

Section 13. Laboratory Considerations

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This section contains information on the laboratory procedures performed in MTN-025.

13.1 Overview and General Guidance

As transmission of HIV and other infectious agents can occur through contact with contaminated needles, blood, blood products, and vaginal secretions, all study staff must take appropriate precautions when collecting and handling biological specimens. Sites must have

appropriate written safety procedures in place before study initiation. Guidance on universal precautions available from the US Centers for Disease Control can be found at the following website:

<http://www.cdc.gov/niosh/topics/bbp/universal.html>

Section Appendix 13-1 provides an overview of the laboratory testing locations, specimens, and methods for MTN-025. Laboratory procedures will be performed in study site clinics or laboratories, approved commercial laboratories and in the MTN Laboratory Center (LC), including the MTN Pharmacology Core (at Johns Hopkins University) and MTN Virology Core (at the University of Pittsburgh). Regardless of testing location, all study staff performing testing must be trained on proper testing methods and associated quality control (QC) procedures prior to performing the tests for study purposes; training documentation should be available for inspection at any time.

All site laboratories will be monitored by the MTN LC which will utilize information from DAIDS monitoring groups (pSMILE, IQA, VQA, etc.) to monitor and certify laboratories for testing. Please refer all questions related to laboratory testing to the MTN LC using the following email address: mtnnetworklab@mtnstopshiv.org.

In addition to the specimen guidelines provided in Section Appendix 13-1, laboratory processing guidelines are provided in Section Appendix 13-2. Although specimen collection volumes may vary somewhat across sites, all sites must ensure that collection volumes collected do not exceed the specifications of their study informed consent forms. The MTN LC may request details of specimen collection containers and volumes for purposes of assisting sites in meeting this requirement.

Ideally, one method, type of test kit, and/or combination of test kits will be used for each protocol specified test throughout the duration of the study. If for any reason a new or alternative method or kit must be used after study initiation, site laboratory staff must perform a validation study of the new method or test prior to changing methods. The MTN LC must be notified before the change and can provide further guidance on validation requirements. Similarly, the MTN LC must be notified when normal ranges are changed.

Provided in the remainder of this section is information intended to standardize laboratory procedures across sites. Adherence to the specifications of this section is essential to ensure that data derived from laboratory testing will be considered acceptable to all regulatory authorities across study sites. It should be noted however that this section is not intended to serve as an exhaustive procedures manual for all laboratory testing. This section must be supplemented with site standard operating procedures (SOPs) for specimen management, processing, and testing.

Notify the MTN LC if you need to send samples to a backup laboratory. Specify to the backup lab the kits which are to be used.

DAIDS requires that rapid test (QC) be performed at least weekly when testing study participant samples, in addition to requirements in package inserts. This regulation must be followed for all MTN-025 testing.

13.2 Specimen Labeling

All containers into which specimens are initially collected will be labeled with SCHARP-provided participant ID (PTID) labels. SCHARP will provide pre-printed labels or a template

that can be used to generate labels. The specimen collection date should also be included on the label. If the date is handwritten, it should be written in indelible ink (such as a Sharpie pen).

When specimens are tested at the local lab, any additional labeling required for on-site specimen management and chain of custody will be performed in accordance with site SOPs.

The following specimens, which are stored for later off-site testing, will be entered into the Laboratory Data and Management System (LDMS) and labeled with LDMS-generated labels:

- Self-collected vaginal fluid swabs for PK and biomarker testing at the MTN LC
- Plasma for storage for HIV testing and testing of study drug levels at the MTN LC
- Intravaginal rings for residual drug analysis
- Hair for detection of drug

Specimens that are tested locally do not need to be logged into LDMS or labeled with LDMS-generated labels.

13.3 Procedures for Specimens That Cannot Be Evaluated

Specimen collection will be repeated (whenever possible) if it is found that specimens cannot be evaluated per site SOPs. Site clinic and laboratory staff will monitor specimen collection, processing, and management as part of ongoing quality assurance (QA) procedures and take action as needed to address any issues or problems.

13.4 Use of LDMS (Laboratory Data Management System)

Frontier Science Foundation (FSTRF) supports the LDMS program which is used to track storage and shipping of laboratory specimens. LDMS must be used at all sites to track the collection, storage, and shipment of the types of specimens listed in Section 13.2. Section Appendix 13-3 provides a guide for logging MTN-025 specimens into LDMS. Detailed instructions for use of LDMS are provided at <https://www.fstrf.org/ldms> (may require a password-contact FTSRF for a password).

All sites are required to maintain the current version of LDMS and monitor updates relating to use of the LDMS. Sites should update LDMS within 3 weeks of the version being available unless there extenuating circumstances. It is crucial to be aware of proper label formats to ensure that specimens are correctly labeled. All sites must routinely back up their LDMS data locally (frequency determined by site) and export their data to FSTRF at least weekly.

Questions related to use of LDMS in MTN-025 may be directed to Edward Livant or LDMS Technical (User) Support. Usual business hours for LDMS User Support are 7:30 am - 6:00 pm (US ET) on Monday and Fridays and 7:30 am - 8:00 pm (US ET) on Tuesdays, Wednesdays, and Thursdays. During business hours, please contact LDMS User Support as follows:

Email: ldmshelp@fstrf.org
Phone: +001 716-834-0900, ext 7311
Fax: +001 716-898-7711

Each site must export its LDMS data to Frontier Science (FSTRF) on a weekly basis. Exported data are used by the MTN Statistical and Data Management Center (SDMC) to

generate a monthly specimen repository report and to reconcile data entered in LDMS with data entered on study case report forms (CRFs), check for errors in LDMS codes, and ensure storage information is entered for archive specimens. Any issues identified during the reconciliation are included in a monthly discrepancy report for each site. Sites are expected to resolve all issues within two weeks of receipt of the report. The MTN LC is responsible for reminding sites to adhere to the two-week timeframe and for following up with sites that do not resolve discrepancies within two weeks.

The MTN SDMC reviews the reconciliation reports for critical samples (e.g., plasma needed for confirmatory HIV testing) that appear to be missing, and works with the LC and site staff to undertake appropriate corrective action. All corrective action should be documented in paper-based clinic and/or laboratory records as appropriate, and entered in the details section of LDMS. The LC and SDMC will discuss and document any items that, although resolved, appear ‘irresolvable in LDMS’.

Sites are encouraged to have a weekly QC of LDMS data versus CRF data to correct discrepancies before they make it to the LDMS reconciliation reports.

Sites may use LDMS to track samples for local testing but these samples must be marked as “never store” in LDMS or they may appear on the LDMS reconciliation reports. This feature will be discontinued when LDMS becomes an online program. This guidance will be updated at that time.

MTN-025 will require the use of the “Other Spec ID” field for plasma storage. See Section 13.7.6 and Appendix 13-4 for details.

The LC recommends you separate your specimens by sample type in the freezers. This may save time in the future when sorting.

13.5 Documentation

Each lab test must have a defined source document that is the first place the result is recorded or generated; this must be described in an SOP. There must be quality control systems in place to ensure that results transcribed from source documents agree with reports going to clinics. Other laboratory records such as quality control results and calibrations should also be treated as source documents. Site labs will have a plan for the storage of these documents so that they are easily retrievable for auditors and network oversight visits.

