Visit Code ☐☐.☐ 1

MTN-011 (135) LR-1 (151)

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - 0
Protocol PTID Chk Cohort

Laboratory Results

Initial Specimen Collection Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

1. Hemogram	Not done/ Not collected ☐ *Go to item 2.*	Alternate Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	
Not reported ☐ 1a. Hemoglobin	☐☐.☐ *g/dL*	Severity Grade *(if applicable)* ☐	*AE Log page #* ☐☐☐ OR *not reportable as an AE* ☐
Not reported ☐ 1b. Hematocrit	☐☐.☐ %		
Not reported ☐ 1c. MCV	☐☐☐.☐ *fL*		
Not reported ☐ 1d. Platelets	☐☐☐☐.☐ *x10³/mm³*	Severity Grade *(if applicable)* ☐	*AE Log page #* ☐☐☐ OR *not reportable as an AE* ☐
Not reported ☐ 1e. WBC	☐☐☐.☐ *x10³/mm³*	Severity Grade *(if applicable)* ☐	☐☐☐ OR ☐
2. HIV Test Results	Not done/ Not collected ☐ *Go to item 3.*	Alternate Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	
2a. HIV EIA	*negative* ☐	*positive* ☐ → *indeterminate* ☐ →	*If positive or indeterminate, complete HIV Test Results.*
3. Hepatitis B 3a. Hepatitis B Surface Antigen	Not done/ Not collected ☐	Alternate Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*non-reactive* ☐ *reactive* ☐

Record abnormal findings on Pre-existing Conditions form or Adverse Experience Log, as applicable.

Laboratory Results (LR-1)	
Purpose:	This form is used to document laboratory results as required or clinically indicated during screening, enrollment, and follow-up for female participants.
	• 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). A complete date is required. • Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. A complete date is required. • Not done/Not collected: Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage.
Results Reporting:	• If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation in Comments. • If the site lab does not produce test results in the units used on this form, the results must be converted before the results are recorded on the form. • If the site lab does not report results to the same level of precision allowed on the form, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%. • 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.
Severity Grade:	• If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results. • Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. • Treat all missing digits in the lab value as zeros. • If the lab value falls between two calculated severity grade ranges, assign it the higher grade. • There may be situations in which a lab value falls within a site's lab normal ranges and also within a gradable range per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*.
AE Log Page #:	• If the lab value is reportable as an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.
Not Reportable as an AE:	• Only mark this box if the lab value is gradable per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.
Item 3:	• If a result is positive/reactive during study follow-up, report the relevant infection(s) as adverse experience(s) on the Adverse Experience Log form.

Visit Code ☐☐.☐ 1

MTN-011 (135) LR-2 (152)

Participant ID

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Protocol PTID Chk Cohort

Laboratory Results

4. Syphilis Serology	*End of form.* ◄ Not done/ Not collected ☐	Alternate Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐
4a. Syphilis screening test *If non-reactive, end of form.* ◄	*non-reactive* ☐	*reactive* ☐ *equivocal* ☐
4a1. Was titer performed?	*yes* ☐	*N/A* ☐ → *If N/A, go to item 4b.*
4a2. Syphilis titer	**1:** ☐☐☐☐	
4b. Syphilis confirmatory test #1: *If non-reactive, go to item 4c.* ◄	*non-reactive* ☐	*reactive* ☐
4b1. Was titer performed?	*yes* ☐	*N/A* ☐ → *If N/A, end of form.*
4b2. Syphilis titer	**1:** ☐☐☐☐	
4c. Syphilis confirmatory test #2:	*non-reactive* ☐	*reactive* ☐ *inconclusive* ☐

Record abnormal findings on Pre-existing Conditions form or Adverse Experience Log, as applicable.

Comments: _____

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Staff Initials / Date

Laboratory Results (LR-2)	
	• Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. A complete date is required. • Not done/Not collected: Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage.
Item 4:	• If a result is positive/reactive during study follow-up, report the relevant infection(s) as adverse experience(s) on the Adverse Experience Log form.