

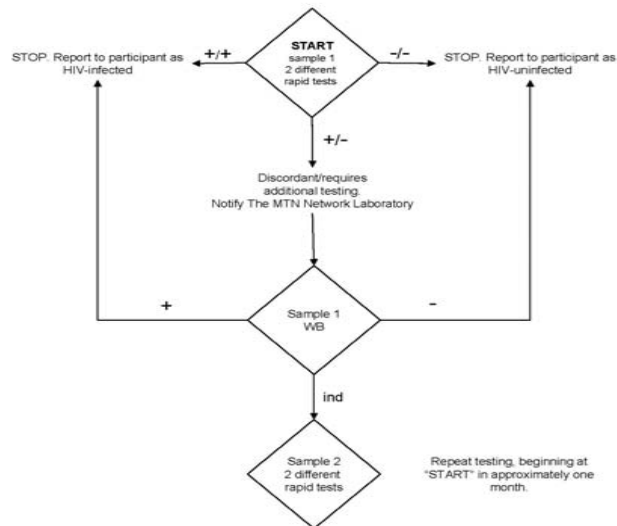
VOICE (MTN-003)

IT'S ALL ABOUT THE ENDPOINTS

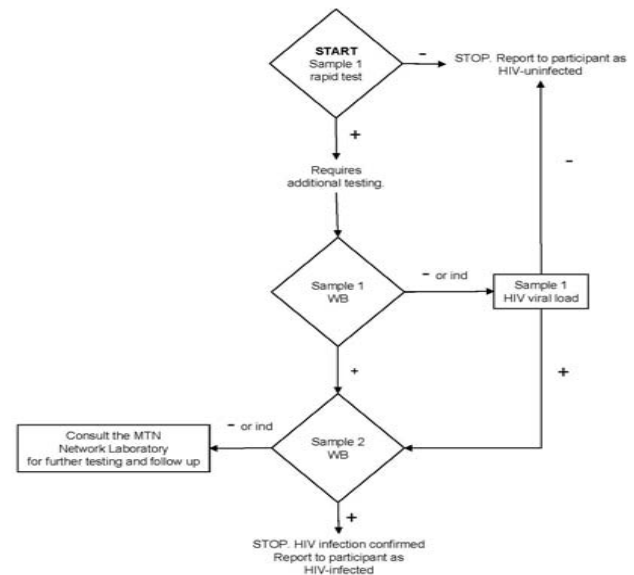
Edward Livant MT (ASCP), MPH
University of Pittsburgh Medical Center
MTN Network Laboratory

Review of “Sample 2”

Algorithm for HIV antibody testing
(screening)



Algorithm for HIV antibody testing
(follow-up and primary endpoint determination)

