Screening Visit
Visit 01.0

Required Forms

- Concomitant Medications Log (CM)
- Demographics (DEM)
- Eligibility Criteria (ECI)
- Pre-existing Conditions (PRE)
- Pregnancy and Lactation History (PLH)
- Pelvic Exam (PE)
- Pelvic Exam Diagrams (non-DataFax)
- Physical Exam (PX)
- Breast Exam (BE)
- Laboratory Results (LR)
- STI Test Results (STI)

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(MTN 029/IPM 039) DF/Net 015 (CM) 423

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

Page # ☐☐

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number *Participant Number* *Chk*

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

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

→ *End of form. Submit to DF/Net.*

Concomitant Medications Log

1

Medication Name

Staff Initials/ Log Entry Date

Indication

Taken for a reported AE?

☐ *yes* ☐ *no*

AE Log page #(s) ☐☐ ☐☐ ☐☐ ☐☐

Date Started ☐☐ ☐☐☐ ☐☐ *dd MMM yy*

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

Dose/Units

Frequency *Mark only one.*

prn ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify* ☐ _____

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*

AE Log page #(s) ☐☐ ☐☐ ☐☐ ☐☐

Date Started ☐☐ ☐☐☐ ☐☐ *dd MMM yy*

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

Dose/Units

Frequency *Mark only one.*

prn ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify* ☐ _____

Route *Mark only one.*

PO ☐ *IM* ☐ *IV* ☐ *TOP* ☐ *IHL* ☐ *VAG* ☐ *REC* ☐ *SC* ☐ *other, specify* ☐ _____

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, and naturopathic preparations.

General 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 DF/Net.
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 generic name of medication. For combination generic medications, record the first three main active ingredients, if applicable.
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: IM: intramuscular; TOP: topical; VAG: vaginal; SC: subcutaneous; alternative routes

(MTN 029/IPM 039) DF/Net 015 (DEM) 001

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number *Participant Number* *Chk*

Form Completion Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

Demographics

1	What is your date of birth?	dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ] OR *If unknown, record age:* [ ][ ] *years*
2	What was your sex at birth?	[ ] *male* [X] *female*
3	Do you consider yourself to be Latina or of Hispanic origin?	[ ] *yes* [ ] *no*
4	What is your race? *Mark all that apply.*	[ ] 4a. American Indian or Alaska Native [ ] 4b. Asian [ ] 4c. Black or African American [ ] 4d. Native Hawaiian or other Pacific Islander [ ] 4e. White [ ] 4f. Other, specify: _____

Purpose:

This form is interviewer-administered and is used to collect participant's demographic information.

General Instructions:

This form is faxed to DF/Net 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	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 4	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 4f.

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Participant ID

___ – ___ – ___

Site Number *Participant Number* *Chk*

Form Completion Date

__ __ *dd* ___ *MMM* __ __ *yy*

Eligibility Criteria

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?

☐ eligible, but participant did not complete all screening procedures → *End of form.*

☐ eligible, but participant declined enrollment → *End of form.*

☐ eligible, but accrual closed prior to enrollment → *End of form.*

☐ not eligible

4 Reason(s) for ineligibility: *Record all applicable codes (see back of form).*

☐ 4a. __ __

☐ 4b. __ __

☐ 4c. __ __

☐ 4d. __ __

☐ 4e. __ __

Comments:

_____

Staff Initials/Date

Purpose:

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

General 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 complete all screening procedures" when a participant begins the screening process and is eligible, but does not return to the clinic to complete screening procedures within the 56-day screening window.
Item 4	Select from the codes below and record a reason code for each reason why the participant was deemed ineligible for study participation. Refer to the Eligibility Checklist for the Screening and Enrollment Visit. If the reason for ineligibility is not listed, record the code "99" (other), and briefly describe the reason in the Comments section.

Reasons for Ineligibility Codes:

