**Follow this guide immediately upon determining a participant’s HIV rapid tests are either both positive or discordant. Refer to the MTN-034 SSP, Protocol, and site SOPs for additional details.**

**I. Next steps when determining HIV status: (complete at same visit as the HIV rapid tests)**

1. Notify MTN LC using query form (do not wait for MTN response to proceed with testing)
2. ProvideHIV post-test counselingfor potential HIV infectionusing the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet** and offer condoms. Explain the immediate procedures to be done.
3. Collect the following blood samples and send to lab for testing/storage:
   1. Sample 2 for HIV Confirmation - (See SSP 9.6.2 for collection instructions)
      1. Geenius HIV Confirmation - EDTA or plain tube 4 mL
      2. HIV-1 RNA PCR (per Local SOP)
      3. CD4+ T cell Count (per Local SOP)
      4. Plasma storage for Algorithm Seroconversion - EDTA 10mL

*\*Can serve as the routine plasma storage if not already collected at the visit.*

* 1. CBC with platelets, and creatinine clearance
  2. If currently using Truvada: DBS

1. Collect specimens for biomarkers: vaginal and cervical swabs and CVL (using Pelvic Exam checklist)
2. Collect dispensed VR or unused tablets and send to pharmacy. Complete the following:
   1. **Participant-Specific Clinic Study Product Accountability Log**
   2. **Ring Insertion and Removal CRF** or **PrEP Provisions and Returns CRF**, as applicable.
   3. **Study Product Request Slip** and **Product Hold Summary/Log CRF** for product HOLD
3. Conduct modified product adherence counseling providing drug level feedback, if scheduled and participant is willing. Complete **Adherence Counseling CRF** and document on the **Adherence Counseling Worksheet**.
4. Document sample storage and laboratory test results, as applicable:
   1. **Specimen Storage CRF** and **LDMS Tracking Sheet**
   2. **HIV Test Result, HIV Confirmatory Results,** and **Local Laboratory Results CRF**
5. Complete all other procedures per the applicable visit checklist except for study product provision, including the **COVID-19 Behavioral Assessment CRF**, if applicable.
   1. The COVID-19 Behavioral Assessment should not be administered in cases where the participant has already completed it twice, or if they have completed it within the past month. I.e., participants will only complete it if they have never completed the CBA CRF, or if they have completed only 1 CBA CRF to date and it was at least 1 month prior to date of confirmed positive HIV test.
6. If confirmation tests can be done and provided to the participant in the same day, encourage the participant to remain at the clinic if her schedule permits.

**II.** **Confirmation Test Outcomes and Next Steps**

**🡪 HIV uninfected**

|  |  |
| --- | --- |
| Sample 2 Test Result | Geenius is Negative or Indeterminant 🡪 HIV RNA viral load below limit of detection   * Notify MTN LC with query form |

**Immediately upon confirmation:**

1. Provide and counsel on test results. (Can be done via phone contact if participant has left the clinic.)
2. RESUME study product by completing the **Study Product Request Slip** and updating **Product Hold Log CRF**
3. Participant resumes study per visit schedule.

**🡪 HIV infected/ Indeterminate**

|  |  |
| --- | --- |
| Sample 2 Test Result | Geenius is Positive (HIV infected) |
| Geenius is Negative or Indeterminate 🡪 HIV RNA viral load is above limit of detection   * Notify MTN LC with query form. Continue product HOLD. * Repeat Geenius one month later with a newly drawn Post HIV Seroconverter Confirmation blood sample. Continue to repeat Geenius testing monthly or as specified by MTN LC until HIV status is confirmed. * Proceed with steps below **only after a positive confirmation**. If determined HIV- uninfected, product can be resume. See HIV-uninfected instructions above. |

**Immediately upon HIV infection confirmation:**

1. PERMANENTLY DISCONTINUE study product by completing **Study Product Request Slip** and the **Product Discontinuation Log CRF. Update the Product Hold CRF to close out the Product Hold since the participant will be permanently discontinued.**
2. Retrieve dispensed VR or unused tablets within 24 hours (if not already done).
3. If participant has left clinic, bring her in for an interim visit as soon as possible for the following steps.
   1. Counsel on HIV infection status
   2. Provide referrals for HIV care and treatment per site SOP
   3. Offer participant to remain in study follow-up with a modified visit/procedure schedule (See considerations in section III below)\*
4. Initiate discussions with LC Virology Core on timing of resistance and retrospective RNA PCR testing. Inform LC of participant’s pregnancy status.

\* For a participant who chooses NOT to remain in the study, request that she complete any Early Termination Visit procedures still permissible for a seroconverter (see III.B-C below). Attempt to bring the participant back one month later for Post HIV Seroconverter Confirmation testing and plasma storage, and repeat Geenius test (if needed).

**III. Further Study Visit Considerations for Seroconverters**

For participants who choose to remain in REACH study follow-up:

1. Use a modified visit checklist through scheduled study exit/Visit 24 (See sample **MTN-034 Post-Seroconverter Visit Checklist)** in place of the regular visit checklist and refer to the **Seroconverter Schedule Tool** (within the Visit Calendar Tool) for post-seroconversion testing schedule**.**
2. At the next clinic visit following HIV confirmation (approximately one month later at next scheduled monthly visit or Early Termination, if applicable), complete the following procedures:
   1. Collect blood samples and test for: HIV-1 RNA, PCR, CD4+ T cell Count, plasma storage for Post HIV Seroconverter Confirmation. (And then at visits every three months hereafter for the remaining follow-up period, or as indicated.)
   2. Administer end of product use behavioral assessments: **Early PUEV/Discontinuers ACASI** and complete the **ACASI Summary/Tracking CRFs** and **Product Preference and Acceptability CRF.** (Behavioral assessments are discontinued hereafter.) Administer the ACASI survey (ring, tablet, or “no product”) that corresponds to the product she was using at the time of the first positive HIV test. If applicable, update Qualitative Participant Log (QPL).
3. Protocol-specified procedures as scheduled at study visits may be performed except for:
   1. HIV-1 testing
   2. Provision/retrieval/collection of study VR(s) or study tablets, and provision of product use instructions
   3. Collection of blood PK, vaginal and cervical swabs for biomarkers, and CVL
   4. Adherence and product preference/acceptability assessments (except for those required immediately following HIV confirmation – See B.b. above)
   5. Provision of HIV pre- and post-test, protocol adherence, and product adherence disclosure counseling. *Note: modified HIV/STI Risk reduction counseling and contraceptive counseling should still be provided.*