All staff reporting results must:

- Be listed on site delegation logs
- Have documentation of training before reporting results
- Have documentation of competency assessment before reporting results, 6 months after training and annually thereafter

In most cases, lab results will be recorded from source document to CRF without any unit conversion. If unit conversion is required from source document to CRF, this must be automated and cannot be done manually. Contact the management team at mtn025mgmt@mtnstopshiv.org if you have questions.

13.6 Urine Testing

The urine tests performed at each study visit will depend on the time point of the visit and the clinical presentation of the participant. In general, at study visits when urine testing is required, a single specimen will be collected and then aliquots will be made for each test when possible. When doing multiple tests from one specimen, an aliquot of urine should first be obtained for pregnancy testing and the remaining specimen should be reserved for chlamydia and gonorrhea testing. Collect urine specimens before collecting any pelvic specimens. Heavy menses may interfere with pregnancy tests – sites should use discretion and contact the MTN LC if there are questions.

13.6.1 Specimen Collection

- As possible, the participant should not have urinated within one hour prior to urine collection.
- Provide the participant with a sterile, plastic, preservative-free screw-top urine collection cup labeled with a SCHARP-provided PTID label.
- Instruct the participant to:
 - Not clean the labia prior to specimen collection.
 - Collect the first 15 to 60 mL of voided urine (not mid-stream).
 - Screw the lid tightly onto the cup after collection.
- Note: only in situations where there is no NAAT testing and a clinician suspects a urinary tract infection, specimens may be collected per local specifications such as mid-stream clean catch.
- At visits when pregnancy testing is required, aliquot 5 to 10 mL for these tests and store the remaining urine at 2°C to 8°C or transfer the urine immediately into the Urine Preservation Tube (UPT) for subsequent chlamydia and gonorrhea testing.

13.6.2 Pregnancy Testing

At visits when pregnancy testing is required, aliquot approximately 5 to 10 mL of urine from the specimen collection cup and pipette from this aliquot for pregnancy testing. If the urine pregnancy test cannot adequately be interpreted because of interfering factors, for example excess blood or extreme cloudiness due to amorphous material, the sample can be spun down and the urine supernatant can be used. If the test continues to have interferences such as gross hemolysis making the test difficult to read, then another urine sample will need to be collected.

Either the Quidel QuickVue One-Step urine hCG or Quidel Quick Vue Combo urine and serum hCG pregnancy test must be used at all sites. Perform the test according to site SOPs and the package insert. Do not perform any other urine pregnancy tests for confirmatory purposes.

The urine only kit and the combo kit are different kits and have different CAP method codes for EQA panels. If sites are running both kits, they must run CAP EQA panels on both kits. In most cases, the CAP results forms will only allow for entry of one kit. Sites can generally submit results to CAP for one kit and do a self-evaluation for the other kit. Consult SMILE, MTN LC or your Primary Network Lab (PNL) in case of questions regarding your EQA panels.

13.6.3 Chlamydia and Gonorrhea Testing

This testing will be done using the Cepheid GeneXpert® or other NAAT as approved by the MTN LC. Sites will perform the testing per site SOPs and the package insert.

Contact the MTN LC for approval to use alternative CG/CT NAAT methods.

13.6.4 Urine Culture

Perform urine culture per local standard of care if ordered by clinician for clinical indications.

13.7 Blood Testing

The blood tests performed at each study visit will depend on the time point of the visit and the clinical presentation of the participant. Perform all tests according to site SOPs and package inserts.

13.7.1 Specimen Collection and Initial Processing

Sites must have processes in place to avoid specimen labeling errors. The MTN strongly recommends that specimens not be labeled in advance of collection. Specimen labeling must occur immediately at the time of collection. Participant Identification must be re-established each time a specimen is collected.

Label all required tubes with a SCHARP-provided PTID label at the time of collection. After collection complete the following:

- Allow plain tubes (red, tiger top or gold top SST non-additive tubes or serum separator tubes) to clot, then centrifuge per site SOPs to yield serum. Serum may be used for tests such as chemistry or syphilis serology as defined in local testing SOP.
 - Gently invert EDTA at least eight times after specimen collection to prevent clotting. If whole blood and plasma are to be taken from the same tube, the whole blood testing must be completed before the tube is centrifuged and plasma aliquots are made. If whole blood is to be used for multiple tests, ensure that the tube is well mixed before removing any specimen.

13.7.2 HIV Testing

Plasma, whole blood and/or serum will be tested for HIV using tests that have been validated at the study site. At all sites, HIV infection status will be assessed per the testing algorithms in protocol Appendices II and III; these algorithms are also provided in SSP Appendix 13-4.

All HIV tests will be performed according to test kit package inserts and site SOPs. All tests and associated QC procedures must be documented on local laboratory log sheets or other laboratory source documents. These documents must capture the start and end/read times of each rapid test. A second independent clinic or laboratory staff member trained in proper HIV testing and result recording procedures must review, verify, and sign-off on rapid test results within the specified timeframes and prior to disclosure of results to participants; this documentation must include the read time for the second checker.

Site laboratory management is responsible to ensure that all HIV testing is done per manufacturer's directions.

Send all HIV testing queries and algorithm related notifications to mtnvirology@mtnstopshiv.org using the MTN Laboratory Core HIV Query Form (Appendix 13-5).

At any time point where HIV rapid testing is performed, two different rapid tests will be used:

- The first rapid test will be the (Fourth Generation) CE-marked Alere HIV Combo rapid test, Alere product number 7D2846 (20 tests) or 7D2847 (100 tests). *Note that there are several different Alere products with similar names and formulations. It is imperative to obtain this specific kit.*
- The second rapid test will be an FDA approved (Third Generation) test, either OraQuick or Unigold. *Note that there are FDA and non-FDA approved versions of these kits – please ensure that only the FDA-approved version is obtained.*
- In cases of potential kit shortages, sites must contact the MTN LC for guidance on backup kit selection. A backup third generation test may be used if the fourth generation kit is unavailable; the LC must be notified via email if this occurs and may send additional guidance.

Study participants may report potential exposures to HIV that would increase the likelihood they are acutely infected during screening, enrollment or post enrollment study visits. Participants may also present with signs and symptoms that are consistent with acute infection. In these cases, even if the participant has 2 negative rapid test results, site clinicians may request an HIV RNA be performed which may detect infection before other tests. For RNA tests done at the clinician's discretion for suspected acute infection, sites must notify the MTN Virology core with an HIV Query form. The Virology core will track these cases and send guidance as needed.

SCREENING/ENROLLMENT

Sites will use two rapid HIV tests at screening and enrollment, the fourth generation CE Marked Alere Combo and a third generation FDA-approved test.

If both rapids are negative, the participant will be considered HIV-uninfected. If both are positive, the participant will be considered HIV-infected.

If the rapid tests are discordant, i.e., one rapid test is positive and one is negative:

- Inform the MTN LC by submitting a query form (Appendix 13-5) to mtnvirology@mtnstopshiv.org. The MTN LC will send guidance within 1 business day.
- In common circumstances, guidance from the MTN LC will be to collect blood and perform a Geenius confirmatory test and plasma viral load (HIV RNA PCR). The site may immediately proceed with these tests as part of HIV status determination as long as a query form is also submitted on the same day. Please note, the participant has not completed enrollment procedures, so blood or plasma may not be stored for future testing at this time.

