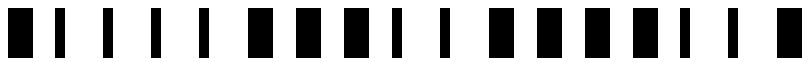


GROUP 2

Visit 4 **Visit Code 24.0**

- Visit Summary (VS-1)
- STI Test Results (STI-1)
- Study Product Accountability (SPA-1)

This page intentionally left blank.



MTN-011 (135)

VS-1 (121)

Visit Code

Participant ID

- - - 0

Protocol PTID Chk Cohort

Visit Summary

Visit Date

dd MMM yy

1. What was the participant's last day of previous menses?	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<i>amenorrheic for past 6 months</i>
2. hCG for pregnancy:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<i>OR</i> <input type="checkbox"/>
3. Has participant's method of contraception/family planning changed since her last visit?	<input type="checkbox"/> <input type="checkbox"/>	<i>If positive, complete Pregnancy Report form and Product Hold/Discontinuation Log.</i>
4. How many new AE Log pages were completed for the female participant at this visit?	<input type="text"/> <input type="text"/>	<i>If yes, complete Family Planning form.</i>
5. How many new Product Hold/Discontinuation Log pages were completed for this visit?	<input type="text"/> <input type="text"/>	
6. Did the female participant complete the CASI Behavioral Questionnaire (BEH)?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
7. Time during visit of study product insertion:	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<i>OR</i> <input type="checkbox"/>
8. Did the couple complete coitus?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<i>If no or not required, go to instructions above item 9.</i>
8a. Time of completion of coitus:	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
Complete item 9 for Group 1 participants only, and only at Visit Code 09.0. For all other visits, leave item 9 blank.		
9. Time of post-coital study product insertion:	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<i>OR</i> <input type="checkbox"/>

Visit Summary (VS-1)	
Purpose:	This form is used to document completion of all Follow-up Visits (required and interim) completed by female participants once enrolled.
Item-specific Instructions:	
Item 1:	If the participant is unable to recall the complete date, obtain participant's best estimate. At a minimum, the month and year are required. Only record dates of menstrual period bleeding. Do not record dates of episodes of expected breakthrough bleeding experienced while a participant is on Depo, Mirena, or other continuous contraceptive method where a woman does not experience a monthly menstrual period.
Item 4:	Record in item 4 how many new AE Log pages were completed for the female participant at this visit. For example, if two new AEs were reported, record "02." Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
Item 5:	Record how many new Product Hold/Discontinuation Log pages were completed for this visit. For example, if two new product holds/discontinuations were reported, record "02." Note that the Visit Code recorded in item 1 of the Product Hold/Discontinuation Log pages should be the same as the Visit Code recorded on this form.
Items 8 and 8a:	Completion of coitus is defined as when the male partner ejaculates into the female partner's vagina.
Item 9:	When recording time, use a 24-hour clock (e.g., 8:12pm is recorded as 20:12).



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	If > 4.5, mark as positive.	Alternate Collection Date				
		dd	MMM	yy		
<input type="checkbox"/> 1b. pH						
<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"/>				
6. Post-coital pH:	Not done	<input type="text"/> <input type="text"/>				

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

Comments: _____

01-AUG-12

N:\hivnet\forms\MTN_011\forms\m011_STI.fm

English

Staff Initials / Date

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.



MTN-011 (135)

SPA-1 (415)

Visit Code

1

Participant ID

- - - 0

Protocol PTID Chk Cohort

Study Product Accountability

Form Completion Date

dd MMM yy

1. Was study product given to the participant for clinic and/or home use? *yes* *no* → *If no, go to item 2.*

1a. Date dispensed:

dd MMM yy

1b. Number of study product applicators dispensed at this visit: 1 2 7 8 *other, specify:* _____

2. Was study product returned by the participant? *yes* *no, specify:* _____ → *If no, end of form.*

2a. Date study product was returned by participant:

dd MMM yy

2b. Number of **used** applicators returned: *used applicators returned*

2c. Number of **unused** applicators returned: *unused applicators returned*

Comments: _____

Study Product Accountability (SPA-1)	
Purpose:	This form is used to document all study product dispensation, and used and unused product returns.
General Information/ Instructions:	This form should be completed at each visit when product is dispensed.
Item-specific Instructions:	
Item 1b:	Mark the box corresponding to the total number of applicators dispensed at this visit. For example, for Group 2 female participants at Visit 6 (26.0), the "8" box should be marked (1 applicator for clinic use, 6 applicators for home use, 1 applicator extra).
Item 2:	This item must be completed when participant returns product from the previous dispensation. For some visits, dispensation and returns will occur on the same day (e.g., Group 1, Visits 3a and 3b; Group 2, Visits 3a and 3b). For other visits, product returns will be several days after dispensation (e.g., Group 1, Visits 6a and 6b; Group 2, Visits 2 and 3a). Always record product returns on the SPA-1 form which documents that dispensation. If study product was not returned, record the reason on the line provided.
Item 2a:	Record the exact day, month, and year study product was returned by the participant.