

VOICE Seroconverter Specimen Collections

Karen Patterson, MPH

Statistical Center for HIV/AIDS Research &
Prevention (SCHARP)

Fred Hutchinson Cancer Research Center

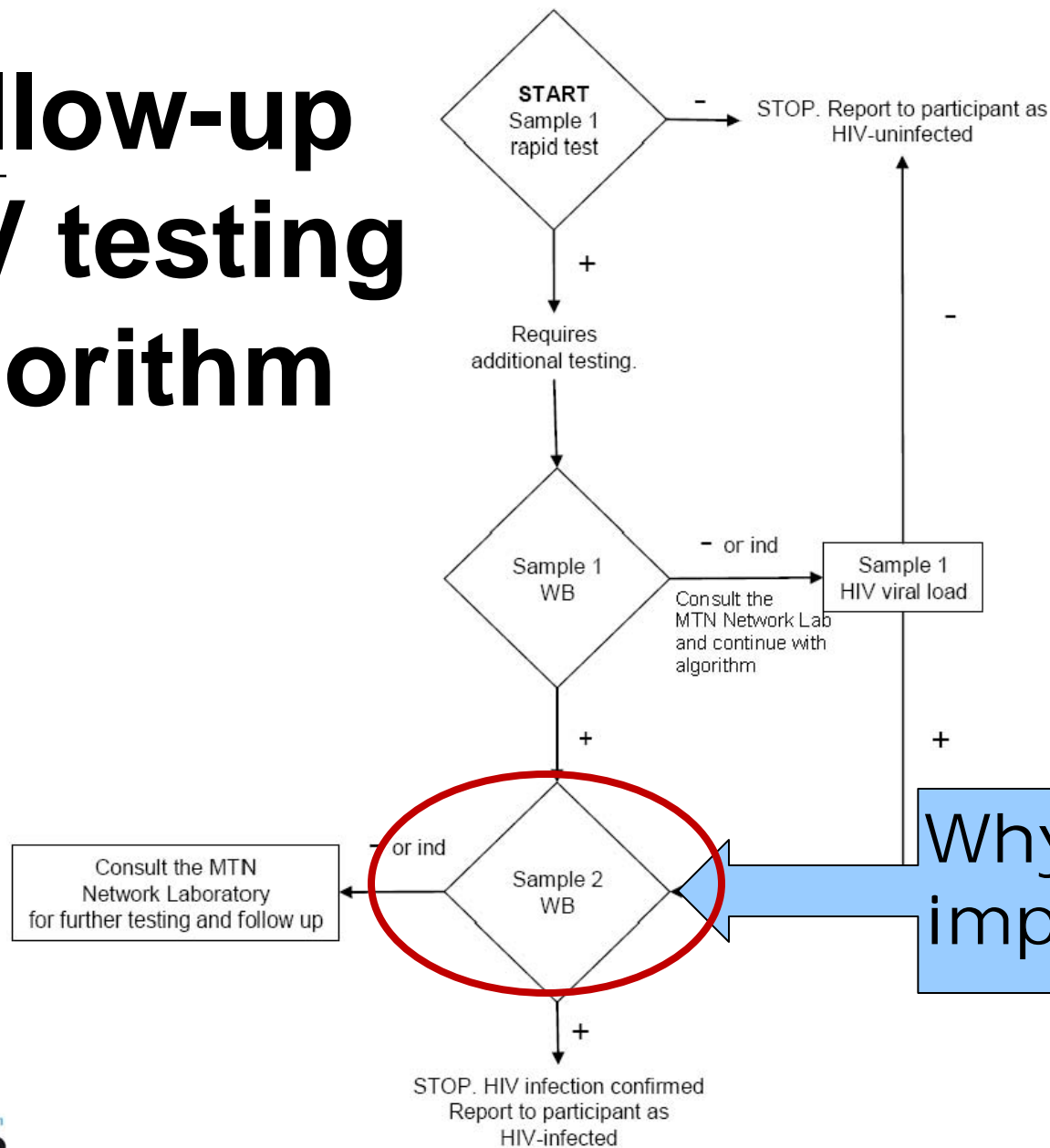
Seattle, WA, USA



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?

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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

(dd-~~MMM~~-yy)

Seroconversion Date*: 02-Jan-11

Expected Collection	Collection Window Opens	Target Date	Collection Window Closes	Actual Collection Date
1-month post-seroconversion**	19-Jan-11	02-Feb-11	15-Feb-11	
3-months post-seroconversion	04-Mar-11	02-Apr-11	18-May-11	
6-months post-seroconversion	19-May-11	03-Jul-11	02-Oct-11	
12-months post-seroconversion	03-Oct-11	02-Jan-12	02-Apr-12	
18-months post-seroconversion	03-Apr-12	03-Jul-12	02-Oct-12	
24-months post-seroconversion	03-Oct-12	01-Jan-13	02-Apr-13	
30-months post-seroconversion	03-Apr-13	03-Jul-13	02-Oct-13	
36-months post-seroconversion	03-Oct-13	01-Jan-14	02-Apr-14	

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)**