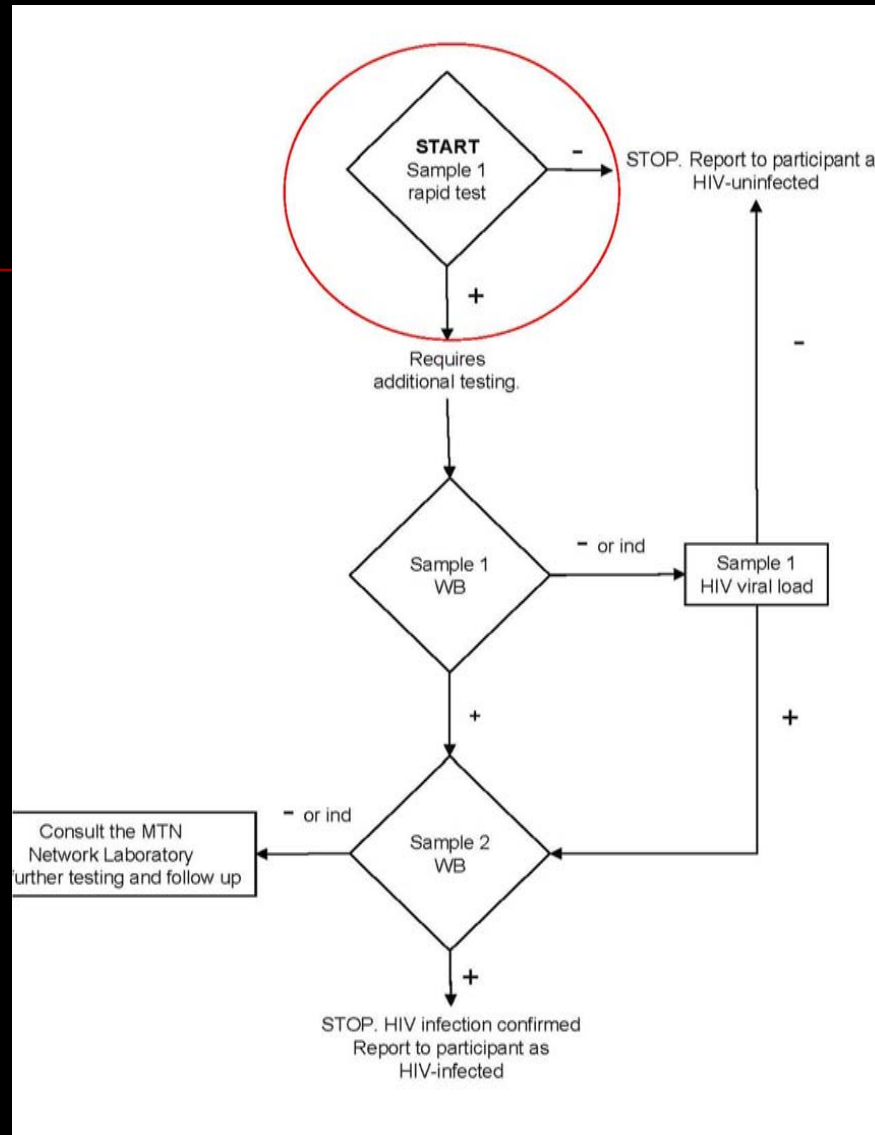


Testing starts here with rapid test (s).

Negative → Stop

Positive → Continue

Discordant → Continue

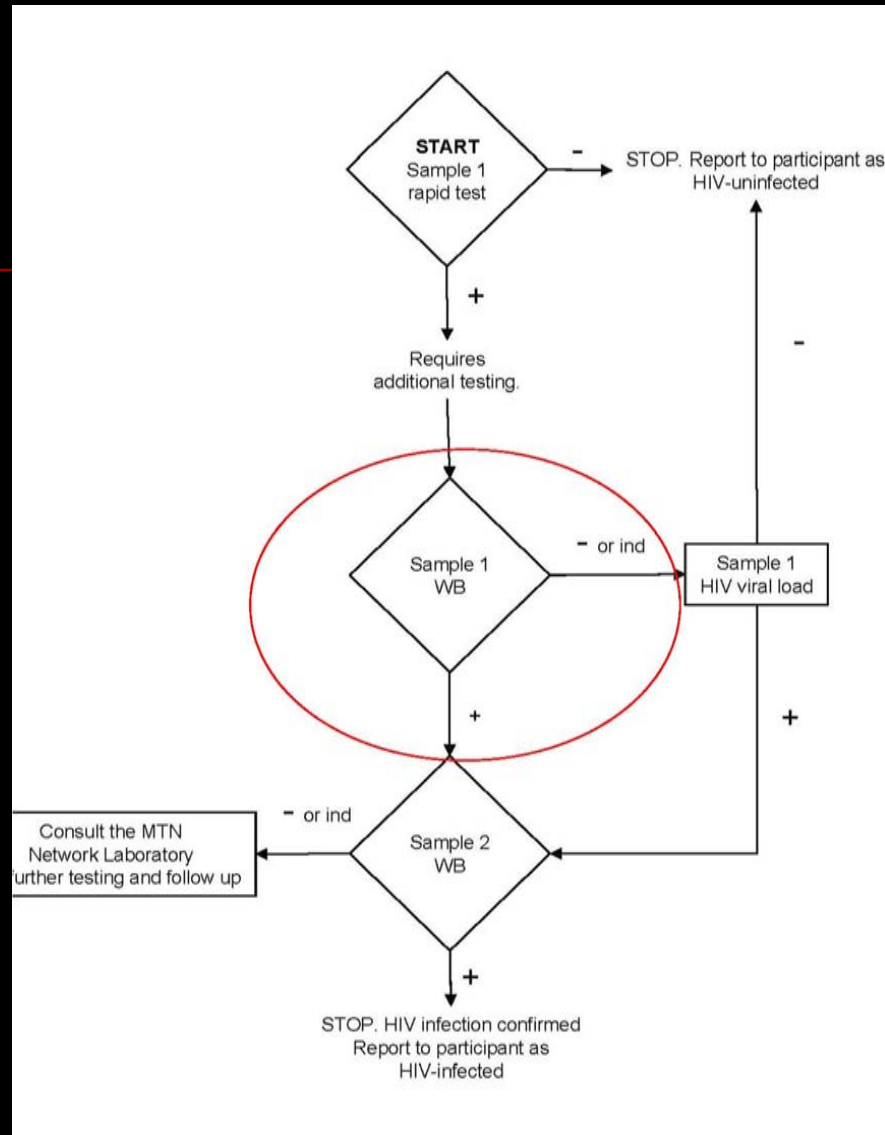


If you had a positive rapid test, you will perform a Western Blot.

