Screening Visit
Visit 01.0

Required forms

- Eligibility Criteria (ECI-1)
- Demographics (DEM-1)
- Pre-existing Conditions Log (PRE-1)
- Concomitant Medications Log (CM-1)
- Safety Laboratory Results (SLR-1)
- HIV Results (HIV-1)
- STI Test Results (STI-1)
- Physical Exam (PX-1)
- Pelvic Exam (PE-1)
- Pelvic Exam Diagrams (non-DataFax)

This page intentionally left blank.

MTN-024/IPM 031 (203) ECI-1 (023)

Participant ID

Site Number – Participant Number – Chk

Eligibility Criteria

Form Completion Date

dd MMM yy

1. Does this participant meet all eligibility criteria? *yes* ☐ *no* ☐ → *If no, go to item 2.*

1a. Obtain signature _____

Signature of Principal Investigator (or designee) *Date*

1b. Obtain signature _____

Signature of second staff member verifying eligibility *Date*

2. Was the participant enrolled? *yes* ☐ *no* ☐ → *If yes, end of form.*

3. Why was the participant not enrolled?

- ☐ participant did not return (refused or lost contact) → *End of form.*
- ☐ eligible but declined enrollment → *End of form.*
- ☐ not eligible

4. Reason(s) for ineligibility: *Mark all that apply.*

- ☐ 4a. <45 or >65 years old
- ☐ 4b. not post-menopausal, as described in the protocol
- ☐ 4c. FSH level <40 ml u/mL
- ☐ 4d. not able to provide adequate locator information
- ☐ 4e. not able or willing to provide written informed consent
- ☐ 4f. pregnant at screening
- ☐ 4g. plans to relocate from study site during study or plans to travel away from site for more than 4 consecutive weeks
- ☐ 4h. diagnosed with urinary tract infection (UTI), which has not resolved
- ☐ 4i. diagnosed with pelvic inflammatory disease, and STI or reproductive tract infection (RTI), which has not resolved
- ☐ 4j. participant has grade 2 or higher pelvic exam finding
- ☐ 4k. does not meet laboratory eligibility criteria
- ☐ 4l. HIV positive at screening or enrollment
- ☐ 4m. does not meet other clinical eligibility criteria
- ☐ 4n. other reason, including investigator decision. Specify: _____

Eligibility Criteria (ECI-1)

Purpose:	This form is used to document participant eligibility for enrollment in this study or reasons for participant ineligibility.

General Information/Instructions:

- Complete this form for each participant screened for this study. Complete and fax this form once it is determined whether the participant will enroll in the study. If not enrolled, this is the only form that is faxed for the participant.
- If the participant has a second screening attempt, update this form with data from the second screening attempt and refax. Do not complete a new form for the second attempt.

Item-specific Instructions:

Items 1a and 1b:	Local site Standard Operating Procedures (SOPs) must specify staff members designated to affirm eligibility.
Item 3:	Mark “participant did not return (refused or lost contact)” when a participant begins the screening process and is eligible, but does not return to the clinic to complete screening procedures within the 45-day screening window.
Item 4:	Mark all reasons for participant ineligibility. Refer to the Eligibility Checklist for the Screening and Enrollment Visit. If the reason for ineligibility is not listed, mark “other reason, including investigator decision,” and specify ineligibility reason on the line provided.

MTN-024/IPM 031 (203) DEM-1 (001)

Participant ID

Site Number – Participant Number – Chk

Demographics

Form Completion Date

dd MMM yy

1. What is your date of birth?	dd MMM yy
2. What was your sex at birth?	☐ *male* ☒ *female*
3. Are you currently married?	☐ *yes* ☐ *no*
4. Do you currently live with your partner?	☐ *yes* ☐ *no*
5. What is your highest level of education?	☐ no schooling ☐ primary school, not complete ☐ primary school, complete ☐ secondary school, not complete ☐ secondary school, complete ☐ attended college or university
6. Do you consider yourself to be Latina or of Hispanic origin?	☐ *yes* ☐ *no*
7. What is your race? *Mark all that apply.*	☐ 7a. American Indian or Alaska Native ☐ 7b. Asian ☐ 7c. Black or African American ☐ 7d. Native Hawaiian or other Pacific Islander ☐ 7e. White ☐ 7f. Other, specify: _____
8. Do you earn an income of your own?	*yes* ☐ *no* ☐ → *If no, end of form.*
8a. How do you earn income? *Mark all that apply.*	☐ *formal employment* ☐ *self-employment* ☐ *other*

