



HPTN 052 (096)

IEV-1 (025)

**Index ID**

-    -    -

Site Number      Index Number      Partner      Chk

**Index Screening/Enrollment  
CD4/Viral Load Results**

**Initial Collection Date**

/    /

dd      MMM      yy

**Instructions:** Complete this form for enrolled participants only.

**Not done/**  
 **Not collected**

**Alternate Collection Date**  
 dd      MMM      yy

/    /

**Enrollment Results**

1. Total lymphocytes     cells/mm<sup>3</sup>

2. Absolute CD4+     cells/mm<sup>3</sup>  
 not available

2a.   .  % **OR**

**Not done/**  
 **Not collected**

**Alternate Collection Date**  
 dd      MMM      yy

/    /

3. RNA PCR of Plasma

<      =      >  
 (less than)      (equal to)      (greater than)

copies/mL **OR**  undetectable

**Specimen Collection Date**

dd      MMM      yy

/    /

**Screening Results**

4. Absolute CD4+     cells/mm<sup>3</sup>  
 not available

4a.   .  % **OR**

Comments: \_\_\_\_\_

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## Index Screening/Enrollment CD4/Viral Load Results (IEV-1)

### Item-specific Instructions:

- **Initial Specimen Collection Date:** Record the date that the first enrollment specimen(s) was *collected* (NOT the date results were reported or recorded on the form). Complete date required.
- **Alternate Collection Date:** This date is to be completed **ONLY** if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. Complete date required.
- **Results Reporting**
  - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
  - If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
  - It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.
  - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, *then* round the converted result if necessary.
- **Item 3:** Mark the less than (<), equal to (=), or greater than (>) box as appropriate and record the value. For example, if the value is 3100 copies, mark the equal to (=) box and record “0003100” in the value. For any value, if the value reported is < 400 copies, mark the less than (<) box and record “0000400” in the value.