

## HPTN052 Joint Lab and Data Communiqué #9

10 December, 2009

This is official study documentation for the HPTN052 trial. Please print and circulate it among relevant staff for their review, and file it in your HPTN052 SSP Manual behind the “Communiqués” tab. This document is considered part of the SSP manual.

### **UPDATE**

In an effort to identify participants who may have been taking ART at enrollment into the HPTN052 study or during the study prior to initiation of study-provided ART, SCHARP is now applying queries to all RNA results < 1000 copies/mL:

- a) at enrollment for all index participants;
- b) at follow-up visits for all Index participants on the delay arm who have not yet initiated ART.

The query reads, "The RNA PCR value for this index participant is less than 1000 copies/mL. Please confirm this result is accurate." To confirm the result, please consult with your lab to ensure there were no transcription errors or other errors in documentation, equipment, quality control, etc. If a correction to the RNA result is needed, update the CRF and fax in. Otherwise, write 'result confirmed correct' on the CRF and re-fax.