MTN 017 Laboratory Training

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Objectives

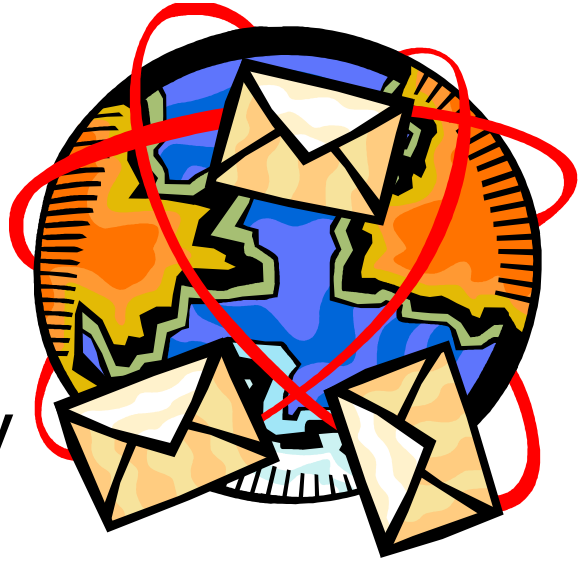
- Overview of Screening Lab testing
- HIV Testing Algorithm
- HIV Result CRF
- Q&A

SSP Lab Section

- This will be your best resource for MTN 017 lab questions
- Make sure you have the most current version
  - Available at www.mtnstopshiv.org

MTN Laboratory Contacts

- Laboratory Center (LC)
  - Pam Kunjara 412-641-6393 pkunjara@mwri.magee.edu



- JHU 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 MID	VST 4 END	VST 5 PD2	VST 6 MID	VST 7 END	VST 8 PD3	VST 9 MID	VST 10 END
UA	X	★	★	★	★	★	★	★	★	★
Urine GC/CT	X	★	★	★	★	★	★	★	★	X
CBC/diff/plt	X	★	★	★	★	★	★	★	★	X
AST/ALT	X	★	★	★	★	★	★	★	★	X
Creatinine	X	★	★	X	★	★	X	★	★	X
HIV serology	X	X	X	X	★	X	X	★	X	X
Plasma archive/storage		X		X			X			X
HBsAg and Ab	X									
Hep C Ab	X									
HSV 1 and 2 Ab	X									
Syphilis	X	★	★	★	★	★	★	★	★	★
Blood for PK (PBMC and plasma)			X (plasma only)	X		X (plasma only)	X		X (plasma only)	X
Coagulation (PT/INR)*	X									

Overview of Lab Testing by Visit

	VST 1 SCR	VST 2 ENR	VST 3 MID	VST 4 END	VST 5 PD2	VST 6 MID	VST 7 END	VST 8 PD3	VST 9 MID	VST 10 END
Rectal HSV detection	★	★	★	★	★	★	★	★	★	★
Anal HPV		X								
Rectal GC/CT	X	X	★	X	★	★	X	★	★	X
Rectal sponge for PK		X	X	X	X	X	X	X	X	X
Rectal sponge for PD			X	X	X	X	X	X	X	X
Rectal sponge immuno*		X		X			X			X
Rectal biopsy Proteomics*		X		X			X			X
Rectal biopsy Histology*		X		X			X			X
Rectal biopsies Pheno*		X		X			X			X
Rectal biopsy Gene Array*		X		X			X			X
Rectal biopsies PD*		X		X			X			X
Rectal biopsies PK*				X			X			X

*Tissue subset only

Overview of Lab Testing

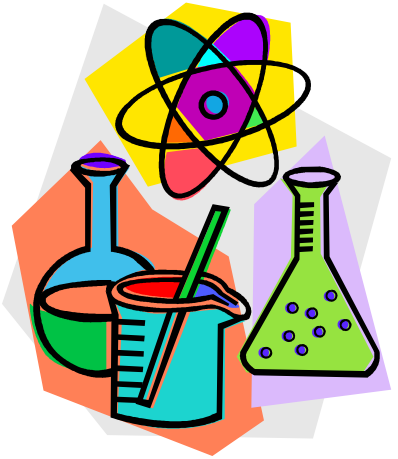
Urine Specimens

- Urinalysis
- NAAT for GC/CT
  - GenProbe Aptima
  - GeneXpert
- *Separate urine for Urinalysis. Refrigerate urine for NAAT*.