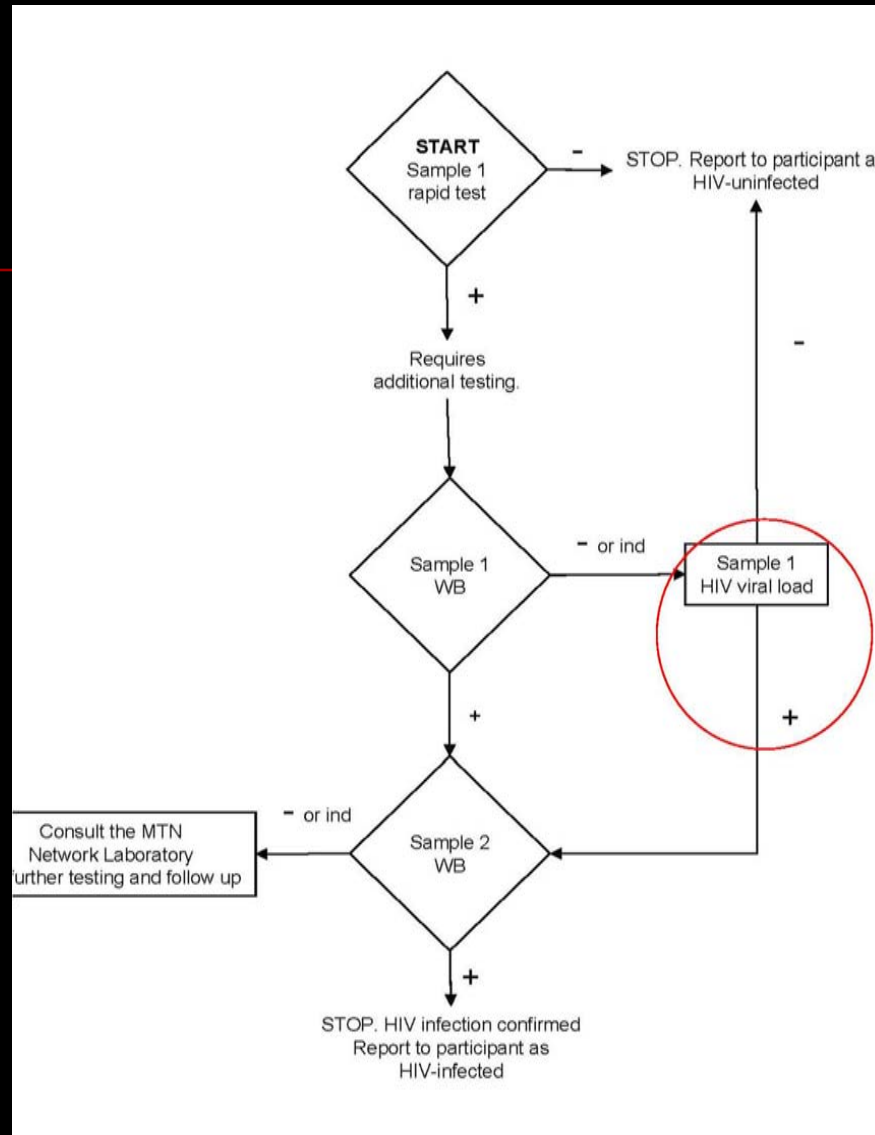
This is “Sample 1”

If the results are negative or Indeterminate, proceed to an RNA.

If the results are positive, proceed to “sample 2”.



