

CARE PrEP HIV Testing and Counseling Guide

Testing Requirements

HIV testing is required for all maternal participants at every visit unless the following criteria are met:

- Documentation of an HIV test performed in the prior 5 days to the study visit is available; make a certified copy of the result and file in participant chart.
- Participant has a confirmed seroconversion (via confirmed test results or ART initiation documentation)

Note: If syphilis testing is required at a visit, the MATRIX-007-approved Syphilis/HIV combination kit must be used; meaning that HIV testing will be included even if the participant can have HIV testing omitted per the above criteria.

HIV Testing Procedures (for testing performed at study visit)

1. Provide pre-test HIV counseling:
 - a. CARE PrEP will perform the first rapid test to screen for possible HIV infection. If the result indicates possible infection, study staff will refer the participant for additional testing to confirm the HIV diagnosis. Participants should be referred directly (warm referral ideally) to the CATALYST site-associated HIV testing services (HTS) unless the participant prefers another testing location.
 - b. Provide pre-test counseling per national guidelines
2. Collect blood sample via finger prick and perform test per site SOP
3. Document testing on the **HIV Testing Log (paper)** and **HIV Test Results CRF (REDCap)**
4. Provide post-test counseling, including results
 - a. Assess client understanding of results and next steps
 - b. **Steps for a NEGATIVE Result:**
 1. Explain the negative rapid result and that no further testing is needed at this time
 2. Provide post-test counseling per national Guidelines
 3. Refer back to CATALYST PrEP provider for any concerns or questions about current PrEP use or interest to restart a method if not currently using one.
 - c. **Steps for a POSITIVE Result:**
 - d. Explain that the rapid test indicates possible HIV infection. The study is not able to provide additional testing but will link the participant with health care services for confirmation testing. Ideally, provide a warm referral to the CATALYST-linked facility HIV Testing Service (HTS).
 - e. Encourage the participant to notify CARE PrEP study staff upon receiving confirmation testing results or plan for study staff to follow-up with HTS directly for results. Make a plan with the participant on how this will happen.
 - f. Remind participant that they may remain in the study regardless of HIV status.
5. Chart Note any relevant information about participant HIV prevention strategies or referrals for further testing, if applicable.

Documenting HIV Confirmation Testing Outcomes

Once confirmatory results are available, results should be viewed with the participant and documented either at a:

- Interim visit (phone contact or in-person): contact is made with participant between scheduled visits
- Scheduled visit: results are reviewed at next scheduled visit

Complete the following procedures:

1. Document results on **Testing Results CRF**
2. **If seroconversion is confirmed:**
 - a. Document a seroconversion in a **Medical Events/Conditions CRF**; document any ART use in the **Medications CRF**.
 - b. Participant can remain in study per regular visit and procedure schedule, except omit HIV testing.
 - c. If not already done by the participant's clinical care team, refer for counseling regarding prevention of vertical transmission.
3. **If confirmed HIV negative:** participant continues with study visit and procedures schedule per protocol.