Visit Code ☐☐.☐ 1

MTN 012/IPM 010 (187) STI-1 (131)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

STI Laboratory Results

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Not done/ Not collected ☐ **Alternate Collection Date** *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

1. HIV

	negative	*positive*	*indeterminate*
1a. HIV EIA	☐	☐	☐

If positive or indeterminate, complete HIV Test Results.

Not done/ Not collected ☐ **Alternate Collection Date** *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

2. SYPHILIS

	non-reactive	*reactive*
2a. Syphilis screening test	☐	☐

If non-reactive, go to item 3.

2a1. Syphilis titer..... **1:** ☐☐☐☐

	negative	*positive*	*indeterminate*
2b. Syphilis confirmatory test	☐	☐	☐

Not done/ Not collected ☐ **Alternate Collection Date** *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

3. Gonorrhea and Chlamydia

	negative	*positive*
3a. *N. gonorrhea* (urine)	☐	☐
3b. *C. trachomatis* (urine)	☐	☐

Comments: _____

☐☐☐☒ 16-FEB-11

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0 1 Language

Staff Initials / Date

STI Laboratory Results (STI-1)

Purpose: This form is used to document STI laboratory results as required or clinically indicated during Screening, Enrollment, and follow-up.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **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 provide an explanation on the Comments line.
- **Repeat Local Laboratory Tests:** Sometimes it is necessary to repeat a local lab test.
  - For a repeat test of the ***same*** **sample**, record only the results considered the most accurate. If a first result was already recorded and faxed to SCHARP DataFax, but the second result is considered more accurate, amend the form to reflect the second result by drawing a line through the first result and writing the second result on the form. Initial and date the change, and refax the amended form to SCHARP DataFax.
  - For a repeat test using a ***different sample*** (e.g., a blood re-draw for a repeat CBC), at Screening or Enrollment, record the repeat test results on the original form by updating the item. Amend the original form to reflect the second result by drawing a line through the first result and writing the second result on the form. Initial and date the change, and refax the amended form to SCHARP DataFax.
  - For a repeat test using a ***different sample*** (e.g., a blood re-draw for a repeat CBC), at follow-up, record the repeat test results on a new form. If the new sample is collected at an unscheduled visit, use an interim visit code. If the new sample is collected at a future scheduled study visit, use that scheduled study visit code. Fax the new form to SCHARP DataFax.

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. Record a complete date.
- **Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. 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. A complete date is required.
- **Not done/Not collected:** If the “Not done/Not collected” box is marked, provide an explanation on the Comments lines.
- **Item 1a:** If the HIV EIA result is positive or indeterminate at screening, enrollment, or follow-up, follow the protocol HIV testing algorithm and record the associated test results on the HIV Test Results form.
- **Item 2a1:** Use leading zeros when recording a syphilis titer level. For example, a titer level of 1:32 would be recorded on the form as “1:0032.”