GROUP 1

Visit 6a
Visit Code 07.0

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

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Visit Code ☐☐.☐ 1

MTN-011 (135) VS-1 (121)

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? ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy* OR ☐ *amenorrheic for past 6 months*

2. hCG for pregnancy: *not required* ☐ *negative* ☐ *positive* ☐ → *If positive, complete Pregnancy Report form and Product Hold/ Discontinuation Log.*

3. Has participant's method of contraception/family planning changed since her last visit? *yes* ☐ *no* ☐ → *If yes, complete Family Planning form.*

4. How many **new** AE Log pages were completed for the female participant at this visit? *# of pages* ☐☐

5. How many **new** Product Hold/Discontinuation Log pages were completed for this visit? *# of pages* ☐☐

6. Did the female participant complete the CASI Behavioral Questionnaire (BEH)? *yes* ☐ *no* ☐ OR *not required* ☐

7. Time during visit of study product insertion: *24-hour clock* ☐☐ (*hr*) : ☐☐ (*min*) OR *not required* ☐

8. Did the couple complete coitus? *yes* ☐ *no* ☐ *not required* ☐ → *If no or not required, go to instructions above item 9.*

   8a. Time of completion of coitus: *24-hour clock* ☐☐ (*hr*) : ☐☐ (*min*)

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: *24-hour clock* ☐☐ (*hr*) : ☐☐ (*min*) OR *not inserted* ☐

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).

Visit Code ☐☐.☐ 1

MTN-011 (135) PX-1 (036)

Participant ID ☐☐☐ ☐☐☐☐-☐-0 (Protocol / PTID / Chk / Cohort)

Physical Exam

Visit Date ☐☐ ☐☐☐ ☐☐ (dd / MMM / yy)

VITAL SIGNS

1.	Weight	☐☐☐ *kg* OR ☐ *not done*	4.	Pulse	☐☐☐ *beats per minute*
2.	Body Temp	☐☐.☐ *°C*	5.	Respirations	☐☐ *breaths per minute*
3.	BP	☐☐☐ / ☐☐☐ *mmHg*	6.	Height	☐☐☐ *cm* OR ☐ *not done*

FINDINGS

		not done	*normal*	*abnormal*	*Notes:*
7.	General appearance	☐	☐	☐	
8.	Genitourinary	☐	☐	☐	
9.	Abdomen	☐	☐	☐	
10.	Lymph Nodes	☐	☐	☐	
11.	Heart/ Cardiovascular	☐	☐	☐	
12.	Lungs/ Respiratory	☐	☐	☐	
13.	Extremities	☐	☐	☐	
14.	Neurological	☐	☐	☐	
15.	Skin	☐	☐	☐	
16.	Eyes	☐	☐	☐	
17.	Ears, Nose, Throat	☐	☐	☐	
18.	Other	☐	☐	☐	

Record abnormal findings on Pre-existing Conditions form or Adverse Experience Log, as applicable.

Physical Exam (PX-1)	
Purpose:	This form is used to document the female participant's vital signs and physical exam findings during screening, enrollment, and follow-up.
General Information/ Instructions:	If abnormal findings are found in items 7–18 transcribe information onto the Pre-existing Conditions form or Adverse Experience Log form, as applicable.
Item-specific Instructions:	
Vital Signs:	Use leading zeros when needed.
Items 7–17:	For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings on the Notes line. If not evaluated, mark the "not done" box.
Item 18:	If no other abnormal findings are identified, mark the "normal" box. If abnormal, specify the body system being referenced and describe the findings on the Notes line.

Visit Code ☐☐.☐ 1

MTN-011 (135) STI-1 (190)

Participant ID ☐☐☐ (Protocol) ☐☐☐☐-☐-0 (PTID, Chk, Cohort)

STI Test Results

Initial Specimen Collection Date ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

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

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

Comments: _____

☐☐☐☒ 01-AUG-12

0 1 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:	• 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.

Visit Code ☐☐.☐ 1

MTN-011 (135) SPA-1 (415)

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: _____

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Staff Initials / Date

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.