01	< 18 years old	**11**	Has significant or uncontrolled active or chronic disease, as defined in protocol
02	< 6 weeks postpartum at Enrollment	**12**	Diagnosed with UTI, STI, and/or RTI at Screening or Enrollment, which has not resolved or undergone complete treatment
03	HIV infected at Screening or Enrollment	**13**	Unwilling to refrain from use of vaginal products during study participation, as reported at Screening
04	Is still breastfeeding child at Enrollment	**14**	Has grade 2 or higher pelvic exam finding at Enrollment or incomplete postpartum involution of the uterus
05	Intends to provide expressed breast milk to her child(ren) or others for consumption after study product initiation	**15**	Unwilling to refrain from receptive sexual activity or insertion of non-study objects into vagina for 24 hours prior to each visit, as reported at Screening
06	Does not agree to use effective method of contraception during protocol-specified time period	**16**	Milk supply < 1 ounce per expression, at Screening and Enrollment
07	Unwilling/unable to express breast milk at least twice daily for the duration of study drug exposure	**17**	Use of oral and/or vaginal preparations of antibiotic or antifungal medications, or other vaginal medication(s), within 5 days prior to Enrollment
08	Unable/unwilling to provide written informed consent	**18**	Unwilling/unable to provide adequate locator information
09	Unwilling/unable to communicate in spoken and written English	**19**	No documented satisfactory Pap result, per protocol
10	Does not agree to refrain from participation in other research studies for the duration of study participation	**20**	Participated in investigational drug/device trial within 30 days prior to enrollment
99	Other, including investigator decision	**21**	Has Grade 2 or higher AST/ALT at Screening

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

Participant ID

Site Number – *Participant Number* – *Chk*

☐ No pre-existing conditions reported or observed.

Staff Initials/Date

→ *End of form. Submit to DF/Net.*

Pre-existing Conditions

1	Condition	Onset Date MMM yy	Staff Initials/Date
	Comments	Ongoing at Enrollment? *yes* ☐ *no* ☐	*Severity Grade* ☐ *OR not gradable* ☐
2	Condition	Onset Date MMM yy	Staff Initials/Date
	Comments	Ongoing at Enrollment? *yes* ☐ *no* ☐	*Severity Grade* ☐ *OR not gradable* ☐
3	Condition	Onset Date MMM yy	Staff Initials/Date
	Comments	Ongoing at Enrollment? *yes* ☐ *no* ☐	*Severity Grade* ☐ *OR not gradable* ☐
4	Condition	Onset Date MMM yy	Staff Initials/Date
	Comments	Ongoing at Enrollment? *yes* ☐ *no* ☐	*Severity Grade* ☐ *OR not gradable* ☐

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 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, rectal 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 ongoing at screening and/or that occur between screening and 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 DF/Net.
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.
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.
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* (Version 2.0), Addendum1: Female Genital Grading Table for Use in Microbicide Studies dated December 2004, and Addendum 3: Rectal Grading Table for Use in Microbicide Studies (Clarification dated May 2012) (as appropriate). If a condition is not gradable, mark "not gradable". Review and update as needed for conditions ongoing at the Enrollment Visit.

(MTN 029/IPM 039) DF/Net 015 (PLH) 041

Participant ID ___ – ___ – ___
Site Number *Participant Number* *Chk*

Visit Date ___ ___ ___
dd *MMM* *yy*

Pregnancy and Lactation History

1 Pregnancy History

1a. Number of full-term live births (≥ 37 weeks) ☐☐

1b. Number of premature live births (< 37 weeks) ☐☐

1c. Number of spontaneous fetal deaths and/or still births (≥ 20 weeks) ☐☐

1d. Number of spontaneous abortions (< 20 weeks) ☐☐

1e. Number of therapeutic/elective abortions ☐☐

1f. Number of ectopic pregnancies ☐☐

2 Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies before study enrollment? ☐ *yes* ☐ *no* → *If no, go to item 3.*

2a. If yes, specify: _____

_____

3 What was the duration of breastfeeding for each child?

	did not breastfeed	*< 6 months*	*6–12 months*	*> 12 months*	*N/A*
3a. First child:	☐	☐	☐	☐	
3b. Second child:	☐	☐	☐	☐	☐
3c. Third child:	☐	☐	☐	☐	☐
3d. Fourth child:	☐	☐	☐	☐	☐
3e. Fifth child:	☐	☐	☐	☐	☐
3f. Sixth child:	☐	☐	☐	☐	☐
3g. Seventh child:	☐	☐	☐	☐	☐
3h. Eighth child:	☐	☐	☐	☐	☐
3i. Ninth child:	☐	☐	☐	☐	☐
3j. Tenth child:	☐	☐	☐	☐	☐

_____
Staff Initials/Date

General Instructions:

Complete this form once for each participant at the Screening Visit.

Item-specific Instructions:

Item 3	Record the duration of breastfeeding for each child reported in items 1a and 1b. Mark “N/A” for the remaining items.