☐ ☐ ☐ ☒ 12-AUG-13

N:\hivnet\forms\MTN_024\forms\m024_DEM.fm

0 1 English

Staff Initials/Date

Demographics (DEM-1)	
Purpose:	This form is interviewer-administered and is used to collect participant's demographic and socioeconomic information.
General Information/Instructions:	
	This form is faxed to SCHARP DataFax only if the participant enrolls in the study. This form is completed at the Screening Visit. Read each item aloud, except item 2, and record the participant's response.
Item-specific Instructions:	
Item 3:	Mark "yes" if the participant is in a legally-binding marriage and has obtained a marriage certificate.
Item 5:	If the participant attended or completed a post-secondary diploma or certificate program mark "attended college or university."
Item 6:	This item is based on self-definition. Per NIH policy, Latina or Hispanic includes a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.
Item 7:	Record the participant's race based on self-definition. In the case of mixed race, mark all that apply and/or "other" and indicate the mixed race background. Per NIH policy, Latina is considered an ethnic group and not a race and should not be entered in item 7f.

Page

MTN-024/IPM 031 (203) PRE-1 (012)

Participant ID

Site Number – Participant Number – Chk

Pre-existing Conditions

☐ No pre-existing conditions reported or observed.
End of form. Fax to SCHARP DataFax.
Staff Initials/ Date: _____

1. Condition	Onset date MMM yy	Staff Initials/Date
Comments	Ongoing at Enrollment? ☐ *yes* ☐ *no*	Severity Grade *grade* ☐ ☐ *not gradable*

2. Condition	Onset date MMM yy	Staff Initials/Date
Comments	Ongoing at Enrollment? ☐ *yes* ☐ *no*	Severity Grade *grade* ☐ ☐ *not gradable*

3. Condition	Onset date MMM yy	Staff Initials/Date
Comments	Ongoing at Enrollment? ☐ *yes* ☐ *no*	Severity Grade *grade* ☐ ☐ *not gradable*

4. Condition	Onset date MMM yy	Staff Initials/Date
Comments	Ongoing at Enrollment? ☐ *yes* ☐ *no*	Severity Grade *grade* ☐ ☐ *not gradable*

Pre-existing Conditions (PRE-1)

Purpose:	The Pre-existing Conditions form serves as the "starting point" or baseline from which study clinicians must determine whether conditions identified during follow-up are adverse events (AEs).

General Information/Instructions:

- At the Screening Visit, record relevant baseline medical history. This includes conditions and symptoms reported by the participant during the baseline medical/menstrual history as well as any conditions identified via pelvic exam, physical exam, or laboratory testing. This includes, but is not limited to, history of hospitalizations, surgeries, allergies, any condition that required prescription or chronic medication (that is, more than 2 weeks in duration), and acute conditions occurring prior to Enrollment.
- At the Enrollment Visit, review and update as needed.
- Do record pre-existing conditions if identified during follow-up. Add a chart note to explain why the PRE entry was added after Enrollment.

Item-specific Instructions:

Page:	Number pages sequentially throughout the study, starting with "01." Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by SCHARP.
Condition:	Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Pre-existing Conditions form. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."
Onset Date:	If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required.
Comments:	This field is optional. Use it to record any additional relevant information about the condition, including any associated signs/symptoms.
Severity Grade:	For each condition, grade the severity according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* and the *DAIDS Female Genital Grading Table for Use in Microbicide Studies* (as appropriate). If a condition is not gradable, mark "not gradable". Review and update as needed for conditions ongoing at the Enrollment Visit.
Ongoing at Enrollment?	Mark "yes" for chronic conditions, as well as any other conditions, ongoing at the Enrollment Visit. If a condition resolves or increases in severity or frequency after the Enrollment Visit, document this in chart notes and/or another document other than this form.

MTN-024/IPM 031 (203) CM-1 (423)

Note: Number pages sequentially (01, 02, 03) for each participant. Page ☐☐

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐
Site Number Participant Number Chk

Concomitant Medications Log

☐ No medications taken at Screening/Enrollment. Staff Initials/Date: _____

☐ No medications taken throughout study. Staff Initials/Date: _____

End of form. Fax to SCHARP DataFax.

1.

