VOICE Seroconverter Specimen Collections

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Overview

- Sample 2
- Post-seroconversion specimen collections
Follow-up HIV testing algorithm

Why is this important?
Sample 2

- Required to determine final HIV status per algorithm
  - Western Blot
- Additional blood drawn for
  - Plasma archive
  - CD4
  - HIV RNA PCR (viral load)

Most important sample for study purposes
Sample 2 – Plasma Archive

Tested by Network Lab to confirm seroconversions

What if Sample 2 plasma archive is missed?
Sample 2 – **Missed plasma archive**

- Attempt to collect as soon as possible

- If not collected:
  - Network Lab cannot confirm HIV status
  - SCHARP cannot count as seroconversion in SMC/DSMB reviews
  - Difficult to assess study progress in achieving required number of endpoints
  - Review required by Endpoint Adjudication Committee
Post-seroconversion specimens

Plasma archive, CD4, and HIV RNA PCR (viral load)

- Repeated post-seroconversion based on Sample 1 date
  - 1-month (next regularly scheduled visit)
    - Omit if algorithm testing still in progress
  - 3-months
  - 6-months
  - Every 6 months thereafter until termination
Post-seroconversion specimens

- Once participant enrolls in MTN015, specimens no longer collected in VOICE
- Ideally, specimens collected as part of regularly scheduled VOICE visits
- Each collection has an allowable window
Guidance and Tools

- SSP Sections 6 and 13
- Sample 2 visit checklist
- HIV Seroconversion in MTN-003: Specimen Collection/Testing and MTN-015 Enrollment Timing
- Operational Reminder – new
- Seroconverter Specimen Collection Tool – new
- Seroconverter checklist - in progress

Available on the MTN web site
## Seroconverter Specimen Collection Tool – new

**MTN 003 (VOICE) Seroconverter Specimen Collection Schedule**
*CD4+ Count, Viral Load, Plasma Archive*

**PTID:** 999-99999-9  
**Staff Initials and Date:**

**TARGET DATE of visit when Sample 1 collected:** 05-Jan-11

**Seroconversion Date:** 02-Jan-11

<table>
<thead>
<tr>
<th>Expected Collection</th>
<th>Collection Window Opens</th>
<th>Target Date</th>
<th>Collection Window Closes</th>
<th>Actual Collection Date</th>
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Summary – Key Points

- Sample 2 plasma archive is key to study
- Draw Sample 2 as soon as possible once need is identified
- Plasma archive, CD4, viral load required with Sample 2 draw and again at designated post-seroconversion time points
- Sites need seroconverter tracking system
  - Use tools
  - Conduct staff refresher training as needed
Questions or Issues

Contact the VOICE Study Management Team (mtn003mgmt@mtnstopshiv.org)