

### Counseling Messages following Rapid HIV Test Results

Test Result	Counseling Message
Two negative Rapid tests	<ol style="list-style-type: none"> <li>1. Test results indicate that you <b>are not infected</b> with HIV.</li> </ol>
Two positive Rapid tests	<ol style="list-style-type: none"> <li>1. Test results indicate that you <b>are infected</b> with HIV.</li> </ol> <p><b>If at screening or enrollment:</b></p> <ol style="list-style-type: none"> <li>1. You are not eligible for MTN-025.</li> </ol> <p><i>Note: Additional post-test counseling and referrals should be provided. Confirmatory testing may be provided as a service, per site discretion, but is not required per protocol. If testing will not be done, skip the rest of these messages]</i></p> <ol style="list-style-type: none"> <li>2. If you choose, additional testing will be done today to confirm this result.</li> <li>3. The testing will be done from a new blood sample and can be conducted today in our lab.</li> <li>4. The additional testing is done to give you information about your health and is not part of the study.</li> <li>5. It is unusual for the additional testing to show a different result.</li> <li>6. Drawing a new blood sample and running the test will take approximately [SITE TO INSERT TIME]. You may wait and receive confirmatory results today, or schedule a separate visit for results.</li> </ol> <p><b>If during follow-up:</b></p> <ol style="list-style-type: none"> <li>1. Additional testing will be done today to confirm this result.</li> <li>2. The testing will be done from a new blood sample and can be conducted today in our lab.</li> <li>3. It is common for HIV prevention studies to do additional testing for study purposes in this situation.</li> <li>4. It is unusual for the additional testing to show a different result.</li> <li>5. Drawing a new blood sample and running the test will take approximately [SITE TO INSERT TIME]. You may wait and receive confirmatory results today, or schedule a separate visit for results.</li> </ol>
One positive Rapid test, one negative Rapid test	<ol style="list-style-type: none"> <li>1. Test results <b>are unclear</b>.</li> <li>2. Additional testing is needed to determine your HIV status.</li> <li>3. The testing will be done from a new blood sample and can be conducted today in our lab.</li> <li>4. Drawing a new blood sample and running the test will take approximately [SITE TO INSERT TIME]. You may wait and receive confirmatory results today, or schedule a separate visit for results.</li> </ol>

### Interpretation of HIV Tests Results Following Geenius Confirmatory Testing

Test Result	Status	Counseling Message
Two positive Rapid tests →  Geenius positive	HIV-infected	<ol style="list-style-type: none"> <li>1. Test results indicate that you <b>are infected</b> with HIV.</li> <li>2. [Provide post-test counseling and referrals for HIV-infected participants as per site SOPs.]</li> </ol>
Two positive Rapid tests →  Geenius negative, HIV-1 indeterminate or other*	HIV status not clear	<ol style="list-style-type: none"> <li>1. Although the HIV rapid tests we ran indicated that you are infected with HIV, the additional tests now indicate unclear results.</li> <li>2. Further testing is needed to determine your HIV status.</li> <li>3. The additional testing may show whether you are infected with HIV or not. No more blood needs to be taken at this time; we will use samples we have already collected.</li> <li>4. You may need to give blood for testing at future visits for your status to be known.</li> <li>5. We expect these additional results to be available [INSERT TIME FRAME – for Gene Xpert sites, probably 1-3 hours and for non-Gene Xpert sites, up to 2 weeks].</li> </ol>
One positive Rapid test, one negative Rapid test →  Geenius negative, HIV-1 indeterminate or other*	HIV status not clear	<ol style="list-style-type: none"> <li>1. Test results <b>are unclear</b>.</li> <li>2. Further testing is needed to determine your HIV status.</li> </ol> <p><b>If at screening or enrollment:</b></p> <ol style="list-style-type: none"> <li>1. [Sites to perform additional testing and associated counseling per local standards of care (as outlined in SOPs) and as directed by the LC.]</li> <li>2. You are not eligible for MTN-025 enrollment until your final HIV status is confirmed.</li> </ol> <p><b>If during follow-up:</b></p> <ol style="list-style-type: none"> <li>1. The additional testing may show whether you are infected with HIV or not. No more blood needs to be taken at this time; we will use samples we have already collected.</li> <li>2. You may need to give blood for testing at future visits for your status to be known.</li> <li>3. We expect these additional results to be available [INSERT TIME FRAME – for Gene Xpert sites, probably 2-3 hours and for non-Gene Xpert sites, up to 2 weeks].</li> </ol>
One positive Rapid test, one negative Rapid test →  Geenius HIV-1 positive	HIV infected	<ol style="list-style-type: none"> <li>1. Test results indicate you <b>are infected</b> with HIV.</li> <li>2. [Provide additional post-test counseling and referrals for HIV infected participants as per site SOPs.]</li> </ol> <p><i>Note: If at enrollment visit, participant is not eligible for MTN-025 enrollment.</i></p>

\*Same counseling message for Geenius results of HIV-2 positive; HIV-2 indeterminate; HIV-2 positive with HIV-1 cross reactivity; HIV untypable

**Interpretation of Additional HIV Tests Performed During Follow-up  
Per Protocol Appendix III**

<b>Test Result</b>	<b>Status</b>	<b>Counseling Message</b>
<b>Additional Testing – Counseling Message Given at a future interim visit</b>		
Geenius negative or HIV-1 indeterminate* →  HIV-1 viral load negative (below limit of detection)	HIV-uninfected	1. Test results show that you <b>are not infected</b> with HIV.
Geenius negative or HIV-1 indeterminate* →  HIV-1 viral load positive (at or above limit of detection)	HIV infected	1. Test results show that you <b>are infected</b> with HIV. 2. Additional testing is needed to confirm your HIV infection for study purposes. 3. [Provide post-test counseling and referrals or follow-up on referrals previously provided as per site SOPs.] 4. This additional testing will be done from a new blood sample. This testing will occur <i>[provide date – testing should occur about 1 month after her positive rapid test(s), or when advised by the LC]</i> . 5. It is common for HIV prevention studies to do additional testing in this situation. 6. It is unusual for the additional testing to show a different result.
Geenius HIV-1 positive→  HIV-1 viral load positive (at or above limit of detection)	HIV-infected	1. Test results show that you <b>are infected</b> with HIV. 2. [Provide post-test counseling and referrals or follow-up on referrals previously provided as per site SOPs.]

\*If Geenius results are HIV-2 positive; HIV-2 indeterminate; HIV-2 positive with HIV-1 cross reactivity; HIV untypable, HIV-1 viral load (Abbott M2000, Roche TaqMan or Gene Xpert) should not be performed. Please consult the MTN LC for guidance to confirm HIV-2 infection and for additional counseling messages, as needed.

**NOTE**

Should you receive a result that is not outlined in one of the tables above, counsel the participant that her results are unclear and additional testing may be required. Contact the MTN Laboratory Center for guidance and additional counseling messages, as needed.