Medication Name | Staff Initials/Log Entry Date

Indication | Taken for a reported AE? ☐ yes ☐ no

Date Started: ☐☐ dd ☐☐☐ MMM ☐☐ yy

Date Stopped: ☐☐ dd ☐☐☐ MMM ☐☐ yy OR ☐ Continuing at end of study

AE Log page(s): ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

Frequency *Mark only one.* ☐ *prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify:* _____

Dose/Units

Route *Mark only one.* ☐ *PO* ☐ *IM* ☐ *IV* ☐ *TOP* ☐ *IHL* ☐ *VAG* ☐ *REC* ☐ *SC* ☐ *other, specify:* _____

2.

Medication Name | Staff Initials/Log Entry Date

Indication | Taken for a reported AE? ☐ yes ☐ no

Date Started: ☐☐ dd ☐☐☐ MMM ☐☐ yy

Date Stopped: ☐☐ dd ☐☐☐ MMM ☐☐ yy OR ☐ Continuing at end of study

AE Log page(s): ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

Frequency *Mark only one.* ☐ *prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify:* _____

Dose/Units

Route *Mark only one.* ☐ *PO* ☐ *IM* ☐ *IV* ☐ *TOP* ☐ *IHL* ☐ *VAG* ☐ *REC* ☐ *SC* ☐ *other, specify:* _____

Concomitant Medications Log (CM-1)

Purpose: All medication(s) that are used by the participant during the study other than study product, must be documented on this form. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs.

General Information/Instructions:

When to fax this form:

- once the participant has enrolled in the study;
- when pages have been updated or additional Log pages have been completed (only fax updated or new pages);
- when the participant has completed study participation; and/or
- when instructed by SCHARP.

Item-specific Instructions:

Page: Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.

No medications taken at Screening/ Enrollment: Mark this box if no medications were taken by the participant from Screening through the Enrollment Visit. This box should only be marked on Page 01.

No medications taken throughout study: Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study.

Medication Name: Record the medication name. Refer to the protocol or study specific procedures manual (SSP) for guidance on whether trade name or generic name should be used.

Indication: For health supplements, such as multivitamins, record "general health." For preventive medications, record "prevention of [insert condition]" (e.g., for flu shot, record "prevention of influenza"). For recreational drugs, record "recreation."

Date Started: If the participant is unable to recall the exact date, obtain participant's best estimate. At a minimum, the year is required.

Date Stopped: At the participant's Termination visit, the "Date Stopped" must be recorded for each medication OR the "Continuing at end of study" box must be marked. At a minimum, the month and year are required.

Frequency: Below is a list of common frequency abbreviations:

prn: as needed	**qd**: every day	**tid**: three times daily	**qhs**: at bedtime
once: one time	**bid**: twice daily	**qid**: four times daily	**other, specify**: alternative dosing schedules

Dose/Units: If the participant does not know the dose or units, draw a single line through the blank response box and initial and date. For prescription combination medications, record the dosage of first three main active ingredients. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon).

Route: Below is a list of common route abbreviations:

PO: oral	IV: intravenous	IHL: inhaled	REC: rectal	**other, specify**: alternative routes
IM: intramuscular	TOP: topical	VAG: vaginal	SC: subcutaneous	

MTN-024/IPM 031 (203) SLR-1 (144)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐-☐☐☐☐☐-☐
Site Number Participant Number Chk

Safety Laboratory Results

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

1. Hemogram

Not done/ Not collected ☐ → *Go to item 2.*

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐

			Severity Grade (if applicable)	AE Log page #	not reportable as an AE
Not reported					
☐ 1a.	Hemoglobin	☐☐.☐ g/dL	☐	☐☐☐	OR ☐
☐ 1b.	Hematocrit	☐☐.☐ %			
☐ 1c.	MCV	☐☐☐.☐ fL			
☐ 1d.	Platelets	☐☐☐☐.☐ $x10^3/mm^3$	☐	☐☐☐	OR ☐
☐ 1e.	WBC	☐☐☐.☐ $x10^3/mm^3$	☐	☐☐☐	OR ☐

Differential

Not done ☐ → *Go to item 2.*

			Severity Grade (if applicable)	AE Log page #	not reportable as an AE
Not reported		Absolute Count			
☐ 1f.	Neutrophils	☐☐☐☐☐ $cells/mm^3$	☐	☐☐☐	OR ☐
☐ 1g.	Lymphocytes	☐☐☐☐ $cells/mm^3$	☐	☐☐☐	OR ☐
☐ 1h.	Monocytes	☐☐☐☐ $cells/mm^3$			
☐ 1i.	Eosinophils	☐☐☐☐ $cells/mm^3$			
☐ 1j.	Basophils	☐☐☐☐ $cells/mm^3$			