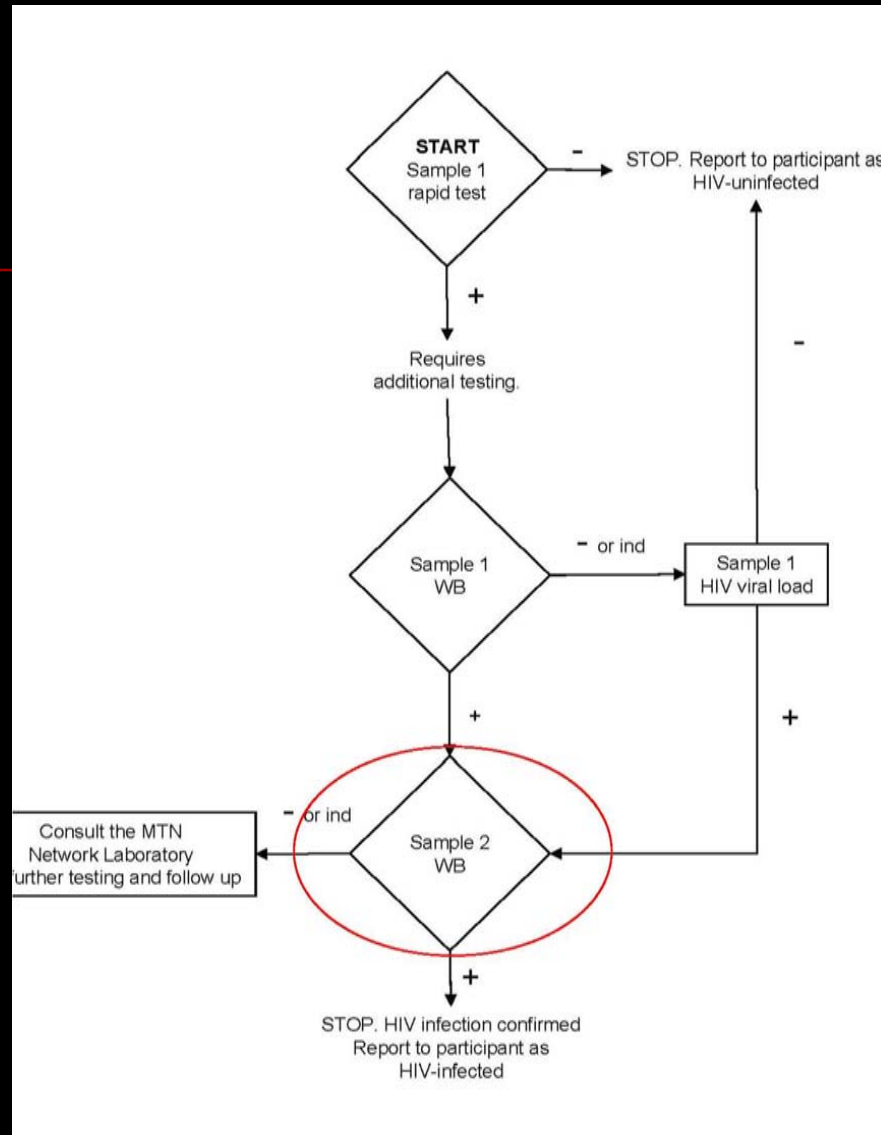
Sites can consider a positive HIV rapid test indication to store plasma archive if possible. This is not a requirement.



If the RNA is Positive, proceed to “sample 2”.

If the sample is negative, the algorithm is complete. We suggest you contact the Network Laboratory or protocol team in this situation for guidance.

If the "Sample 2" Western Blot is negative or indeterminate, contact the MTN Network Laboratory for guidance.



If the "Sample 2" Western Blot is positive, local HIV diagnostic testing is complete. The Network Laboratory will do a third confirmatory test.

Know the differences: Sample 1 versus Sample 2

- What triggers a sample 2?.
 - Positive HIV rapid test with a positive HIV Western Blot
- Sample 2 requires collection of additional specimens.
- Use the Sample 2 checklist.

The checklist shows what specimens are needed at Sample 2:

