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HPTN NL Communiqué 3

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 Procedures.

UPDATES

Section 10 of the HPTN 046 SSP Versions 1.0 thru 5.0, instructed the sites to store dried blood spots (DBS) at 'room temperature'.

This communiqué is written to allow the site laboratories the option of storing DBS in a -20°C freezer. Changes will be made to the next version of the SSP as follows:

10.7.2 Dried Blood Spot (DBS) Preparation and Storage

Allow filter paper cards to air dry at room temperature (18-25° C) for as 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). They 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 desiccant bag for storage. ~~Store samples at room temperature, not exposed to sun or heat.~~ **Samples should be stored at either room temperature (18 to 25°C) or at -20°C or below. Do not expose to sun or heat.** Dried blood spots need to be entered into the LDMS and stored in an appropriate location so they can be easily retrieved when necessary.

No changes to the current protocol are needed.

A handwritten signature in black ink, appearing to read "P. Richardson".

Prepared by Paul Richardson

March 3rd 2010