FOLLOW UP

Sites will use two rapid HIV tests at each follow up visit the fourth generation CE Marked Alere Combo and a third generation FDA-approved test.

If the rapid tests are negative, the participant will be considered HIV-uninfected.

If both rapid tests are positive, the CE marked Geenius confirmatory assay will be performed from a separate blood draw which is collected on the same day. With this additional sample, the site will also collect blood for CD4, viral load (HIV RNA PCR) and plasma storage. If the site is unable to collect the sample because the participant is unwilling or other reason, they should try to recall the participant as soon as possible.

If one rapid test is positive and one rapid test is negative (discordant results), follow procedures identical to those after two positive rapids. Collect blood from a separate blood draw on the same day and proceed immediately with Geenius testing, CD4, and HIV RNA viral load at the local lab. You may also notify the MTN LC using the query form (Appendix 13-5) if technical guidance is needed. However, do not wait for MTN approval or MTN LC response to the query form to proceed with Geenius, CD4, and HIV RNA viral load testing. SCHARP will send the LC monthly reports of discordant rapids encountered during follow up. The LC will monitor these reports and may request kit lot information from sites.

If the Geenius is positive, HIV infection is considered confirmed for study purposes per the algorithm.

If the Geenius is negative or indeterminate, notify the MTN LC using the query form (Appendix 13-5) and use the results of the HIV RNA viral load to determine the need for further testing. A viral load result above the limit of detection will be considered positive and the Geenius will be repeated on a new sample taken approximately 1 month later for confirmation. A viral load result below the limit of detection will be considered negative; based on this result, the participant will be considered HIV-uninfected. A viral load result of “detected, below the limit of detection” may require further guidance before HIV status is finalized.

When collecting blood to repeat Geenius, even though seroconversion is not yet confirmed at this point, collect additional blood for post seroconversion sample testing (CD4, RNA and plasma storage) along with the repeat Geenius. Testing for the RNA and CD4 should proceed immediately.

HIV DNA testing will only be used in rare circumstances where HIV infection status cannot be determined from Geenius and HIV RNA viral load results (for example, if Geenius is indeterminate with one major band such as p24, and HIV RNA viral load is detected but below the limit of detection). Samples for DNA testing can only be collected with approval from the MTN LC.

Kit inventories should be monitored closely and re-supply orders placed at least 8-12 weeks in advance of actual need (or longer if needed per site procurement policies and procedures). Notify the MTN LC immediately if any kit inventory or quality control problems are identified, so that appropriate action can be taken.

ADDITIONAL GUIDANCE

- Fourth Generation rapids
 - Fourth Generation rapids contain two test bands: one for antigen and one for antibody
 - For purposes of the testing algorithms, if either test line is present, the result is positive.
 - Testing logs need to differentiate Antigen positive, Antibody positive, Dual positive, negative.
 - The Quality Control must include antigen and antibody positive samples. Sites will use the Alere Combo control (Cat# 7D2252). Alternate controls require LC approval.

- Geenius
 - Manual reading and reporting of test cassettes is not allowed in MTN-025. In the event that the Reader Instrument is down, sites must revert to backup.

- Sites must maintain printouts of Geenius reports that include the PTID, Visit code, sample date and testing date.
- QC must be run each week study participants are tested, in addition to requirements in the package insert.
- The LC suggests labelling cassettes so that the label can be seen in the image displayed on the Geenius reports.
- *HIV-1 Indeterminate results*
 - Staff members should be observing the cassette when they place it in the instrument.
 - If no bands are visible on the cassette but the reader gives an indeterminate result, the technician can cancel the run and re-read the cassette. This must be done within the allowable read time for the cassette.
 - If the second read is negative, this result can be accepted.
 - If the second read is still indeterminate:
 - Accept the result
 - Proceed with the algorithm and notify the LC as required for enrolled participants.
- *HIV-2 positive or indeterminate results*
 - HIV-2 Positive results: if the Geenius reports an HIV-2 positive result, contact the LC with an HIV query form. The LC will send guidance on a case by case basis. Wait for guidance from LC before proceeding with the algorithm.
 - HIV-2 Indeterminate results:
 - If no bands are visible on the cassette but the reader gives an indeterminate result, the technician can cancel the run and re-read the cassette. This must be done within the allowable read time for the cassette.
 - If the second read is negative, this result can be accepted.
 - If the second read is still indeterminate:
 - Accept the result
 - Notify the LC as required for enrolled participants. The LC will send guidance on a case by case basis. Wait for guidance from LC before proceeding with the algorithm.

NOTE: HIV-2 is rare in the countries where HOPE is conducted, but all HIV-2 positive or indeterminate results must be evaluated. In cases of HIV-2 positive or indeterminate results, product should continue to be held and the MTN-025 PSRT consulted on further product use management, including progression to permanent discontinuation if HIV-2 infection is confirmed, and clinical care (see also SSP section 6.5).

13.7.3 Syphilis Testing

Syphilis testing will be performed using a rapid plasma reagin (RPR) screening test followed by a confirmatory microhemagglutinin assay for *Treponema pallidum* (MHA-TP) or *Treponema pallidum* haemagglutination assay (TPHA) for reactive samples.

Any RPR, MHA-TP, and TPHA test may be used at each study site; however, titers must be obtained and reported for all positive RPR tests. RPR tests may be performed on either serum

or plasma. MHA-TP and TPHA tests must be performed on serum. All testing and QC procedures must be performed and documented in accordance with study site SOPs.

For reactive RPR tests observed during screening, a confirmatory test (MHA-TP or TPHA) result must be received and appropriate clinical management action taken prior to enrollment in the study (see SSP section 10.7.1). Clinical management should include repeat RPR tests semi-annually following syphilis diagnosis to confirm treatment effectiveness. If the RPR titer does not decrease four-fold or revert to sero-negative within six months after treatment, the PSRT should be consulted for further management and to determine if an Adverse Event has occurred (see SSP section 10.7.3). Please consult the MTN-025 Protocol Safety Review Team (PSRT) with any questions related to syphilis testing to confirm treatment effectiveness and/or interpretation of unusual test results. Questions related to result interpretation vis-à-vis eligibility and enrollment in the study should also be directed to the PSRT.

13.7.4 Hematology Testing

Complete blood counts with five-part differentials will be performed at all sites. Each of the following must be analyzed and reported:

- Hemoglobin
- Hematocrit
- Mean Corpuscular Volume
- Platelets
- White blood cell count with differential
 - Absolute neutrophil count
 - Absolute lymphocyte count
 - Absolute monocyte count
 - Absolute eosinophil count
 - Absolute basophil count

These tests will be performed on EDTA whole blood per local site SOPs.

13.7.5 Serum Chemistries

The following chemistry tests will be performed on serum per local SOPs:

- Aspartate aminotransferase (AST)
- Alanine transaminase (ALT)
- Creatinine

13.7.6 Plasma Storage

Note: in MTN-025, the term “plasma archive” will only be used for enrollment storage for endpoint determination.

For plasma storage, use whole blood collected in EDTA tubes. If the blood is held at room temperature, plasma must be processed and frozen within 4 hours of collection. If the blood is kept refrigerated or placed on ice, plasma must be processed and frozen within 24 hours of collection. Plasma should be stored frozen on site $\leq -70^{\circ}\text{C}$ until requested for shipping and/or testing by the MTN LC.