Overview of Lab Testing

Blood Specimens

- Red top or Green top tube (Na Hep)
  - Chemistries
    - ALT
    - AST
    - Creatinine – Calculation tool for Creatinine clearance available www.mtnstopshiv.org
  - Hepatitis B Surface Antigen and Antibody
  - Hepatitis C Antibody
  - Syphilis Serology
  - HSV Testing

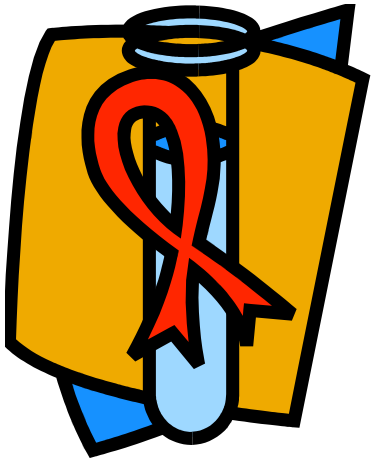


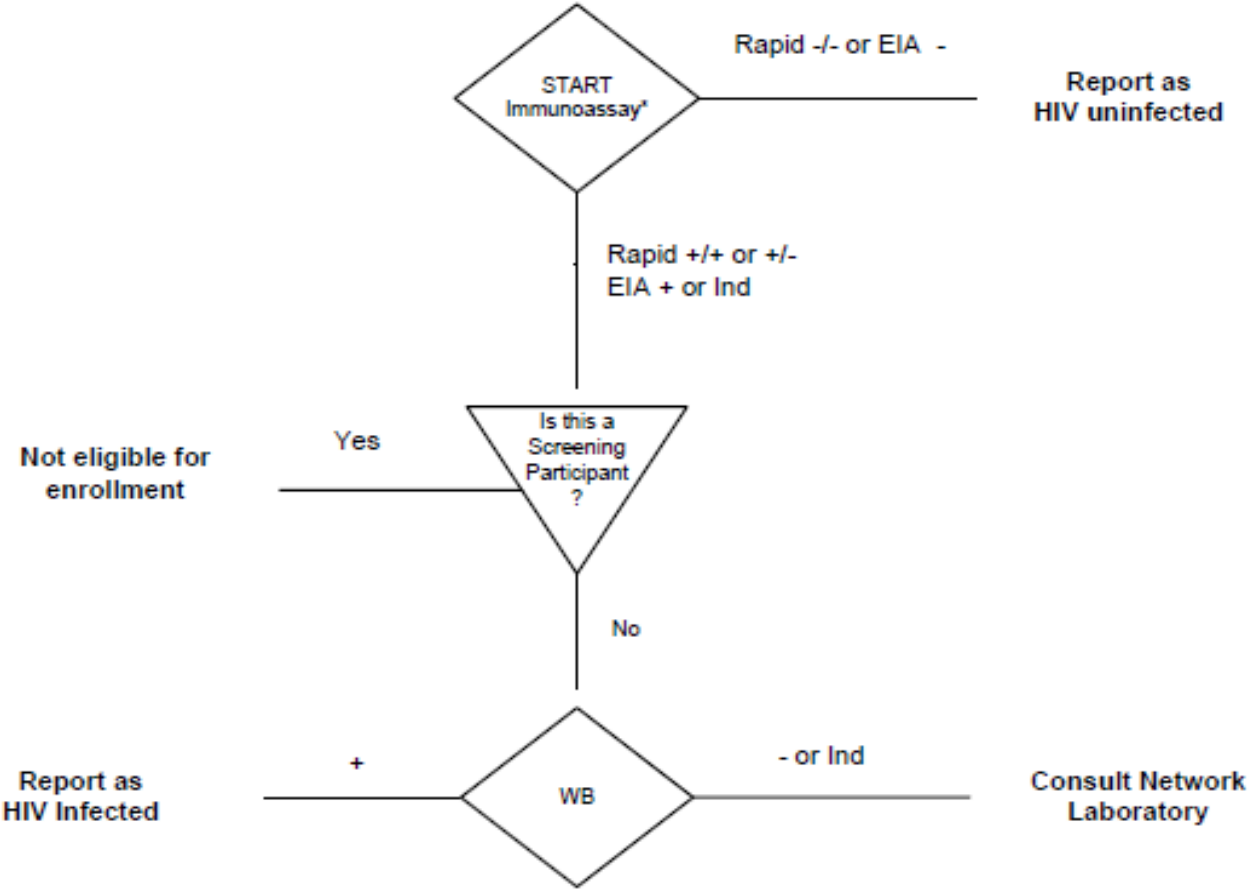
Overview of Lab Testing

Blood Specimens

- Whole blood: blue top tube (Na Citrate)
  - 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

SCHARP

HIV-1, Page 1 of 1

SAMPLE: DO NOT FAX TO DATAFAX

MTN-017 (198)

HIV-1 (140)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number | Participant Number | Chk

HIV Results

Initial Specimen Collection Date

dd MMM yy

	Not done/ Not collected	kit code	Alternate Collection Date dd	MMM	yy	negative	positive	indeterminate
1. Rapid HIV test 1:	☐	☐☐	☐☐	☐☐☐	☐☐	☐	☐	
2. Rapid HIV test 2:	☐	☐☐	☐☐	☐☐☐	☐☐	☐	☐	
3. HIV-EIA:	☐		☐☐	☐☐☐	☐☐	☐	☐	☐

If any are positive at Screening or Enrollment, participant is ineligible.
If any are positive during follow-up, complete HIV Confirmatory Results form and Clinical Product Hold/Discontinuation Log.

If indeterminate at Screening, participant is ineligible.
If indeterminate during follow-up, complete HIV Confirmatory Results form and Clinical Product Hold/Discontinuation Log.

4. Was plasma stored for the Network Lab (Confirmatory HIV Serology)? *yes* ☐ *no* ☐ *not required* ☐ → *If no or not required, end of form.*

Note: *Plasma storage for the Network Lab is required at all End Period Visits, any time there is a positive rapid or EIA HIV test result during follow-up, and any time Sample 2 is collected.*

4a. Plasma for storage collection date: dd ☐☐ MMM ☐☐☐ yy ☐☐

Comments:

☐ ☐ ☐ ☒ 12-NOV-12

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0 1 English

Staff Initials/Date

HIV Results (HIV-1)

