST 4-6</th>
<th>VST 7-12</th>
<th>VST 13 Final Dose</th>
<th>VST 14-16</th>
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<td>UA and Culture</td>
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<td>★</td>
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<td>Urine GC/CT</td>
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<td>HSV-1, HSV-2, HBsAg, and HCV Serologies</td>
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<td>Plasma PK (Vsts 3 and 13: pre and 30-60 or 120 mins)</td>
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<td>X</td>
<td>7 and 8</td>
<td>♦</td>
<td>X</td>
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★ As indicated, ♦ Randomized assigned time points
## Overview of Lab Testing by Visit

<table>
<thead>
<tr>
<th>VST 1 SCR</th>
<th>VST 2 ENR</th>
<th>VST 3 Dose</th>
<th>VST 4-6</th>
<th>VST 7-12</th>
<th>VST 13 Final Dose</th>
<th>VST 14-16</th>
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<td>7 and 8</td>
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<td>Rectal Biopsies for GE, Histology, T Cell Pheno, and Proteomics</td>
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<td>♦</td>
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</tbody>
</table>

★ 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

START Immunoassay*

Rapid +/- or EIA -
Report as HIV uninfected

Rapid +/- or +/- EIA +

Is this a Screening Participant?

Yes
Not eligible for enrollment: Report as HIV Infected

No

HIV Confirmation Test

Report as HIV Infected

- or Ind
Consult Laboratory Center

*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?