

## HPTN NL Communique # 5

HPTN 052

SSP section 10: Laboratory Procedures, version 1.6

**This is official study documentation for the HPTN 052 trial. Please circulate it among relevant staff for their review, print it out, and place it at the end of your 052 SSP Manual, Section 10: Laboratory Communiques.**

Date: February 15, 2011

**This communique is a notification of change to the SSP version 1.6. The SSP will be updated when a new version of the SSP is released. New text is bolded; deleted text is marked with a strikethrough.**

**Table 10-1:** HPTN 052 Required Laboratory Assays

STD Diagnosis		
Urine PCR for Chlamydia trachomatis (CT) and Neisseria gonorrhoea (GC) for men	All sites	NAT (nucleic acid testing)
PCR for CT and GC in women using endocervical swab or urine (NOTE: urine may be <b>used with an assay that is approved for use by the NL</b> , in the ProbeTec System or GenAptima System; <del>urine may not be used in the Roche system</del> ) <b>Any change in testing methodology must be approved by the NL.</b>	All sites	NAT (nucleic acid testing)
Syphilis serology	All sites	Not specified

### 10.5.2 Urine

Urine will be collected for pregnancy (women only), Chlamydia and gonorrhoea (men only). ~~Once LoA#2 to V. 3.0 is approved by all applicable IRB/ECs at your site, and if the Probetec or GenAptima system is used, .~~ Urine can be collected and used from women for Chlamydia and gonorrhoea testing **with an assay that is approved for use by the NL.**