2. Serum Chemistries

Not done/ Not collected ☐ → *End of form.*

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐

			Severity Grade (if applicable)	AE Log page #	not reportable as an AE
Not reported					
☐ 2a.	AST (SGOT)	☐☐☐☐ U/L	☐	☐☐☐	OR ☐
☐ 2b.	ALT (SGPT)	☐☐☐☐ U/L	☐	☐☐☐	OR ☐
☐ 2c.	Creatinine	☐.☐☐ mg/dL	☐	☐☐☐	OR ☐
		OR			
		☐☐☐.☐ µmol/L			

☐☐☐☒ 12-AUG-13

N:\hivnet\forms\MTN_024\forms\m024_SLR.fm

01 English

Staff Initials/Date

Safety Laboratory Results (SLR-1)

Purpose:	This form is used to provide data on the participant's baseline and follow-up laboratory test results.
General Information/Instructions:	
	Use this form to report the hematology, differential, and liver and renal function test results as they become available. Do not fax the form to SCHARP DataFax until all results are available and the participant has enrolled in the study.
Initial Specimen Collection Date:	Record the date that the first specimen was collected (NOT the date the results were reported or recorded on the form) for this visit. 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.
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 in Comments.
Repeat testing:	If any or all of the lab tests listed on this form are repeated (re-drawn) between the Screening and Enrollment Visit, document the repeated results on the same SLR form assigned Visit Code 1.0. Line through the original result(s), record the new result(s) and the Alternate Collection Date for each repeat test result.
Results Reporting:	• Results should be documented on the form using the units present on the source laboratory results document. If the units present on the form do not match your source results report, contact the MTN-024/IPM 031 Management Team. Note that the following units are equivalent: IU/L = U/L I/l x 100 = % 10^9/L = 10^3/mm^3 = 10^3/μL For creatinine, only record the result in the units listed on the source document. • If the site lab does not report results to the same level of precision allowed on the form, 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%. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the form. For example, a lab-reported hemoglobin value of 11.05 g/dL would be recorded as 11.1 g/dL. A lab-reported hemoglobin value of 11.04 g/dL would be recorded as 11.0 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.
Severity Grade:	• If any 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 result. If value is below Grade 1, leave the severity grade box blank. • Always compare the severity grade range to the value that was recorded on the form (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. • Record any Grade 1 or higher lab values on the Pre-existing Conditions form.
Item-specific Instructions:	
Visit Code:	Record the visit code assigned to this visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

MTN-024/IPM 031 (203) HIV-1 (140)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number Participant Number Chk

HIV Results

Specimen Collection Date

☐☐ dd ☐☐☐ MMM ☐☐ yy

	Not done/ Not collected	*negative*	*positive*	*indeterminate*	
1. HIV	☐	☐	☐	☐ →	*If any are positive at Screening participant is ineligible. If indeterminate, consult Network Lab. If any are positive during follow-up, complete HIV Confirmatory Results form and Clinical Product Hold/ Discontinuation Log.*

Comments:

HIV Results (HIV-1)	
Purpose:	This form is used to document the participant's HIV results.
General Information/Instructions:	
	Record test results on this form as they become available. Fax this form into SCHARP DataFax once results for all collected specimens are recorded on the form.
Specimen Collection Date:	Record the date that the first specimen was collected (NOT the date results were reported or recorded on the 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 in the Comments.

MTN-024/IPM 031 (203) STI-1 (190)

Visit Code . 1

Participant ID

Site Number – Participant Number – Chk

STI Test Results

Initial Specimen Collection Date: dd MMM yy

		Alternate Collection Date (dd MMM yy)			
1. VAGINAL WET PREP STUDIES	Not done/ Not collected → *Go to item 2.*				
1a. Homogeneous vaginal discharge	Not done		*negative*	*positive*	*Only required if assessment for BV performed.*
1b. Whiff test	Not done		*negative*	*positive*	*Only required if assessment for BV performed.*
1c. Clue cells > 20%	Not done		*negative*	*positive*	*Only required if assessment for BV performed.*
1d. *Trichomonas vaginalis*	Not done		*negative*	*positive*	
1e. Buds and/or hyphae (yeast)	Not done		*negative*	*positive*	
2. Trichomonas rapid test	Not done/ Not collected		*negative*	*positive*	
3. N. gonorrhea	Not done/ Not collected		*negative*	*positive*	Collection Type: *urine* / *vaginal*
4. C. trachomatis	Not done/ Not collected		*negative*	*positive*	Collection Type: *urine* / *vaginal*

