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HPTN NL Communique # 2

HPTN 057

This is official study documentation for the HPTN 057 trial. Please circulate it among relevant staff for their review, print it out, and place it at the end of your 057 SSP Manual, Section 10: Laboratory Communiques.

UPDATES

Section 10.5.5 Maternal HIV Testing will be updated in the next SSP version to include the bolded text below:

10.5.5 Maternal HIV Testing.

HIV testing will be performed during the first maternal screening visit for women who do not have a documented HIV-1 infection. A confirmatory HIV test will be performed if documented confirmation is not available.

In the interest of participant safety, the Network Laboratory considers the following to be “documented HIV-1 infection” or “documented confirmation” for the purposes of this study:

“A Western Blot or IFA confirmed, HIV positive result that has been reported during a time that the reporting lab has demonstrated proficiency in HIV testing as defined by the Network Lab.”

If this documented HIV infection is not available maternal screening should be performed by rapid HIV or EIA followed by a confirmatory WB or IFA using the same sample.

The final confirmatory result must be performed using an FDA approved assay.

The Network Lab may approve the enrolment of a participant who does not meet these specific requirements on a case by case basis. The NL may advise additional testing and/or additional documentation and needs to be contacted prior to enrollment.

Please contact Networklab@hptn.org for further clarification if required.

CLARIFICATIONS

None at this time

UPCOMING

The Laboratory Section (10) of the HPTN 057 SSP will be updated.

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Prepared by: Paul Richardson



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