



HPTN 052 (096)

IFV-1 (126)

Visit Code [ ][ ][ ] . [ ]

Index ID

Index ID [ ][ ][ ] - [ ][ ][ ] - 00 - [ ]  
Site Number Index Number Partner Chk

Index CD4/Viral Load Results

Initial Collection Date

Initial Collection Date [ ][ ] [ ][ ][ ] [ ][ ]  
dd MMM yy

Instructions: Complete form for Enrollment, Quarterly, and Yearly visits and as clinically needed.

Alternate Collection Date

Not done/ Not collected  dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]

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

2. Absolute CD4+ [ ][ ][ ][ ] cells/mm<sup>3</sup>

2a. [ ][ ][ ] . [ ] % OR

not available

If CD4 ≤ 250 cells/mm<sup>3</sup> and the participant has not yet received study medication, re-draw specimen for confirmatory test and complete another CD4/Viral Load Results form.

Alternate Collection Date

Not done/ Not collected  dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]

3. RNA PCR of Plasma

< (less than) = (equal to) > (greater than) viral copies/mL [ ][ ][ ][ ][ ][ ][ ][ ] copies/mL OR undetectable

If RNA ≤ 1000 copies/mL and/or the participant has NOT been on ART for 24 weeks, end of form.

3a. Was the previous RNA PCR value for this participant > 1000 copies/mL? yes  no  If no, end of form.

3b. Why is this participant's RNA > 1000 copies/mL? Mark all that apply.

- recent systemic illness  newly confirmed virologic failure as defined by the protocol
- vaccination  ongoing virologic failure
- obvious nonadherence to study medications  other, specify: \_\_\_\_\_

Complete Index Virologic Failure Assessment.

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

---

## Index CD4/Viral Load Results (IFV-1)

### Item-specific Instructions:

- **Initial Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. 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: RNA PCR of Plasma**
  - 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.
  - If RNA > 1000 copies/mL and the participant has been receiving study medication for at least 24 weeks, re-draw specimen for confirmatory test and complete another CD4/Viral Load Results form.
  - If RNA result is larger than 7-digits, record the result as “= 9999999” and record the actual result in Comments.