

HPTN 035 Operational Reminders



Plasma Archive at Study Exit

- ❖ HPTN 035 participants who have not previously been identified as seroconverters will complete final HIV counseling and testing at their study exit visits. At these visits, 5 mL of whole blood is collected in a lavender top tube for HIV testing and plasma archive (unless an alternative blood volume has been approved by the HPTN Network Lab).
 - ❖ This blood sample is “sample 1” in the HPTN 035 follow-up HIV testing algorithm.
 - ❖ HIV rapid tests are performed using blood from this sample. If one or more rapid tests are reactive, a Western blot (WB) is performed using blood from this sample.
 - ❖ All remaining blood from this sample is processed to yield at least four 0.5 mL aliquots of plasma which must be logged into LDMS and stored at -70° C within 24 hours of collection.
- ❖ If a WB performed on sample 1 is positive or indeterminate, “sample 2” (5 mL of whole blood in a lavender top tube) is collected for WB testing. All remaining blood from this sample is processed to yield at least four 0.5 mL aliquots of plasma which must be logged into LDMS and stored at -70° C within 24 hours of collection.
- ❖ Given the above instructions, any participant with a positive or indeterminate WB on sample 1 will have two sets of plasma aliquots stored as they exit the study. The two sets will have different specimen collection dates and must be logged into LDMS using the correct specimen collection dates.
- ❖ Please notify the CORE, SDMC, and Network Lab immediately if any of the above-listed procedures are not followed or if four 0.5 mL aliquots of plasma are not archived at each time point.
- ❖ Please also notify the Network Lab immediately if any sample 2 WB results are indeterminate or negative. The Network Lab will then advise on next steps to determine the participant’s HIV status.