- Western Blot
- Plasma archive
- CD4
- HIV RNA

PTID:	Visit Date:	Visit Code:
Initials	Procedures	
	1. Provide and document HIV counseling and testing per site SOPs	
	2. Provide sample 1 test result(s) and counseling	
	3. Provide HIV/STI risk reduction counseling and condoms	
	4. Collect 25 mL blood in lavender top (EDTA) tubes and perform the following: <ul style="list-style-type: none"> <input type="checkbox"/> Western Blot <input type="checkbox"/> Plasma archive <ul style="list-style-type: none"> ⇒ Store a minimum of 6x1 mL aliquots <input type="checkbox"/> CD4+ T cell count test <input type="checkbox"/> HIV-1 RNA PCR test [additional blood needed for clinically-indicated testing also may be collected at this time]	
	5. Provide referrals if needed/requested	
	6. Offer HIV counseling and testing for partner(s)	
	7. Inform participant of MTN-015 and her potential eligibility	
	8. If the Sample 2 results will be reported to the clinic prior to when the next monthly visit is scheduled/due, schedule an interim visit as needed.	
	9. Fax all required DataFax forms to SCHARP DataFax: <ul style="list-style-type: none"> <input type="checkbox"/> HIV Western Blot Test Results <input type="checkbox"/> Specimen Storage/PK <input type="checkbox"/> Seroconverter Laboratory Test Results 	

Blood draw volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes.

Specimen Collection at Sample 2

- Specimens Required at Sample 2
 - Plasma Archive
 - Must store minimum 6 mL of plasma; draw 12-15 mL of whole blood
 - Local Testing-draw amounts vary with site criteria
 - CD4 Count
 - RNA HIV-1 Viral Load
 - HIV-1 Western Blot

Importance of Plasma archive

- Enrollment plasma archive and Sample 2 plasma archive have an even higher importance than routine visit archives
- Why?

Importance of Plasma archive

- Enrollment plasma archive and Sample 2 plasma archive have an even higher importance than routine visit archives
- Why?
 - Plasma archive from enrollment shows that the participant was uninfected at enrollment. It is the only archive sample before the participant is on product.

Importance of Plasma archive

- Enrollment plasma archive and Sample 2 plasma archive have an even higher importance than routine visit archives
- Why?
 - Sample 2 archive may help give a better idea of when infection occurred.

Importance of Plasma archive

- Enrollment plasma archive and Sample 2 plasma archive have an even higher importance than routine visit archives
- Why?
 - Sample 2 archive is usually the earliest plasma available for resistance testing after infection. Resistance patterns can change over time.

Importance of Plasma archive

- Enrollment plasma archive and Sample 2 plasma archive have an even higher importance than routine visit archives
- Why?
 - The plasma from enrollment and sample 2 are crucial to verify true endpoints.

Specimen Collection at Sample 2 and Enrollment

- If there is a problem with these plasma archives (missed, lost, sample damaged, etc..)
 - You do not need to wait for permission from the NL or protocol team to call back participant
 - Notify the NL or protocol team immediately to report problem and get guidance on documentation.
 - These are the most precious samples in VOICE.

Additional Topics



Urine Dipstick Discussion

- Any Siemens dipstick can be used-the tests in the different combinations (4, 9) are the same.
- Any abnormal results on dipsticks should trigger participant follow up, even if not a protocol analyte for VOICE. (Bilirubin, Blood, etc...)
- Should all sites consider using the 4 test strip?

Operational Reminders From NL

- LDMS Reconciliations-why do I have to fix these CRF's?
 - Because this will be the only way to resolve the errors and have correct data at SCHARP.
- DAIDS requires you run QC at least once per week for rapid tests if you test participants that week.

Operational Reminders From NL

- Make sure to use the Quidel Urine Pregnancy Kit. Do not use the Urine + Serum combo kit.
- Why?
 - Because the combo kit has not been validated for use with vaginal gels. The urine kit has been validated for use with gels.

Examples of Emerging Issues

- Issue: Staff omitted RNA viral load from follow up algorithm
- Response: Make sure staff review algorithm frequently and note differences between screening and follow up

Examples of Emerging Issues

- Issue: Staff did not take swabs for storage during a pelvic exam
- Response: Review procedures for the sample collection required during pelvic exams

Examples of Emerging Issues

- Issue: Repeat labs missed.
- Response: Make sure to review procedures for when to repeat tests

Examples of Emerging Issues

- Issue: Missed plasma archive enrollment
- Response:
 - Make all efforts possible to get enrollment archive samples. These are very precious because they cannot be truly recollected after the participant has started product.
 - If it is missed or there is a problem in processing, recollect as soon as possible.

Examples of Emerging Issues

- Issue: Specimens collected outside the office at a home and a workplace.
- Response: Specimens cannot be collected outside of the clinic.

Examples of Emerging Issues

- Issue: Participant enrolled who had exclusionary lab results
- Response: Add additional reviews if necessary

Examples of Emerging Issues

- What do these examples teach us?
 - Review the checklists prior to participant visits.
 - Review procedures frequently.

Thank You-Questions?

What the heck was he saying????