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Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐ (Site Number – Participant Number – Chk)

Visit Date ☐☐ ☐☐☐ ☐☐ (dd MMM yy)

Pelvic Exam

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, end of form.*

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)*	
☐ *Vulvar tenderness*	☐ *Vaginal abrasions or lacerations*	☐ *Cervical motion tenderness*	☐ *Adnexal masses (based on bimanual exam; not pregnancy or infection-related)*
☐ *Bartholin's or Skene's gland abnormality*	☐ *Vaginal tenderness*	☐ *Cervical discharge*	☐ *Uterine masses (based on bimanual exam)*
	☐ *Abnormal vaginal discharge* → *slight* ☐ *moderate* ☐ *pooling* ☐		☐ *Uterine tenderness*
			☐ *Adnexal tenderness*
Vulvar lesions	**Vaginal lesions**	**Cervical lesions**	☐ *Abnormal blood or bleeding, describe:* _____
☐ *Ulcer*	☐ *Ulcer*	☐ *Ulcer*	
☐ *Blister*	☐ *Blister*	☐ *Blister*	
☐ *Pustule*	☐ *Pustule*	☐ *Pustule*	
☐ *Peeling*	☐ *Peeling*	☐ *Peeling*	
☐ *Ecchymosis*	☐ *Ecchymosis*	☐ *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): ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

_____
Staff Initials/Date

Purpose:

This form is used to document the participant's pelvic exam assessment.

General Instructions:

Transcribe information from the **Pelvic Exam Diagrams** form (non-DataFax) onto this form for submission to DF/Net.

Item-specific Instructions:

Item 2	Note that observation of any unexpected genital blood or bleeding is considered an abnormal finding. If unexpected blood or bleeding is observed, mark "Abnormal findings" and in item 2a, mark "Abnormal 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 the AE descriptive text (this does not apply to observances of blood or bleeding). • **Abnormal blood or bleeding, describe:** If unexpected 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. • Each instance of unexpected 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 the Study-specific Procedures (SSP) manual for more information/guidance as needed.

(MTN 029/IPM 039) DF/Net 015

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

Participant ID

			–					–	

Site Number *Participant Number* *Chk*

Exam Date

dd *MMM* *yy*

☐ no normal variants or abnormal findings observed

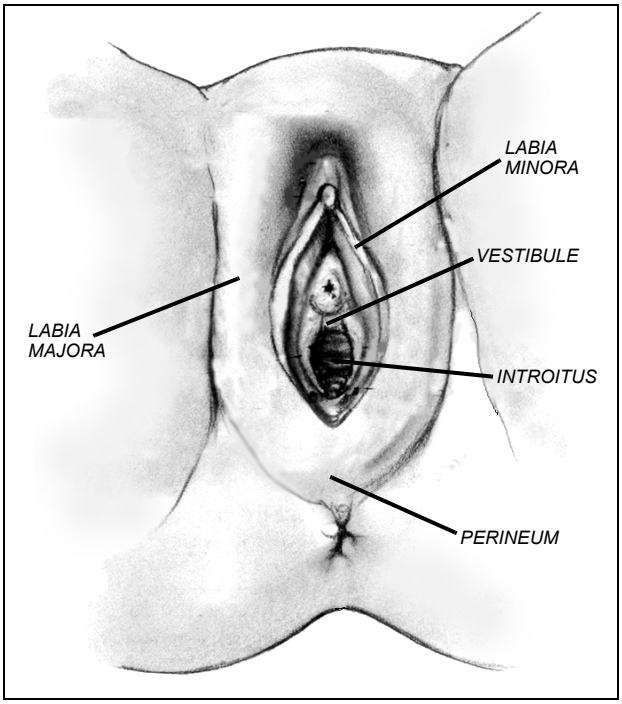
Speculum Type (screening only)

Pederson ☐ *Graves* ☐ *Cusco* ☐

Speculum Size (screening only)

