



MTN-011 (135)

STI-1 (190)

Visit Code

Participant ID

- - - 0

Protocol PTID Chk Cohort

STI Test Results

Initial Specimen Collection Date

dd MMM yy

1. Vaginal Wet Prep	Not done/Not collected	Alternate Collection Date				
	<input type="checkbox"/>	dd	MMM	yy		
	negative	positive				
<input type="checkbox"/> 1a. Homogeneous vaginal discharge	<input type="checkbox"/>	<input type="checkbox"/>				
Not done						
<input type="checkbox"/> 1b. pH <input type="text"/> <input type="text"/>	<i>If > 4.5, mark as positive.</i>	positive				
<input type="checkbox"/> 1c. Whiff test	negative	positive				
<input type="checkbox"/> 1d. Clue cells \geq 20%	negative	positive				
<input type="checkbox"/> 1e. <i>Trichomonas vaginalis</i>	negative	positive				
<input type="checkbox"/> 1f. Buds and/or hyphae (yeast)	negative	positive				
2. Trichomonas Rapid Test	Not done/Not collected	Alternate Collection Date				
	<input type="checkbox"/>	dd	MMM	yy	negative	positive
					<input type="checkbox"/>	<input type="checkbox"/>
3. <i>N. gonorrhoeae</i>	Not done/Not collected	Alternate Collection Date				
	<input type="checkbox"/>	dd	MMM	yy	negative	positive
					<input type="checkbox"/>	<input type="checkbox"/>
4. <i>C. trachomatis</i>	Not done/Not collected	Alternate Collection Date				
	<input type="checkbox"/>	dd	MMM	yy	negative	positive
					<input type="checkbox"/>	<input type="checkbox"/>
5. Pre-coital pH:	Not done	<input type="text"/> <input type="text"/>				
	<input type="checkbox"/>					
6. Post-coital pH:	Not done	<input type="text"/> <input type="text"/>				
	<input type="checkbox"/>					

Complete or update Pre-existing Conditions or Adverse Experience Log, as applicable.

Comments: _____

01-AUG-12

STI Test Results (STI-1)	
Purpose:	This form is used to document Vaginal Wet Prep and STI Test Results during screening, enrollment, and follow-up for female participants.
General Information/ Instructions:	<ul style="list-style-type: none"> • 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. Record the reason why the result is not available on the Comments lines.
Item-specific Instructions:	
Items 1–4:	If a test result(s) recorded on this form indicates that the participant has a new (or increased severity) laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as an adverse experience on an Adverse Experience (AE) Log.
Item 1:	If a vaginal wet prep was performed but not all assays were completed, mark the “Not done/Not collected” box for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason on the Comments lines.
Item 1a:	Mark the “positive” box if homogeneous vaginal discharge was observed.
Item 1d:	Mark the “positive” box if 20% or more of the cells were clue cells.
Item 1e:	Mark the “positive” box if trichomonads were observed.
Item 1f:	Mark the “positive” box if yeast buds and/or hyphae were observed.
Item 5:	Record the result of the pre-coital vaginal fluid pH.
Item 6:	Record the result of the post-coital vaginal fluid pH.