

HPTN NL Communiqué # 4

HPTN 052

SSP section 10: Laboratory Procedures, version 1.6

This is official study documentation for the HPTN 052 trial. Please circulate it among relevant staff for their review, print it out, and place it at the end of your 052 SSP Manual, Section 10: Laboratory Communiqués.

Date: October 18, 2010

This communiqué is a clarification to the Lab Communiqué #2 (dated September 14, 2009), and supercedes information contained in that communiqué. Please note that this communiqué references Appendix II (attached) of the HPTN 052 protocol, Version 3.0, dated 20 November 2006. The SSP will be updated when a new version of the SSP is released. New text is bolded; deleted text is marked with a strikethrough.

1. Clarification:

Table 1

Laboratory Assay	Performance Site	Specific Kit, Procedure, or Instrument
HIV/AIDS Related Assays		
HIV EIA Antibody Test	All sites	Rapid Testing: Trinity Biotech Uni-Gold® or Oraquick®, or Bio-Rad EIA, and Western Blot Kit or alternative HIV test kit (Rapid, EIA, WB/IFA) approved by the U.S. FDA. <u>A list of approved kits can be found online at: http://www.fda.gov/cber/products/testkits.htm</u>
HIV Western Blot (Confirmatory)	Sites may use either Western Blot or IFA	Bio-Rad Western Blot Kit or alternative HIV WB or IFA test kit approved by the U.S. FDA. <u>A list of approved kits can be found online at: http://www.fda.gov/cber/products/testkits.htm</u>
HIV IFA (Confirmatory)		Fluorognost HIV-1 IFA

10.2.1 HIV Antibody Testing Algorithm

However, sites may use their own, validated HIV antibody testing algorithm for screening as long as U.S. FDA approved test kits are used. If an alternative HIV testing algorithm is used for screening, it must be contained in the site's HIV antibody testing (HIV EIA antibody test/Western blot/IFA) SOP and approved by the HPTN-NL.

The requirements outlined below must be followed for sites using rapid HIV tests at screening for eligibility for the Index Case and Partner, and for Partner follow-up. (Please note: two rapid tests are required at both screening and Partner HIV testing during follow-up):

- ~~If only one rapid HIV test is used, the test must be U.S. FDA approved. If positive, a Western Blot or IFA must be performed using a U.S. FDA approved test to confirm the result.~~
- When using two rapid HIV tests, one of them must be U.S. FDA approved. If positive or discordant, a Western Blot or IFA must be performed using a U.S. FDA approved test to confirm the result.
- When using two rapid HIV tests in parallel where a third rapid HIV test is used as a tie-breaker, one of the two tests run in parallel **MUST** be U.S. FDA approved.

Please note the following:

- If the results of the parallel rapid HIV testing are discordant and the U.S. FDA approved test is the negative result, and the tie-breaker result is also negative, no further testing is required.
- If the results of the parallel rapid HIV testing are discordant and the U.S. FDA approved test is the positive result, a tie-breaker test is not necessary(though a site may have to perform one based on their site-specific requirements), and a HIV Western Blot test must be performed using a U.S. FDA approved test.
- If HIV ELISA testing is used, the test must be U.S. FDA approved. If positive, a Western Blot or IFA must be performed using a U.S. FDA approved test to confirm the result.
- If a combination of rapid HIV tests and HIV ELISA is used, the algorithm must be reviewed and approved by the HPTN Network Laboratory to ensure that the site is using U.S. FDA approved tests.

Finally, in the event that a negative partner seroconverts at any time during followup, sites must follow the HIV antibody testing algorithm outlined in Appendix II of the protocol to confirm HIV status.

Detailed in Table 1 and section 10.2.1 is information on the use of US FDA approved test kits for HIV-1 testing in HPTN 052. The FDA web site is updated periodically and should be checked on a routine basis to ensure that the kits in use on site are still available and FDA cleared. Several companies offer two versions of the kits: one that is available internationally that is not FDA approved and one that is FDA approved. Two of the FDA approved assays are Trinity Biotech Uni-Gold™ Recombigen® and OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. These are assigned different catalog numbers than the non-FDA approved kits. There are several other FDA approved kits available. Sites should check the FDA list quarterly for any updates and check with the Network Laboratory regarding any rapid test kit, EIA or WB kit in use. Any changes in kit methodology must be validated and approved by the NL.

Table 1 will be updated with the removal of the names of the kits and will state:

Rapid Testing: A rapid HIV test or HIV ELISA test that has been approved by the FDA.

A list of approved kits can be found online at:

<http://www.fda.gov/cber/products/testkits.htm>

Appendix II. HIV Antibody Testing Algorithm for Endpoint Ascertainment at Follow-up

(Partner Only)

