

Department of Pathology
HIV Prevention Trials Network (HPTN) Laboratory
Pathology 306 / 600 N. Wolfe Street
Baltimore, Maryland 21287-6417
Principal Investigator 410-614-4734 / Fax 410-614-3548
Deputy Director 410-614-6736 / Fax 410-614-0430
Financial Manager 410-614-6738 / Fax 410-614-0430
Admin. Coordinator 410-614-6808 / Fax 410-614-0430
QA/QC Coordinators 410-502-0435 / Fax 410-614-0430



HPTN NL Communiqué #2

HPTN 046

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

Date: April 17, 2009

UPDATES

There are no updates at this time.

CLARIFICATIONS

As specified in the current SSP and protocol, blood will be collected for infant HIV testing by real-time Roche Amplicor HIV-1 DNA PCR at 2 and 5 weeks and 3, 6, 9 and 12 months. HIV EIA/rapid testing will be performed at 18 months only. HIV testing should be completed as described in section 5.6 of this SSP manual and according to one of the two algorithms included as Figures 10-2 and 10-3. *Note: Quantitative RNA PCR may be used if DNAPCR is not available.*

Recently, some laboratories have been performing HIV RNA testing in place of HIV DNA testing, Because of this; some infant participants no longer have sufficient plasma available at key visits for protocol-required testing. **In the future, the HPTN NL is to be notified in any instance when your site laboratory cannot perform the HIV DNA PCR assay**, before testing is performed using the alternative HIV RNA PCR assay. This will allow the HPTN NL to assist the site and laboratory in determining the best course of action.

The notification should go to the following staff:

Susan Eshleman, HPTN NL PI	seshlem@jhmi.edu
Estelle Piwowar-Manning, HPTN NL Deputy Director	epiwowa@jhmi.edu
Paul Richardson, HPTN Sr QA/QC coordinator	pricha18@jhmi.edu
Vanessa Cummings, HPTN QA/QC coordinator	vcummin1@jhmi.edu
LeTanya Johnson-Lewis, HPTN QA/QC coordinator	ljohns18@jhmi.edu

CC the HPTN NL

Networklab@hptn.org

In the correspondence to the NL, please include the reason why the testing cannot be performed. For the following reasons, please provide the information indicated below.

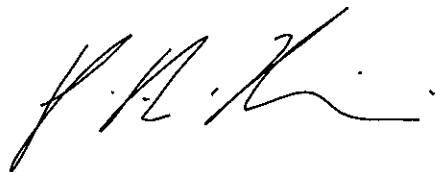
REASON	INFORMATION REQUIRED
HIV DNA PCR Kits not available	indicate when the kits were ordered and when the order is due in
VQA copy control/ blinded pellets not available	indicate inventory issues and when the order was placed)
VQA performance issues	Provide details for recent VQA HIV DNA PCR panels
LDMS lock out due to invalid runs	Provide details and date(s) of lock out
Other	Provide details as needed

Please also indicate which participant samples would be affected, and how many subjects would be affected at each study visit:

- Enrollment
- Week 2
- Week 5
- Month 3
- Month 6
- Month 9
- Month 12
- Confirmatory issues

Finally, please provide the number of aliquots of plasma you have remaining for each participant at the relevant visit(s). Do not use these aliquots for testing without approval from the HPTN NL.

The NL may recommend alternative testing strategies, such as (1) send the DNA to another laboratory for testing, (2) perform the testing without the VQA controls; repeat the testing with the VQA controls when they become available, (3) perform HIV RNA PCR testing, (4) use alternate test methodologies, or (5) invite participant back for additional plasma collection for storage.



Paul Richardson
Senior QA/QC Coordinator
HPTN Network Laboratory