There are three situations that require plasma specimen storage:

**Table 13-1
Volume Guide for Plasma Storage**

Plasma Specimen	Draw volume	Minimum Plasma Required
Enrollment archive; Routine storage (Month 1 and 2, quarterly, PUEV, Termination Visit)	~10 mL	4 mL
Follow-up HIV testing algorithm Storage	~15 mL	6 mL
Post-seroconversion	~15 mL	6 mL

To simplify shipping procedures, MTN-025 will identify three types of specimen storage in LDMS in the “other SPEC ID” field. For sites using the LDMS tracking sheets (Appendix 13-7), this will be identified on that form. For sites not using the LDMS tracking sheets, a mechanism will be required for the clinic to relay the type of archive to the LDMS laboratory.

Sites will enter

- “RPS” for enrollment and Routine Plasma Storage recorded on the Specimen Storage CRF,
- “CON” for HIV Seroconversion Confirmation Plasma recorded on the HIV Test Results CRF,
- “SER” for Seroconverter Plasma recorded on the Seroconverter Laboratory Results CRF.

The “other SPEC ID” field is free text and the three letter codes will need to be entered exactly. This information will be tracked in the LDMS reconciliations and will show a discrepancy if the information in LDMS does not match the information recorded on the CRF. (See Appendix 13-3)

For all three types of plasma listed in Table 13-1:

- If the minimum volume specified in Table 13-1 is not obtained, notify the MTN LC.
- Use LDMS to label and track all aliquots.
- Store all aliquots frozen on site $\leq -70^{\circ}\text{C}$.
- The MTN LC will send instructions when shipping and/or testing is required.
- If samples are hemolyzed, store the aliquots as per normal and enter comments in LDMS.

For routine plasma storage, standard processing per site SOPs should be performed.

Spin blood at room temperature in a centrifuge according to either one of these techniques:

- Single spun: Spin blood at 1200-1500 RCF (g-force) for 10 minutes, remove plasma.
- Double spun: Spin blood at 800 g for 10 minutes, place plasma in a tube to spin again at 800 g for 10 minutes, remove plasma.

Plasma must be stored in 1 ml aliquots. Prepare as many 1 mL aliquots as possible.

Plasma storage is allowable in the protocol at any visit after enrollment “as indicated”. Any positive HIV test results after enrollment is to be considered an indication for plasma storage. Store plasma for all post enrollment positive HIV results.

Short draws / missed collections:

- If plasma collection is missed or less than 3.5 mL stored, for enrollment, HIV endpoint related, or PUEV, the participant is to be called back to obtain the required amount of plasma. Notify the LC but do not wait for a response to recall the participant.
- If Month 1 or Month 2 is missed, notify the LC and collect plasma as scheduled at the next regularly visit.
- If routine quarterly plasma storage is between 3.5 mL and 2 mL stored, notify the LC and collect plasma as scheduled at next quarterly visit.
- If routine quarterly plasma storage is less than 2 mL stored, contact the LC for guidance.

Leftover Specimens: Leftover specimens may be temporarily stored for site QA purposes and problem resolution for all participants. This process must be described in an SOP or on-site policy that indicates how long the samples will be stored. Local guidelines and regulations must be followed in these situations. Only specimens from participants who have consented to long-term storage may be stored longer for future research. Sites that save these specimens for long-term storage must have a plan to identify which participants have consented to this. Contact the management team for assistance as needed.

Procedures for plasma storage when a participant has discordant or positive rapids at a visit where routine plasma storage is also required (Month 1, Month 2, Quarterly, PUEV, and Termination Visits):

For sites conducting venipuncture for HIV rapid testing:

1. Store a minimum of 4 mL of plasma with the LDMS code “RPS” from the first collection where specimen was drawn for rapid HIV tests.
2. Once HIV rapid test results are available, collect and store an additional minimum of 6 mL of plasma with the LDMS code “CON”. Use this specimen for Geenius, HIV viral load. CD4 testing is also done on whole blood from this draw.
3. The total minimum plasma stored in this situation is now 10 mL.

For sites conducting Fingerstick HIV rapid testing:

1. Once the fingerstick HIV rapid test results are available, collect and store 6 mL of plasma with the code “CON” in LDMS. Use this specimen for Geenius, HIV viral RNA. CD4 testing is also done on whole blood from this draw.
2. The total minimum plasma stored will remain 6 mL. You do not need to draw a separate tube for routine plasma storage.
3. On the Specimen Storage CRF, mark “not required” for item “Plasma storage” and add a note that item plasma storage was not required due to HIV confirmatory plasma storage in the text field “Reason plasma not stored/not required.”

13.7.7 CD4+ T Cell Count

CD4+ T cell counts are only performed for participants in conjunction with the follow-up HIV testing algorithm and during post-seroconversion follow up, if applicable, per protocol Section 7.6.1.

Site laboratories will test EDTA whole blood by flow cytometry for absolute CD4+ T cell counts per local SOPs. Testing will be performed on FDA approved instruments per site SOPs and package inserts. Sites must participate in United Kingdom External Quality Assurance (UKNEQAS) programs and be approved by the Immunology Quality Assurance (IQA) group to perform this testing.

13.7.8 HIV RNA PCR

HIV RNA PCR (viral load) testing is only performed for participants in the follow-up HIV testing algorithm, and during post-seroconversion follow up, if applicable, per protocol Section 7.6.1. On a case-by-case basis, sites may perform HIV RNA PCR on screening participants with discordant rapid test results, per guidance by the MTN LC.

All sites will participate in the Viral Quality Assurance (VQA) program. HIV RNA viral loads will be performed on EDTA plasma using methods approved by the MTN LC. All testing will be performed according to site SOPs and package inserts.

13.8 Testing of Vaginal Specimens

Collect urine specimens before pelvic specimens. Refer to the current Pelvic Exam checklist on the MTN-025 website under *study implementation tools* for further information on the required sequence of specimen collection and diagnostic procedures to be performed during scheduled pelvic exams.

13.8.1 Wet Mount for Candidiasis and BV

Wet mount testing for candidiasis and BV is only done when clinically indicated.

Wet mount procedures for this study consist of two different preparations —saline prep and potassium hydroxide (KOH) prep —for diagnosis of bacterial vaginosis, and candidiasis. Trichomoniasis may also be observed on saline wet mounts.

Prior to site activation and throughout the study, MTN LC requires semi-annual wet mount proficiency testing and administers a web-based proficiency test approximately every six months. The MTN LC will post wet mount slides on the MTN website for this purpose every 6 months; results will be entered directly on the website (contact: Michele Austin: maustin@mwri.magee.edu or Lorna Rabe: lrabe@mwri.magee.edu). The MTN LC will report results back to the Laboratory Manager and also specify any corrective action that may be needed based on the results. Contact the MTN LC for additional information and guidance on performing and documenting the proficiency testing. Also contact the MTN LC when new laboratory staff is hired, so that appropriate training can take place prior to such staff performing wet mounts for study purposes.

Wet mount results are recorded directly onto appropriate laboratory log sheets or other laboratory source documents as specified in site SOPs.

