



HPTN 052 (096)

ICC-1 (021)

Visit Code [ ][ ][ ] . [ ]

Visit Code

Index ID

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

Index Complete Chemistries

Initial Collection Date

dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]

Instructions: For all index participants: Complete form for Enrollment, Quarterly, Post-ART Initiation (Week 2), and Yearly visits and for the two scheduled monthly visits following ART initiation. For delayed arm participants: Complete this form also at the ART initiation visit.

1. LIVER FUNCTION TESTS
Not done/Not collected [ ]
Alternate Collection Date dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]
1a. Alkaline phosphatase [ ][ ][ ][ ] U/L
1b. AST (SGOT) [ ][ ][ ][ ] U/L
1c. ALT (SGPT) [ ][ ][ ][ ] U/L
1d. Total bilirubin [ ][ ] . [ ] mg/dL
AE Severity Grade [ ] AE Log Page # [ ][ ][ ]

2. ELECTROLYTES
Not done/Not collected [ ]
Alternate Collection Date dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]
2a. Sodium [ ][ ][ ] mEq/L
2b. Potassium [ ][ ] . [ ] mEq/L
2c. Chloride [ ][ ][ ] mEq/L
2d. Phosphorus (Phosphate) [ ][ ] . [ ] mg/dL
2e. Bicarbonate [ ][ ] mEq/L
AE Severity Grade [ ] AE Log Page # [ ][ ][ ]

3. RENAL FUNCTION TESTS
Not done/Not collected [ ]
Alternate Collection Date dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]
3a. Creatinine [ ][ ] . [ ] mg/dL
AE Severity Grade [ ] AE Log Page # [ ][ ][ ]

4. OTHER CHEMISTRIES
Not done/Not collected [ ]
Alternate Collection Date dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]
4a. Albumin [ ][ ] . [ ] g/dL
AE Severity Grade [ ] AE Log Page # [ ][ ][ ]

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

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## Index Complete Chemistries (ICC-1)

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.

### 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.
  - 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%.
- **AE 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.
- **AE Log Page #:** Record the page number of the AE Log which is most closely associated with the abnormal lab value.