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

Comments:

STI Test Results (STI-1)	
Purpose:	This form is used to document Vaginal Wet Prep and STI Test Results by the local site laboratory.
General Information/Instructions:	
	Complete this form at the Screening Visit and at other visits where these tests are performed during follow-up.
Initial Specimen Collection Date:	Record the date that the first specimen was collected (NOT the date the results were reported or recorded on the form) for this visit. 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.
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 in Comments.
Visit Code:	Record the visit code assigned to this visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
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 “Not done/Not collected” for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason in Comments.
Item 1a:	Mark “positive” if homogeneous vaginal discharge was observed.
Item 1c:	Mark “positive” if 20% or more of the cells were clue cells.
Item 1d:	Mark “positive” if trichomonads were observed.
Item 1e:	Mark “positive” if yeast buds and/or hyphae were observed.

MTN-024/IPM 031 (203) PX-1 (036)

Visit Code . 1

Participant ID

Site Number – Participant Number – Chk

Physical Exam

Visit Date dd MMM yy

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

FINDINGS *Items 9–15 may be omitted from assessment after the Enrollment Visit.*

	not done	*normal*	*abnormal*	*Notes*
7. General appearance	☐	☐	☐	
8. Abdomen/Gastrointestinal	☐	☐	☐	
9. Neck	☐	☐	☐	
10. Lymph Nodes	☐	☐	☐	
11. Heart/Cardiovascular	☐	☐	☐	
12. Lungs/Respiratory	☐	☐	☐	
13. Extremities	☐	☐	☐	
14. Neurological	☐	☐	☐	
15. Skin	☐	☐	☐	
16. Other	☐	☐	☐	

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

Comments:

Physical Exam (PX-1)	
Purpose:	This form is used to document the participant's vital signs and physical exam findings.
General Information/Instructions:	
	Complete this form at the Screening, Enrollment, and the 4-Week and 8-Week Visits and the 12-Week Final Clinic Visit. If abnormal findings are found, for items 7–16, transcribe the information onto the Pre-existing Conditions or Adverse Experience form(s).
Item-specific Instructions:	
Vital Signs:	Use leading zeros as applicable.
Item 1:	This item is required at Screening only.
Items 7–15:	For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings in Notes. If not evaluated, mark "not done" and record the reason in Notes. Normal findings may also be described in Notes, but is not required.
Item 16:	If no other abnormal findings are identified, mark "not done."

MTN-024/IPM 031 (203) PE-1 (138)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Pelvic Exam

Visit Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

1. Vaginal pH — *not done* ☐ ☐☐.☐ *If > 4.5, mark positive.* → *positive* ☐

2. Pelvic exam assessment: *not done* ☐ *abnormal findings* ☐ *no abnormal findings* ☐ → *If no abnormal findings, go to item 3.*
   → *If not done, end of form.*

2a. Abnormal findings. *Mark all that apply.*

VULVAR	VAGINAL	CERVICAL	GENERAL/OTHER
☐ vulvar edema	☐ vaginal edema	☐ cervical edema and/or friability	☐ odor *(vaginal)*
☐ vulvar erythema	☐ vaginal erythema	☐ cervical erythema	☐ condyloma, specify location: _____
☐ vulvar rash	☐ vaginal masses *(polyps, myomas, possible malignancy)*	☐ cervical masses *(polyps, myomas, possible malignancy)*	☐ adnexal masses *(based on bimanual exam; not pregnancy or infection-related)*
☐ vulvar tenderness	☐ vaginal abrasions or lacerations	☐ cervical motion tenderness	☐ uterine masses *(based on bimanual exam)*
☐ Bartholin's or Skene's gland abnormality	☐ vaginal tenderness	☐ cervical discharge	☐ uterine tenderness
Vulvar lesions	Abnormal vaginal discharge	Cervical lesions	☐ adnexal tenderness
☐ ulcer	☐ slight	☐ ulcer	☐ observed blood or bleeding; describe:
☐ blister	☐ moderate	☐ blister	_____
☐ pustule	☐ pooling	☐ pustule	_____
☐ peeling	Vaginal lesions	☐ peeling	_____
☐ ecchymosis	☐ ulcer	☐ ecchymosis	_____
	☐ blister		_____
	☐ pustule		
	☐ peeling		
	☐ ecchymosis		