Prepare wet mount slides according to study site SOPs as follows:

Non-immediate wet mount examination in laboratory:

- Immediately following collection of vaginal fluid from the lateral vaginal wall via swab, place the swab in a glass or plastic tube with approximately six drops (100 µL) sterile physiologic saline. Snap off the shaft of the swab and cap the tube.
- Deliver the tube to the laboratory for testing for immediate examination.
- Use a pencil to write the PTID and specimen collection date on one side of the frosted end of two microscope slides (one for KOH and one for clue cells). Affix a SCHARP-provided PTID label to the other side of the slides (on the frosted end, under the pencil markings) and write the specimen collection date in indelible ink (e.g. Sharpie pen) on each label.
- Remove the swab from the saline and smear vaginal fluid specimens onto each slide.
- Apply one drop of 10% KOH to one slide and immediately perform whiff test for a “fishy” amine odor. Then apply cover slip and allow a couple minutes for the bacteria and epithelial cells to lyse before reading.
- Apply one drop of sterile physiologic saline to the second slide, emulsify with the vaginal fluid specimen, and then apply coverslip. Examine immediately at 10X magnification for epithelial cells, budding yeast, and pseudohyphae. Examine at 40X magnification to determine whether observed epithelial cells are clue cells and quantitate the cells. Clue cells are irregularly bordered squamous epithelial cells that are completely covered with bacteria (*Gardnerella vaginalis*). Clue cells must comprise at least 20% of the observed epithelial cells for the saline prep to be considered positive for clue cells.
- Examine the KOH slide at both 10X and 40X magnification for yeast and pseudohyphae.
- Note: if motile trichomonads are noted on the saline wet prep, these can be reported to the clinician. If *Trichomonas vaginalis* is seen on the wet mount but the OSOM Rapid *Trichomonas* test is negative, report as positive by wet mount only

13.8.2 Rapid Test for Trichomoniasis

This testing will be done using the OSOM Rapid *Trichomonas* test with vaginal swabs per site SOPs approved by the MTN LC. The kit provides Dacron swabs for this test.

- Affix a SCHARP-provided PTID label to a clean glass or plastic tube with a cap.
- Collect specimen using kit-provided swab from the lateral vaginal wall (fluids also may be collected from the posterior fornix; avoid collecting specimens from the cervix).
- Immediately place the swab in the labeled tube, break off the shaft of the swab, and cap the tube.
- Testing is expected to be performed during the participant visit. However, specimens may be stored at room temperature for 24 hours or refrigerated for 36 hours before testing.

13.8.3 Papanicolaou (Pap) Test

Pap smears will be performed at all sites. At visits when Pap smears are required, ecto- and endocervical cells will be collected after all tissues have been visually inspected and all other required specimens have been collected. Specimen collection, slide preparation, slide interpretation, and QC procedures must be performed and documented in accordance with study site SOPs. There is no required external review of these procedures by the MTN.

At some study sites, Pap smear results may include notations of findings associated with certain STIs (e.g., trichomoniasis). Because Pap smear methods are not adequately sensitive and specific for STIs (including HPV), Pap smear findings associated with STIs should not be used to diagnose any STIs (see SSP section 10.7.2 for how to handle incidental findings of STI/RTIs on Pap smears).

13.8.4 Self-Administered Vaginal Swabs for PK and biomarker testing

At enrollment and all scheduled follow-up visits, vaginal fluids are self-collected from the posterior fornix using a Dacron swab with a plastic shaft for analysis at the MTN LC.

- Refer to the current version of Section 10 of the SSP for specimen collection procedures.
- Place the swab in an empty labeled cryovial with no preservative and cap the vial.
- Deliver the tube and an LDMS Specimen Tracking Sheet to the local LDMS laboratory.
- Using the LDMS Tracking Sheet, log the cryovial into LDMS (specimen type = VAG. See Section Appendix 13-4 for LDMS for additive codes) and label the vial with a LDMS label.
- Freeze at $\leq -70^{\circ}\text{C}$ within 8 hours of collection.

13.8.5 Intra-Vaginal Ring Storage

All returned used rings will be stored in the laboratory. If returned rings are noted to have been partially eaten by rodents, these should not be sent to the lab for transport to Paraxel. The rings should be placed in Biohazard bin for destruction and documented per your site product accountability SOP. The ring should be noted as “not stored” in Rave with a comment.

If the damage is not noted in the clinic and the ring is transported to your local lab, the lab should notify the clinic and destroy the ring. If the ring has already been entered in LDMS, change the sample status to DSR and add a comment.

Please notify the LC when rings are noted to have been damaged by rodents.

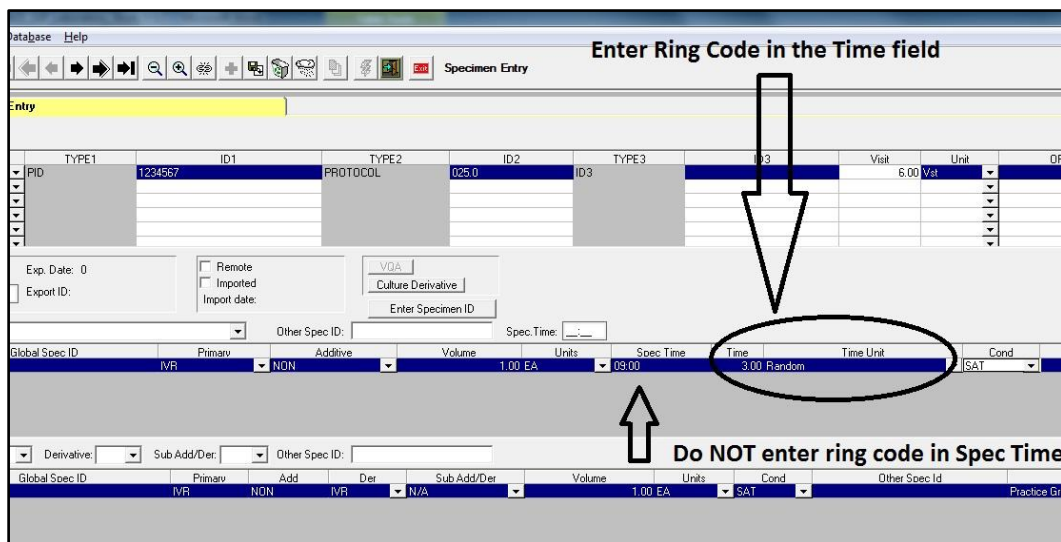
The key outcome of this process is storing a dry ring to prevent microbial growth on the ring.

Returned Ring Processing:

1. All used returned rings are transported to the laboratory labeled with PTID, Date, Visit code and Ring Code.
2. Rinse the ring in water.
 - a. If not processing in a biological safety hood the person should wear protective eye wear, lab coat or gown, and gloves when rinsing. Do not rinse in a sink because the ring is covered with potentially infectious material.
 - b. To prevent aerosols, place the ring in a disposable container with tap water, swirl the ring gently, remove and blot dry with disposable paper towels.
 - c. Discard the towels with other biohazardous material. Decontaminate the water used for rinsing before discarding per local guidelines for biohazard waste disposal. Decontaminate the area used to process the ring.
 - d. Do not use any soaps, cleaners or chemicals to rinse the ring. Use only tap water.

3. Place the ring in a new unused bag.
4. Affix a label to the new bag with PTID, visit code, date and ring code.
5. Enter the ring in LDMS using the codes in Appendix 13-4.
 - a. Rings will be returned to the clinic with a “Ring Code” which will designate the order of use.
 - b. Enter the Ring Code in the “Time” field in LDMS. (See Image 1 below: the ring code must be entered in the “Time” field and NOT the “Specimen Time” field.)
 - c. If the Ring Code comes back as “unknown” or “UNK”, enter the code as 99.9.
6. Store the ring at room temperature.
7. Shipping guidance will be provided by the LC.

