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HPTN NL Communique

HPTN 046

This is official study documentation for the HPTN 046 trial. Please circulate it among relevant staff for their review, print it out, and place it at the end of your 046 SSP Manual, Section 10: Laboratory Communiques.

UPDATES

There are no updates at this time.

CLARIFICATIONS

1. HIV-1 RNA PCR assays for maternal and infant plasma will be performed locally (on-site), provided that the site is certified. The sites will **only** perform HIV-1 RNA PCR assays in real-time if used for clinical management of the patient. These results can then be submitted to SCHARP via Laboratory Results Forms. Blood should continue to be collected according to the schedule in the Laboratory Section of the SSP, but plasma should be stored for viral load and genotyping. Otherwise, this assay will be performed at the end of the study on samples selected by the protocol virologist.
2. **Dried Blood Spot (DBS) Preparation and Storage**
 - a. Dried blood spots are to be prepared from mothers at the following time points: 3rd trimester screening or on or before day 3 pp within 3 days of birth, at 2 and 6 weeks, and at 3, 6, 12 and 18 months.
 - b. Dried blood spots are to be prepared from infant blood at the following time points: within 3 days of birth, at 2 and 6 weeks, and at 3, 6, 9, 12 and 18 months.
 - c. Dried blood spots should be prepared in the laboratory from an EDTA blood tube. The EDTA tube should be well mixed before preparing the DBS. Pipette 50 ul of whole blood directly onto the center of each spot on the filter paper so that it fills up the circle. Two or three blood spots should be collected.
 - d. We recommend using the **903 Protein Saver™ card by Whatman.**
 - e. Allow filter paper cards to air-dry at room temperature for at least 2 hours (do not place filter paper in heat or sun; spread cards in one layer – they should not be placed on top of one another). Filter paper cards can be hung by clothespins to a line to air dry completely. Place each dried card

in its own ziplock bag with its own individual dessicant bag for storage.
Store samples at room temperature, not exposed to sun or heat.

3. Dried Blood Spots will be stored on infants and mothers at all visits where DNA/RNA/NVP resistance plasma is stored. 2-3 DBS (50 uL per spot) will be stored for each participant. DBS are stored only if there is enough specimen. No additional blood will be drawn to enable storage of DBS

UPCOMING

The Laboratory Section (10) of the HPTN 046 SSP is being updated.