☐ 2b. Other abnormal findings, specify (include anatomical location): _____

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

3. Were any new pelvic finding AEs reported at this visit? *yes* ☐ *no* ☐ → *If no, end of form.*

3a. AE Log page (#)s: ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

Pelvic Exam (PE-1)

Purpose:	This form is used to document the participant's pelvic exam assessment.
General Information/Instructions:	
	Complete this form at Screening, Enrollment, and the 4-Week and 8-Week visits, the 12-Week Final Clinic Visit, and early termination visit (as applicable), and when a clinically indicated pelvic exam is performed during interim visits. Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to DataFax.
Item-specific Instructions:	
Item 1:	Vaginal fluid pH is required at Enrollment Visit, 4-Week and 8-Week Visit and the 12-Week Final Clinic Visit.
Item 2:	Note that observation of any genital blood or bleeding is considered an abnormal finding, regardless of whether the blood is expected (menstrual blood, for example). If blood or bleeding is observed, mark "abnormal findings" and in item 2a, mark "observed blood or bleeding; describe" and describe on the lines provided.
Item 2a:	• Mark the box to the left of each abnormal finding observed. If an observed abnormal finding is not listed, mark "other abnormal findings, specify" and describe the abnormal finding on the line provided, including anatomical location. In general, for abnormal findings reported as adverse events on an AE Log, use text from item 2a as AE descriptive text finding (this does not apply to observances of blood or bleeding). • Observed blood or bleeding; describe: If blood or bleeding is observed, mark this item and in the space provided, briefly describe the color, amount, and location of the blood/bleeding. If known, specify if the blood was menstrual or non-menstrual. Assess the blood/bleeding for AE reporting purposes. Per Study-specific Procedures (SSP) manual section 7, all bleeding occurring during follow-up that is different from the participant's baseline bleeding pattern is an AE. This may include unusually heavy or prolonged menses, as well as non-menstrual bleeding different from baseline. • Each instance of observed blood/bleeding should be assessed for severity grade per the applicable rows of the *Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Addendum 1: Female Genital Grading Table for Use in Microbicide Studies (FGGT)*. Refer to SSP manual section 7 for more information/guidance as needed.

THIS IS NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.

MTN-024/IPM 031 (203)