small ☐ *medium* ☐ *large* ☐

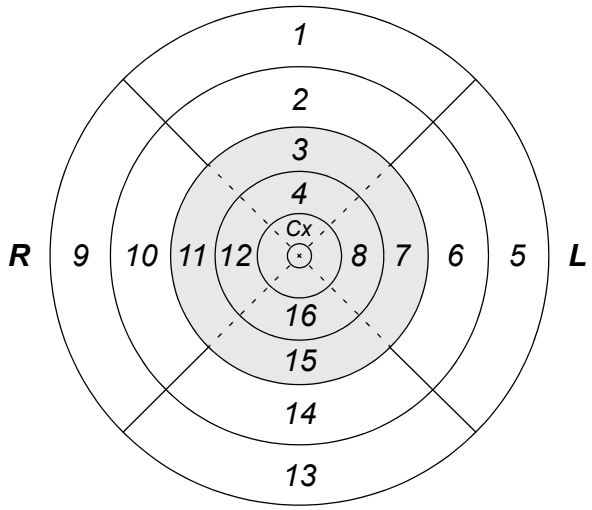
External Genitalia



Legend for Vagina/Cervix

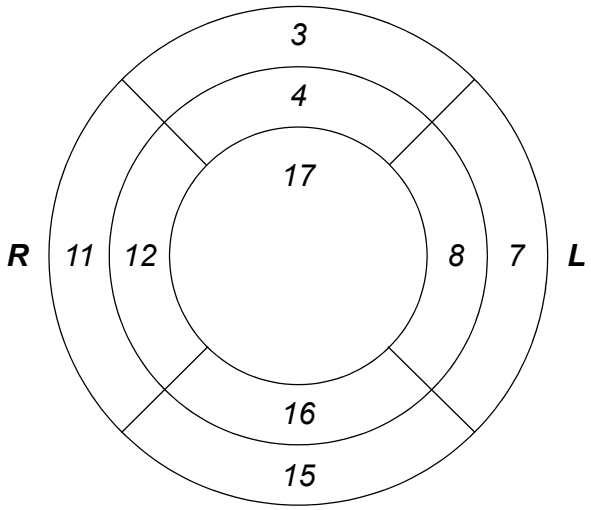
1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina, 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: Anterior



Posterior

Cervix: Anterior



Posterior

Version 2.0, 22-APR-16

Staff Initials/Date

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 Instructions:

This form is completed at every scheduled study visit, from Screening through Day 16 (or an Early Termination Visit, if applicable), and whenever a pelvic exam is clinically indicated during the study. This is a non-DataFax form and should not be faxed to DF/Net 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).

(MTN 029/IPM 039) DF/Net 015 (PX) 036

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐ (*Site Number – Participant Number – Chk*)

Visit Date ☐☐ ☐☐☐ ☐☐ (*dd MMM yy*)

Physical Exam

Vital Signs — *Vital Signs: Initials/Date:* _____

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

FINDINGS: *Items 8–18 may be omitted from assessment after the Screening Visit.*

		not done	*normal*	*abnormal*	*Notes:*
7	General appearance	☐	☐	☐	
8	Abdomen/Gastrointestinal	☐	☐	☐	
9	Head, eye, ear, nose, and throat	☐	☐	☐	
10	Oral mucosa	☐	☐	☐	
11	Neck	☐	☐	☐	
12	Lymph Nodes	☐	☐	☐	
13	Heart/Cardiovascular	☐	☐	☐	
14	Lungs/Respiratory	☐	☐	☐	
15	Extremities	☐	☐	☐	
16	Neurological	☐	☐	☐	
17	Skin	☐	☐	☐	
18	Other _____	☐	☐	☐	

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

Comments:

_____
Staff Initials/Date

Purpose:

This form is used to document the participant's vital signs and physical exam findings.

General Instructions:

If abnormal findings are found, for items 7–18, transcribe the information onto the **Pre-existing Conditions** or **Adverse Experience Log** form(s).

Item-specific Instructions:

Vital Signs	Use leading zeros as applicable.
Item 1	This item is required at Screening only.
Items 7–17	For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings in Notes. If the evaluation was required, but not done, mark "not done" and record the reason in the Notes. Normal findings may also be described in Notes, but it is not required.
Item 18	If no other abnormal findings are identified, mark "not done."

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Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐

Site Number *Participant Number* *Chk*

Visit Date ☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Breast Exam

		Yes	*No*	*Description*
1	Is the skin intact?	☐	☐	
2	Was erythema present?	☐	☐	
3	Any tenderness to palpation?	☐	☐	
4	Swelling?	☐	☐	
5	Induration?	☐	☐	
6	Mass(es)?	☐	☐	
7	Nipple discharge?	☐	☐	
8	Other finding(s)?	☐	☐	

Specify: _____

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

Comments:

_____
Staff Initials/Date

Purpose:

This form is used to document the participant's breast exam findings.

General Instructions:

Complete this form at the Screening, Enrollment, and Day 16 Visits, and if indicated. If abnormal findings are found, transcribe the information onto the **Pre-existing Conditions** or **Adverse Experience** form(s), as applicable.

Item-specific Instructions:

Items 1-7	Describe abnormal findings in the Description. Normal findings may also be noted in the Description, but it is not required.
Description	If an abnormal finding is noted, please specify which breast had the abnormal finding.

