

HPTN NL Communique # 3

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 Communiques.

Date: August 19, 2010

This communique consists of an updated laboratory reminder regarding partner seroconversion and related sample collection and storage. Reference Table 10-3a, 10-3b and 10-4 in SSP section 10, version 1.6

Follow-up procedures **must** be performed for the Index Case **AND** the Partner as outlined in Section 5.3.6 of the protocol, and in Section 10 of the SSP, Tables 10-3a, 10-3b, and 10-4 - identified as "Partner Seroconverts" in each table. The "seroconversion" visit procedures should be performed and the required samples should be collected when the results of the second Western blot confirmatory testing are provided to the Partner. [See Appendix II of the protocol for the HIV antibody testing algorithm]. If it is not possible to collect the required samples at the "seroconversion" visit (e.g. you believe that the Partner may not return for the second Western blot confirmatory result), it is acceptable to collect them at the visit when the results of the first confirmatory Western blot test results are provided to the Partner.

Please note that the procedures and samples collected at the Partner Seroconversion visit are **CRITICAL** for determining the primary endpoint of the study (HIV transmission between the Index and Partner) and include the following stored specimens:

- **Index:** Plasma (includes two 10 mL tubes - 1 for storage, 1 for genotyping), PBMCs, and genital secretions (either semen or cervical)
- **Partner:** Plasma (includes two 10 mL tubes - 1 for storage, 1 for genotyping), Serum, PBMCs, and genital secretions (either semen or cervical)

If either the Index Case or Partner has not consented to long term storage, plasma (one 10 mL tube) should still be collected and stored for HIV genotyping and genital secretions should still be collected and stored to determine cervical/seminal HIV-1 RNA.

The HPTN NL requires **2** plasma samples to confirm the seroconversion and for genotyping from both the partner and index. These samples must come from the FIRST visit at which the the Partner is tested as HIV positive (a quarterly or yearly visit as well as an interim visit) as well as the Partner Seroconversion Visit. Plasma is normally stored on both the Partner and Index at both quarterly and yearly visits and is collected again from both participants at the Partner Seroconversion Visit. If the partner comes in for an interim visit for HIV testing, plasma must be stored from both the partner and the index.

The PSC-1 (partner specimen collection) and ISC-1 (index specimen collection) DataFax forms need to be completed at each visit. If a specimen type is required but not collected, please enter a comment directly on the form (does not matter where except it has to be inside the margins) stating the reason the sample was not collected.

Please email 052mgmt@hptn.org if you have any questions about the requirements for these visits.