Participant ID

Site Number – Participant Number – Chk

Pelvic Exam Diagrams

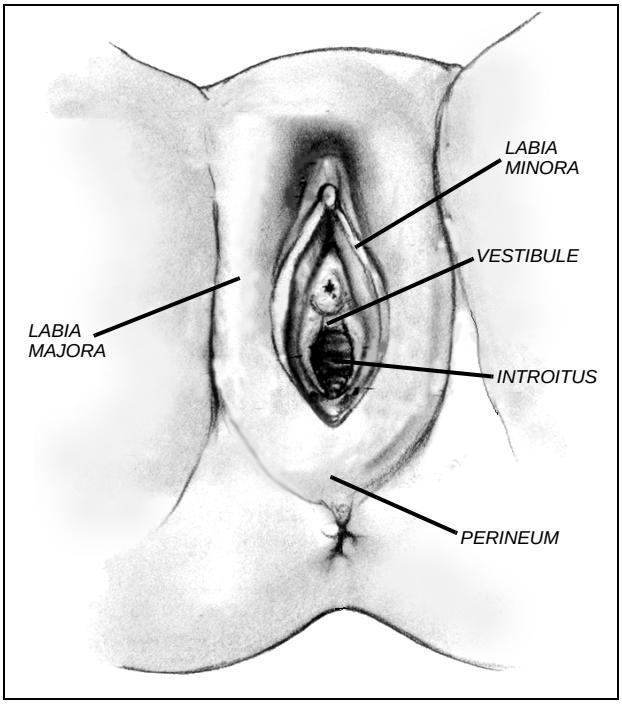
Exam Date: dd MMM yy

☐ no normal variants or abnormal findings observed

Speculum Type (screening only): *Pederson* ☐ *Graves* ☐ *Cusco* ☐

Speculum Size (screening only): *small* ☐ *medium* ☐ *large* ☐

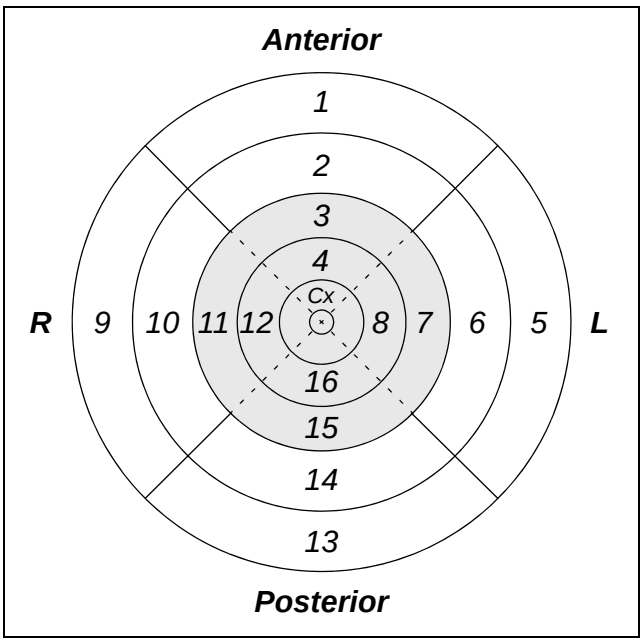
External Genitalia



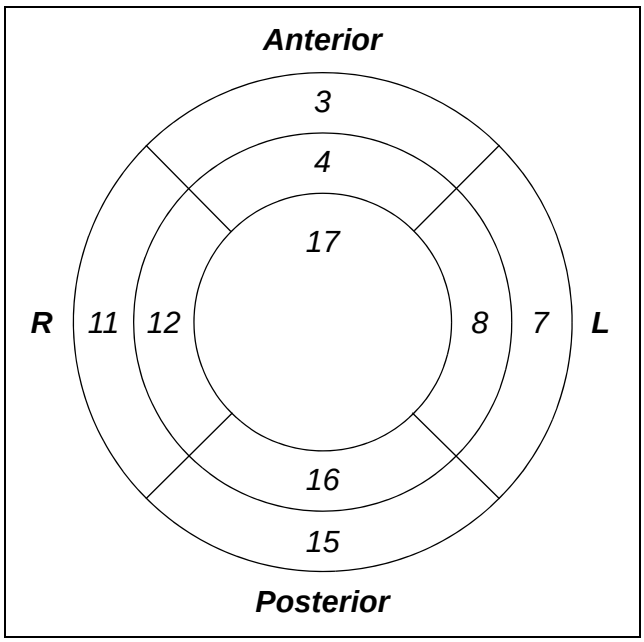
Legend for Vagina/Cervix

1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina, proximal half
11. Right lateral fornix
12. Cervical trunk, right lateral
13. Posterior vagina, distal half
14. Posterior vagina, proximal half
15. Posterior fornix
16. Cervical trunk, post
17. Cervical face

Vagina



Cervix



Pelvic Exam Diagrams (non-DataFax)

Purpose: This form is used to document all variants of normal and all abnormal findings observed during study pelvic exams (screening through termination/study exit).

General Information/Instructions:

This form is completed at the Screening Visit, the Enrollment Visit, the 4-Week and 8-Week Visits, the 12-Week Final Clinic Visit, and whenever a pelvic exam is clinically indicated during the study. This is a non-DataFax form and should not be faxed to SCHARP DataFax. Transcribe information onto the appropriate Pelvic Exam DataFax form for submission to DataFax and store this form in the participant's chart notes.

Item-specific Instructions:

Findings: All variants of normal (normal findings) and all abnormal findings must be documented on this form. Variants of normal need only be recorded on this form, and not on any of the Pelvic Exam DataFax forms. The following findings are considered normal variants:

- expected menstrual and non-menstrual bleeding
- anatomic variants
- gland openings
- Nabothian cysts
- mucus retention cysts
- Gartner's duct cysts
- blood vessel changes other than disruption
- skin tags
- scars
- cervical ectopy

If there are no variants of normal or abnormal findings observed mark the "no normal variants or abnormal findings observed" box.

Documenting findings on the cervix: If helpful, draw the os in the center of the diagram labeled "Cervix" (lower right corner).