Image 1: Ring Code entry



13.9 Hair Storage

Hair samples will be collected for drug levels.

- Materials required:
 - Scissors
 - Piece of tin foil
 - (2) SHARP PTID labels
 - Ziploc bag
 - Alcohol swabs
 - Desiccant pellet

Suggest making these “hair kits” ahead of time.

Sites will follow this procedure for hair collection:

1. Step 1: Clean the blades of a pair of scissors with an alcohol pad and allow blades to completely dry. *Clean scissors blades between patients*
2. Step 2: Lift up the top layer of hair from the occipital region of the scalp. Isolate a small thatch of hair (~50 fibers of hair) from underneath this top layer.

- a. *Can use hair clip to keep top layer of hair away if easier.*
 - b. *Use your discretion when choosing where to collect hair samples and feel free to sample from more than one location if desired. Note that while the occipital region is ideal, collection points may vary if necessary to preserve a participant's hairstyle or conceal the location where hair was cut.*
3. Step 3: Cut the small hair sample as close to the scalp as possible
 4. Step 4: Keep your fingers on the part of the hair that was FURTHEST away from the scalp and put the hair sample down on an unfolded piece of tin foil
 5. Step 5: Put a patient label over the end of the hair sample that was FURTHEST away from the scalp
 - a. NOTE: If hair very short just let it fall into the piece of tin foil and no need to label the distal end
 6. Step 6: Refold the foil over to completely enclose the hair and place a study ID label on the folded piece of foil
 7. Step 7: Place the folded piece of foil inside the plastic (e.g. Ziplock®) bag (each bag will have a desiccant pellet) and seal the bag.
 8. Step 8: Protect the specimens from light and store at room temperature until shipments are requested by the MTN LC. See Section Appendix 13-4 for LDMS for codes.

13.9.1 Hair PK Validation Subset

At Zimbabwe sites, participants are asked to consent to collection of a larger hair sample taken (approximately 200 strands instead of 50 strands) just one time for validation purposes. All enrolled participants are asked to consent to hair collection as part of the enrollment informed consent. The sites at the Zimbabwe CTU will ask participants for verbal agreement to take a larger sample at their remaining visit, until the point in which 75 samples are obtained. Verbal agreement for this collection should be documented in the chart notes.

A small token of appreciation may be offered to these participants, IRB approval must be obtained for any tokens provided. For participants who agree to having a larger hair sample collected at their M1 visit, follow the same procedure as routine hair collection with this additional guidance:

- Select participants with hair styles that will allow for additional hair collection (this will usually entail taking small samples of hair from two separate sites on the head for this one-time procedure)
- The amount of hair collected at routine visits is ~50 strands; in this case, take two separate samples of ~100 strands each from 2 or 3 sites on the head to collect ~200 strands. Taking the hair from multiple locations will avoid leaving any noticeable disruptions to the hair style
- Combine all the hair collected into one sample and follow all other procedures
- Enter the code "VAL" in the "other specimen ID" in LDMS
- Keep an electronic log (Excel or word document) of PTIDs and visits where the additional samples are taken. Provide regular updates to FHI 360 and the MTN LC about progress made.

13.10 Specimen Shipping Specifications

Returned IVR

- Starting with first M1 visit, sites will ship all returned IVR to Parexel each week.
- Once sites have completed all M1 visits, shipping frequency may be adjusted.
- No shipping requests or lists will be provided by the LC or SCHARP; sites will be responsible to ship weekly.

- Parexel is not currently an LDMS lab; sites will include an electronic manifest in “Character Separated Values” CSV/.csv Excel format in the Shipment notification email. The LC may send alternate shipping guidance if Parexel implements LDMS.
- The LC suggests arranging the rings physically and in LDMS in a fashion to facilitate shipping. This can include storing the rings in a container that can also be used for shipping; the shipment can then be created using the “Mark to ship function” in LDMS.
- The MTN prefers Biocair or Fed-Ex for these shipments. Contact the MTN LC to use other carriers.

All other Samples

- Plasma, vaginal swabs and hair samples will remain on site until requested. In most cases, shipping lists will be provided for these samples.
- Plasma and Vaginal Swab dry ice shipments should be sent World Courier or Biocair.
- Hair samples are non-infectious and should be sent Fed-Ex.

General Specifications

- Ensure temperature sensitive shipments arrive on business days when receiving lab staff is available. When in doubt (such as holiday schedules), contact the receiving lab before scheduling the shipment.
- Copy the MTN LC on all MTN sample shipment notification emails, regardless of destination.
- Shipping labs are primarily responsible to confirm receipt of shipments. The LC may also track this.
- Sites must QC shipments before sending, including but not limited to:
 - If there is a shipping request, make sure that all requested samples have been included. If you do not have samples available for any of the requests, contact the LC for guidance. Maintain the LC response for documentation.
 - Make sure to include the number of aliquots indicated on the sample shipping list (Excel sheet attached).
 - Make sure that all physical aliquot global ID’s match exactly what is on the shipping manifest, including their positioning in the box.
 - Shipping Box structure and labelling must meet all IATA and local regulations for the type of shipment being sent.
 - Make sure that all relevant import/export permits are included.
 - Cryobox Box labeling
 - The top of the box should have:
 - Site name
 - LDMS batch number
 - Box X of X (example: Box 1 of 2) for all boxes in the LDMS batch (at least the box number is required).
 - Studies (Protocol number)
 - Sample type
 - The side of the box should have:
 - Site name
 - LDMS batch number
 - Box number
 - You must notify the receiving lab when sending shipments. Make sure to include at a minimum:
 - Shipment date
 - Tracking information
 - Electronic version of shipping manifest: format may vary

- Include a paper copy of the manifest or box map in the shipment in addition to other shipping documentation.
- Please include your Courier Job Number(s) if using World Courier.
- Shipment destination addresses are not included in this SSP because they may change. The LC will relay these to the sites via email.
- Sites may use the MTN World Courier account only with written authorization. Sites will be invoiced for unauthorized charges.

Section Appendix 13-1
Overview of Laboratory Testing Locations, Specimens, and Methods for MTN-025

Assay	Testing Location	Specimen Type	Tube/Container	Kit/Method
Urine Pregnancy Test	Clinic/Local Lab	Urine	Plastic screw top cup	Quidel Quick Vue
Urine NAAT for Gonorrhea and Chlamydia (neat method)	Local, Regional, or MTN Network Lab	Urine	Plastic screw top cup	Cepheid Gene Expert or LC approved alternative method
Urine Culture	Local Lab	Urine	Plastic screw top cup	Not specified
HIV Rapid Tests	Clinic/Local Lab	Plasma, Whole Blood, Or Serum	EDTA or plain tube	At least one FDA approved test
HIV Geenius	Local Lab	Plasma, Whole Blood, Or Serum	EDTA or plain tube	CE approved Geenius
Complete Blood Count	Local Lab	Whole Blood	EDTA tube	Not specified
Chemistries (AST, ALT, Creatinine)	Local Lab	Serum	Plain or serum separator tube	Not specified
Syphilis Serology	Local Lab	Serum or Plasma	EDTA, plain or serum separator tube	Not specified
CD4+ T Cell Count*	Local Lab	Whole Blood	EDTA tube	Not specified
HIV-1 RNA PCR*	Local Lab	Plasma	EDTA tube	Approved method
Plasma	Stored at Local Lab	Plasma	EDTA tube	N/A
Pap Smear	Local Lab	Ecto- and Endocervical Cells	Slides/LBC	Not specified
Vaginal wet preparation	Clinic/Local Lab	Vaginal Fluid Swab	sterile tube	Microscopy
Trichomonas Rapid Test	Clinic/Local Lab	Vaginal Fluid Swab	Plastic Tube	OSOM Rapid Test
Vaginal Swab	Stored at Local Lab	Vaginal Swab	Cryovial	MTN LC procedure
Residual Drug Analysis	Stored at Local Lab	Vaginal ring	Biohazard Bags	Contract Laboratory procedure

* These tests are only done for participants who have positive HIV rapid tests in the follow-up HIV testing algorithm and for post seroconversion follow up when applicable.

