

MTN 015 (143)

LAB-1 vb(149)

Visit Code

□□.□□

1

Participant ID

□□□-□□□□□□-□
Site Number Participant Number Chk

Laboratory Results—Revised--Version 2

Initial Collection Date

□□ □□□ □□□
dd MMM yy

Not done/ Not collected 1. T CELL SUBSETS

Alternate Collection Date
dd MMM yy
□□ □□□ □□□

1a. Absolute CD4+ $cells/mm^3$
□□□□

1b. CD4+ OR □□□.□□ %

Not done/ Not collected 2. HIV RNA

Alternate Collection Date
dd MMM yy
□□ □□□ □□□

2a. HIV RNA PCR (plasma): > = < $viral\ copies/mL$
□□□□□□□□ OR target not detected

2a1. HIV RNA PCR kit lower limit of detection: 20 40 $viral\ copies/mL$
 OR □□□

Not done 2b. Second HIV RNA PCR (plasma): > = < $viral\ copies/mL$
□□□□□□□□ OR target not detected

2b1. HIV RNA PCR kit lower limit of detection: 20 40 $viral\ copies/mL$
 OR □□□

Not done/ Not collected 3. PREGNANCY TEST

Alternate Collection Date
dd MMM yy
□□ □□□ □□□

3a. Test result negative positive → If positive, complete Pregnancy Report and History form.

Comments:

Laboratory Results—Revised--Version 2 (LAB-1)	
Purpose:	This form is used to document absolute CD4+, HIV plasma RNA, and pregnancy test results obtained during the study.
General Information/ Instructions:	<p>Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax when results for all collected specimens are available and recorded.</p> <p>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. A complete date is required.</p> <p>Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a day after the Initial Collection Date. A specimen collected for the same visit but on a later date should be recorded on the same form only when obtained within the same visit window. A complete date is required.</p> <p>Not done/Not collected: For every test, mark either the "Not done/Not collected" box or enter a test result. If a result is not available, mark the "Not done/Not collected" box.</p>
Item-specific Instructions:	
Item 1a:	If automatically calculated, record the CD4+ percentage that was reported for the specimen in item 1a. If the CD4+ percentage is not available (was not reported and would have to be manually calculated), mark the "not available" box.
Item 2a:	Record the participant's HIV RNA PCR result exactly as it appears on the lab report source documentation. If result is "target not detected", mark the "target not detected" box and do not enter any numbers in the "viral copies/mL" boxes. If the result is "<20 Below Range" or "<40Detected", leave the "Target not detected" box blank, and mark the "<" box and the number "00000020" or "00000040" in the "viral copies/mL" boxes. Note that the ">" symbol is "greater than" and the "<" symbol is "less than."
Item 2b:	If a second HIV RNA PCR result was obtained for the specimen, record the result here (refer to instructions for item 2a above) and complete item 2b. If a second HIV RNA PCR result was not obtained for the specimen, mark the "Not done" box and go to item 3.
Item 3:	Note that a Pregnancy Report and History form is required to be completed once for each pregnancy, not for each positive pregnancy test result.