Visit Code ☐☐.☐ 1

MTN 012/IPM 010 (187) LR-1 (135)



**Participant ID**

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

## Laboratory Results

**Initial Specimen Collection Date**

☐☐ ☐☐☐ ☐☐

*dd* *MMM* *yy*

**Not done/ Not collected** ☐

**Alternate Collection Date** *dd* *MMM* *yy*

**1. HEMOGRAM** ☐☐ ☐☐☐ ☐☐

| | Not reported | | | Severity Grade *If applicable* | AE Log Page # | Not reportable as an AE |
|---|---|---|---|---|---|---|
| 1a. Hemoglobin | ☐ | ☐☐.☐ | *g/dL* | ☐ | ☐☐☐ | OR ☐ |
| 1b. Hematocrit | ☐ | ☐☐.☐ | *%* | | | |
| 1c. MCV | ☐ | ☐☐☐.☐ | *fL* | | | |
| 1d. Platelets | ☐ | ☐☐☐☐.☐ | *x10$^3$/mm$^3$* | ☐ | ☐☐☐ | OR ☐ |
| 1e. WBC | ☐ | ☐☐☐.☐ | *x10$^3$/mm$^3$* | ☐ | ☐☐☐ | OR ☐ |

**Not done**

**DIFFERENTIAL** ☐ → ***If not done, go to item 2.***

| | Not reported | Absolute Count *cells/mm3* | Severity Grade *If applicable* | AE Log Page # | Not reportable as an AE |
|---|---|---|---|---|---|
| 1f. Neutrophils | ☐ | ☐☐☐☐ | ☐ | ☐☐☐ | OR ☐ |
| 1g. Lymphocytes | ☐ | ☐☐☐☐ | ☐ | ☐☐☐ | OR ☐ |
| 1h. Monocytes | ☐ | ☐☐☐☐ | | | |
| 1i. Eosinophils | ☐ | ☐☐☐☐ | | | |
| 1j. Basophils | ☐ | ☐☐☐☐ | | | |

Comments: _____

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0 1 Language

Staff Initials / Date

# Laboratory Results (LR-1)

**Purpose:** To document safety laboratory results as required or clinically indicated during screening, enrollment, and follow-up.

**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.

**Alternate Collection Date**: This date is to be completed ONLY if the specimen is collected after the Initial Specimen Collection Date for this same visit. A complete date is required.

**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 on the Comments lines.
- 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.
- If the site lab does not report results to the same level of precision allowed on the CRF, 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.

Visit Code ☐☐.☐ 1

MTN 012/IPM 010 (187) LR-2 (136)



**Participant ID**

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

## Laboratory Results

### 2. CHEMISTRIES

| Not done/ Not collected | Alternate Collection Date dd MMM yy | | U/L | Severity Grade If applicable | AE Log Page # | Not reportable as an AE |
|---|---|---|---|---|---|---|
| ☐ | ☐☐ ☐☐☐ ☐☐ | 2a. AST (SGOT) | ☐☐☐☐ | ☐ | ☐☐☐ | OR ☐ |
| ☐ | ☐☐ ☐☐☐ ☐☐ | 2b. ALT (SGPT) | ☐☐☐☐ | ☐ | ☐☐☐ | OR ☐ |
| ☐ | ☐☐ ☐☐☐ ☐☐ | 2c. Creatinine ..... | mg/dL ☐☐.☐ | ☐ | ☐☐☐ | OR ☐ |

2c1. Calculated creatinine clearance: ..... ☐☐☐ *mL/mm*

2d. Weight ..... ☐☐☐ *kg*

### 3. URINE TESTS

| Not done/ Not collected | Alternate Collection Date dd MMM yy |
|---|---|
| ☐ | ☐☐ ☐☐☐ ☐☐ |

| Not done | | | negative or trace | 1+ | 2+ | 3+ | 4+ | Severity Grade If applicable | AE Log Page # | Not reportable as an AE |
|---|---|---|---|---|---|---|---|---|---|---|
| ☐ | 3a. | Protein ..... | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐☐☐ | OR ☐ |

| | | | negative | positive |
|---|---|---|---|---|
| ☐ | 3b. | Glucose ..... | ☐ | ☐ |
| ☐ | 3c. | Blood ..... | ☐ | ☐ |
| ☐ | 3d. | Leukocyte esterase (LE) ..... | ☐ | ☐ |
| ☐ | 3e. | Nitrites ..... | ☐ | ☐ |
| ☐ | 3f. | Culture ..... | ☐ | ☐ |

Comments: _____

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Staff Initials / Date

## Laboratory Results (LR-2)

**Item-specific Instructions:**

**Alternate Collection Date**: This date is to be completed ONLY if the specimen is collected after the Initial Specimen Collection Date for this same visit. A complete date is required.

**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 on the Comments lines.
- 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.
- If the site lab does not report results to the same level of precision allowed on the CRF, 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 2c1:** When calculating the participant's creatinine clearance, use the age and weight of the participant at the time the blood specimen is drawn. If the participant was not weighed at the visit when the blood specimen was drawn, but was weighed at a previous visit (within the allowable window for creatinine clearance per the SSP Manual), record the weight from the previous visit. Also, record in the "Alternative Collection Date" boxes the date of the previous visit when the participant was weighed. If the participant has a creatinine value but cannot have his creatinine clearance calculated (due to missing weight data), line through the response boxes and initial and date.