Section Appendix 13-2
MTN-025 LAB SPECIMEN PROCESSING GUIDELINES — PELVIC AND URINE SPECIMENS

Assay	Primary Specimen	Additive/Container	Minimum Volume	Testing Specifications	Handling Requirements
NAAT for GC/CT	Urine	Sterile Urine Container- No additive	15 mL	Batched per local discretion	Transfer into Cepheid transport tube within 24 hours. Refer to package insert for storage prior to testing
hCG	Urine	Urine Container- No additive	5 mL	Locally in real time	Room temp-test within 8 hours Refrigerate-test within 72 hours
Pap Smear	Cervical Cells	Slide	N/A	Locally in real time	Locally Defined
Vaginal pH	Vaginal Fluid	None-performed at bedside	N/A	Locally in real time	Done immediately at bedside
Wet Mount	Vaginal Fluid Swab	Saline if testing delayed	N/A	Locally in real time	Done immediately if a microscope is in the clinic or within 8 hours if the specimen must be transported to the lab.
Trichomonas Rapid Test	Vaginal Fluid Swab	Plastic Tube	N/A	Locally in real time	Test within 24 hours at room temperature; 36 hours if refrigerated or frozen
Vaginal Swab for Biomarkers/PK	Vaginal Fluid Swab	Cryovial	N/A	Stored locally for shipment	Freeze within 8 hours
Vaginal Ring Residual Drug Analysis	Vaginal Ring	Specimen bag	N/A	Stored locally for shipment	Room Temperature

Section Appendix 13-3
MTN-025 LAB SPECIMEN PROCESSING GUIDELINES — BLOOD SPECIMENS

Assay	Additive/Container	Minimum Volume	Testing Specifications	Handling Requirements
AST, ALT, and Creatinine	Plain Tube (No additive) or SST	Locally defined	Locally in real time	Locally Defined
Syphilis Serology	Plain Tube (No additive) or SST	Locally defined	Locally in real time	Locally Defined
Full Blood Count	EDTA Tube	Locally defined	Locally in real time	Locally Defined
HIV Rapid Tests and Geenius	EDTA	Locally defined	Locally in real time	Locally Defined
CD4+ T Cell Count	EDTA Tube	Locally defined	Locally in real time	Locally Defined
HIV-1 RNA PCR	EDTA Tube	Locally defined	Locally in real time or shipped to the MTN LC	Locally Defined
Enrollment Archive; Routine Storage*	EDTA Tube	4 mL plasma	Stored and shipped for analysis in batches.	If at room temp, freeze within 4 hours. If refrigerated or on ice after collection, freeze within 24 hours.
Plasma Storage for Algorithm *		6 mL plasma		
Plasma Storage: Post seroconversion*		6 mL plasma		

*Refer to Section XX for more information on plasma archive requirements.

Section Appendix 13-4
LDMS Specimen Management Guide to Logging in MTN-025 Specimens

Sample	Primary	Primary Additive	Primary Volume	Primary Units	Aliquot Derivative	Aliquot Sub Add/Derv	Aliquot Volume	Aliquot Units
Vaginal Swab	VAG	NON	1	EA	SWB	N/A	1	EA
Plasma for Storage ¹	BLD	EDT	Variable	mL	PL 1/2	N/A	1-2	mL
Ring for storage*	IVR	NON	1	EA	IVR	NA	1	EA
Hair	HAR	NON	1	EA	HAR	N/A	1	EA

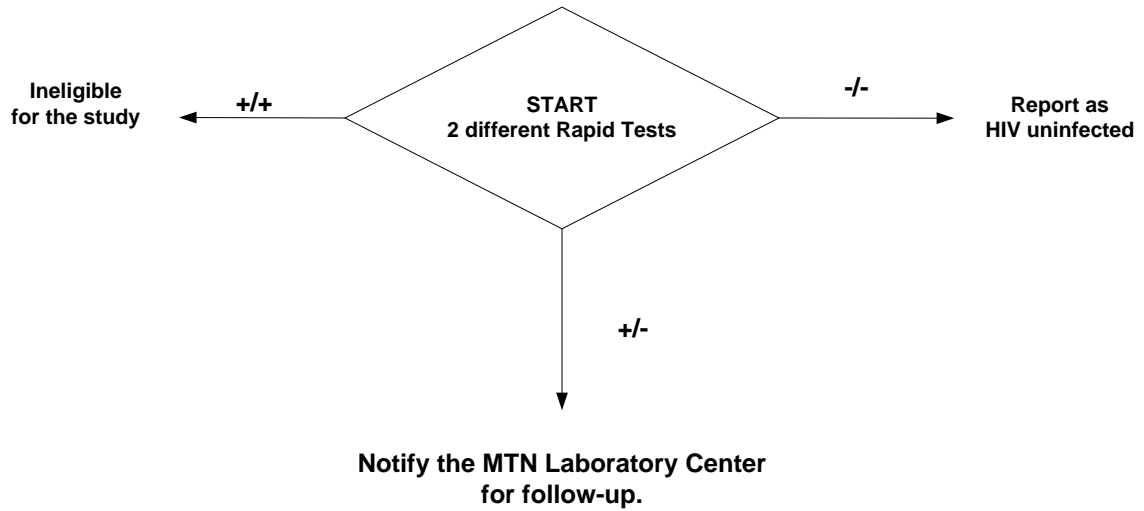
*Enter Ring code in the "Time" field. Use "Random" for units.

1. In the "Other Spec ID" field of the aliquot line (between "Cond" and "Group ID"), specify the type of plasma storage to coincide with the LDMS tracking sheets. This field is free text and must be entered exactly as shown below.