(MTN 029/IPM 039) DF/Net 015 (LR) 144

Visit Code ☐☐.☐

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Site Number – Participant Number – Chk)

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

Laboratory Results

1	hCG FOR PREGNANCY	*Not done/ Not collected* ☐	*negative* ☐	*positive* ☐ →	*not required* ☐		*If newly positive, complete Clinical Product Hold/ Discontinuation Log and Pregnancy Report form.*
2	HIV	*Not done/ Not collected* ☐	*negative* ☐	*positive* ☐	*indeterminate* ☐ →		*If positive at Screening participant is ineligible. If positive during follow-up, complete HIV Confirmatory Results form and Clinical Product Hold/Discontinuation Log. If indeterminate, consult Network Lab.*
3	DIPSTICK URINALYSIS TESTS	*Not done/ Not collected* ☐ →	*Go to item 4.*	Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐			
	3a. Leukocyte esterase (LE)	*Not done* ☐	*negative* ☐	*1+* ☐	*2+* ☐	*3+* ☐	
	3b. Nitrites	*Not done* ☐	*negative* ☐	*positive* ☐			
	3c. Protein	*Not done* ☐	*negative* ☐	*trace* ☐	*1+* ☐ *2+* ☐ *3+* ☐ *4+* ☐	Severity Grade *If applicable* ☐	AE Log Page # ☐☐ Not reportable as an AE OR ☐
	3d. Glucose	*Not done* ☐	*negative* ☐	*trace* ☐	*1+* ☐ *2+* ☐ *3+* ☐ *4+* ☐	☐	☐☐ OR ☐
	3e. Culture	*Not done* ☐	*negative* ☐	*positive* ☐ →	*Complete Adverse Experience Log when applicable.*		
4	SERUM CHEMISTRIES	*Not done/ Not collected* ☐ →	*End of form.*	Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐			
	4a. AST (SGOT)	*Not done* ☐	☐☐☐☐ *U/L*	Severity Grade *If applicable* ☐	AE Log Page # ☐☐	Not reportable as an AE OR ☐	
	4b. ALT (SGPT)	*Not done* ☐	☐☐☐☐ *U/L*	☐	☐☐	OR ☐	

Comments:

Staff Initials/Date _____

Purpose:

This form is used to provide data on the participant's baseline and follow-up laboratory test results.

General Instructions:

Use this form to report the hCG for pregnancy, HIV serology, and liver and renal function test results as they become available. Do not fax the form to DF/Net until all results are available and the participant has enrolled in the study.

Item-specific Instructions:

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 LR 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-029 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/mL • 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 or Adverse Experience Log, as applicable.

(MTN 029/IPM 039) DF/Net 015 (STI) 190

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐ (Site Number – Participant Number – Chk)

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

STI Test Results

1 VAGINAL WET PREP STUDIES

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

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

	Not done	*negative*	*positive*	
1a. Homogenous vaginal discharge	☐	☐	☐	*Only required if assessment for BV performed.*
1b. Whiff test	☐	☐	☐	*Only required if assessment for BV performed.*
1c. Clue cells ≥ 20%	☐	☐	☐	*Only required if assessment for BV performed.*
1d. Trichomonas vaginalis	☐	☐	☐	
1e. Buds and/or hyphae (yeast)	☐	☐	☐	

2 STI SEROLOGY

Not done/ Not collected ☐ → *Go to item 3.*

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

2a. Syphilis screening test: ☐ *Non-reactive* ☐ *Reactive* → *If non-reactive, go to item 3.*

2a1. Syphilis titer: **1:** ☐☐☐☐

Not done/ Not collected ☐

2b. Syphilis confirmatory test: Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐ — *negative* ☐ *positive* ☐ *indeterminate* ☐

		Not done/ Not collected	Alternate Collection Date dd MMM yy	*negative*	*positive*
3	Trichomonas rapid test	☐	☐☐ ☐☐☐ ☐☐	☐	☐
4	Cervical *N. gonorrhea*:	☐	☐☐ ☐☐☐ ☐☐	☐	☐
5	Cervical *C. trachomatis*:	☐	☐☐ ☐☐☐ ☐☐	☐	☐
6	Urine *N. gonorrhea*:	☐	☐☐ ☐☐☐ ☐☐	☐	☐
7	Urine *C. trachomatis*:	☐	☐☐ ☐☐☐ ☐☐	☐	☐
8	HSV-1-swab:	☐	☐☐ ☐☐☐ ☐☐	☐	☐
9	HSV-2-swab:	☐	☐☐ ☐☐☐ ☐☐	☐	☐

Staff Initials/Date _____

Purpose: This form is used to document the results of vaginal wet prep and STI tests performed by the local site laboratory.

General Instructions:

Complete this form at the Screening Visit and at other visits where these tests are performed during follow-up.

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. A complete date is required.
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	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.
Items 1–9	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 Log** (AE).
Item 1	If a vaginal wet prep was performed but not all assays were completed, mark “Not done” 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.