Purpose: This form is used to document the participant's HIV rapid test or EIA results, and plasma storage for HIV confirmatory testing as specified in the protocol.

General Information/ Instructions: Record test results on this form as they become available. Fax this form into SCHARP DataFax once results for **all** collected specimens are recorded on the form.

- **Initial Specimen Collection Date:** Record the date that the first specimen was collected (NOT the date results were reported or recorded on the form). A complete date is required.
- **Alternate Collection Date**: This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form.
- **Not done/Not collected:** Mark this box in the event that a specimen was not collected or if the specimen was collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available in the Comments.

Item-specific Instructions:

Visit Code: Record the visit code assigned to this visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Items 1 and 2: Record the assigned two-digit rapid test kit code. *Note: More test kit codes may be added to the list as the study proceeds.*

Kit Code	Rapid Test
01	Determine
02	OraQuick
03	Uni-Gold Recombigen
04	Bioline
05	Clearview Statpak

If item 1, 2, or 3 is positive (meaning the participant had at least one positive HIV test result) during follow-up, complete a new HIV Confirmatory Results form and a Clinical Product Hold/Discontinuation (PH) Log.

Item 3: If positive during follow-up, complete a new HIV Confirmatory Results (HCR) form and a Clinical Product Hold/Discontinuation (PH) Log.

Collection of Rectal Specimens

- NAAT for GC/CT
  - *Product gel may cause interference during testing. Please be sure to avoid gel during collection.*
  - Use Gene Xpert collection swab.
  - After collection place the swab in the transport tube, break off shaft and cap. The specimen can now remain at 2-30°C for 30 days.
  - The results are sent to the clinic and are reported on a CRF.

Any Questions?