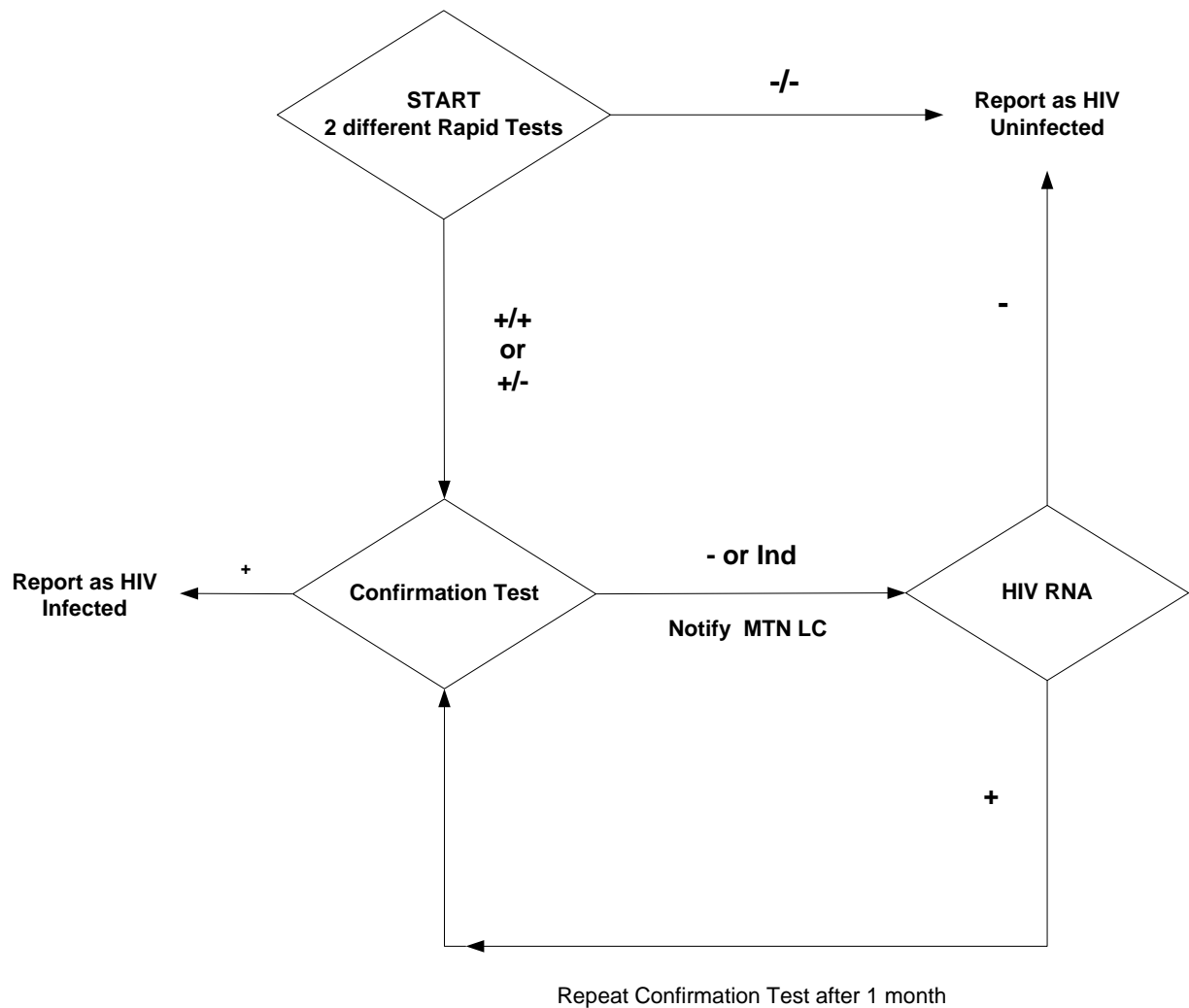
LDMS Tracking Sheet-Plasma Storage Type	Corresponding CRF	"Other Spec ID" Code
Enrollment Plasma Storage/DPV	Specimen Storage	RPS
Plasma for HIV Seroconversion Confirmation	HIV Test Results	CON
Seroconverter Plasma Storage	Seroconverter Laboratory Results	SER

Section Appendix 13-5
MTN-025 HIV Testing Algorithms

ALGORITHM FOR HIV ANTIBODY TESTING- SCREENING/ENROLLMENT



ALGORITHM FOR HIV ANTIBODY TESTING FOR FOLLOW-UP



Ind: Indeterminate test results
LC: Laboratory Center

**Section Appendix 13-6
MTN Network Lab HIV Testing Query Form**

MTN Laboratory Center HIV Testing Notification & Query Form

Study	MTN-025
PTID	
Site/Contact Person	
Last Update	Click here to enter a date.

Form Closed

Please check one:

- Notification (LC response not required)
- Query (Waiting for LC Response)

VISIT CODE:

VISIT DATE: Click here to enter a date.

SITE COMMENTS/QUERY:

	Rapid Test 1	Rapid Test 2	Confirmatory Assay	HIV RNA	Other Test
Testing Date					
Kit Name			Geenius		
Result					

LC RESPONSE:

Participant Final Outcome

- HIV NEGATIVE
- HIV POSITIVE
- OTHER (Please describe further)

**Section Appendix 13-7
LDMS Tracking Sheets**

MTN-025 Enrollment Visit LDMS Specimen Tracking Sheet

For login of stored specimens into LDMS

Page 1 of 1

Participant ID		Visit Code		Specimen Collection Date	
<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>	02.0		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<small>Site Number</small>	<small>Participant Number</small>	<small>Chk</small>	<small>dd</small>	<small>MMM</small>	<small>yy</small>

# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQOT DERIVATIVE	OTHER SPEC ID	INSTRUCTIONS FOR PROCESSING LAB
	Blood (BLD) <i>Enrollment Plasma Archive</i> Collection Time ____ : ____ <i>hour : min</i>	EDT	PL1/2	RPS	Prepare as many 1.0 mL aliquots as possible with a total volume of aliquots ≥ to 4mL. If sample is collected and held at room temp, freeze within 4 hours. If refrigerated after collection, freeze within 24 hours.
	Vaginal swab for PK/Biomarkers (VAG)	NON	SWB	N/A	Place Dacron swab in a labeled cryovial containing with no additive. Store sample tubes at ≤-70°C within 8 hours of analysis.

Comments: _____

Initials: _____ / _____ LDMS Data Entry Date: / _____
Sending Staff Receiving Staff dd MMM yy LDMS Staff

Version 1.0, 01AUG16

MTN-025 Follow-up Visit LDMS Specimen Tracking Sheet

For login of stored specimens into LDMS

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# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB ADD/DER	OTHER SPEC ID	INSTRUCTIONS FOR PROCESSING LAB/ PLASMA COLLECTION TIMES
	Blood (BLD) <i>Routine Plasma Storage</i>	EDT	PL1/2	N/A	RPS	PLASMA COLLECTION TIME Collection Time hour : min
	Blood (BLD) <i>Plasma for HIV Seroconversion Confirmation</i>	EDT	PL1/2	N/A	CON	PLASMA COLLECTION TIME Collection Time hour : min
	Blood (BLD) <i>Seroconverter Plasma Storage</i>	EDT	PL1/2	N/A	SER	PLASMA COLLECTION TIME Collection Time hour : min
	Vaginal swab for PK/Biomarkers (VAG)	NON	SWB	N/A	N/A	Place Dacron swab in a labeled cryovial containing with no additive. Store sample tubes at $\leq -70^{\circ}\text{C}$.
	Hair (HAR)	NON	HAR	N/A	N/A	Store at room temperature
	Used vaginal ring (IVR)	NON	IVR	NA	NA	Store at room temperature. Ring Code (s) □□.□ □□.□ □□.□

Comments: _____

Initials: _____
Sending Staff Receiving Staff

LDMS Data Entry Date: □□ / □□□□ / □□ / _____
dd MMM yy LDMS Staff

Version 1.0, 01AUG16