

## MTN-020 (ASPIRE) Operational Guidance 2: Plasma Storage for HIV Algorithm and Routine Storage at Same Visit

**To:** ASPIRE site labs, clinic staff and site leadership

**From:** MTN Management team

This guidance becomes effective November 15, 2012.

This communication is to update procedures for plasma storage at visits where there is both routine plasma storage and HIV algorithm required plasma storage. This situation occurs if there are positive or discordant HIV rapids at a visit in which plasma storage is already required per protocol: *quarterly, semi-annual, annual, PUEV, Termination Visit*. This communication augments and modifies guidance in Section 13.7.6 of the SSP.

Procedures for plasma storage when a participant has discordant or positive rapids at a visit where routine plasma storage is also required (Quarterly, Semi-Annual, Annual, PUEV, Termination Visits):

For sites conducting **venipuncture** for HIV rapid testing:

1. Store a minimum of 4 mL of plasma with the LDMS code "RPS" from the first collection where specimen was drawn for rapid HIV tests.
2. Once HIV rapid test results are available, collect and store an additional minimum of 6 mL of plasma with the LDMS code "CON". Use this specimen for HIV Western Blot, HIV viral load, and CD4 testing.
3. The total minimum plasma stored in this situation is now 10 mL.

For sites conducting **Fingerstick** HIV rapid testing:

1. Once the fingerstick HIV rapid test results are available, collect and store 6 mL of plasma with the code "CON" in LDMS. Use this specimen for HIV Western Blot, HIV viral RNA, and CD4 testing.
2. The total minimum plasma stored will remain 6 mL. You do not need to draw a separate tube for routine plasma storage.
3. On the SS-1 CRF, mark "not required" for item 3 and in the comments at the bottom add a note that item 3 not required due to HIV confirmatory plasma storage.

This guidance will be incorporated into SSP section 13.7.6 the next time SSP updates are made.

This guidance becomes effective November 15, 2012. It is being distributed November 1, 2012 to allow sites time to make put the guidance in effect.

**All Operational Guidance documents must be printed and filed with regulatory documentation.**