

Day 1

Visit 03.0

Required Forms

- Follow-up Visit Summary (FVS)
- Pelvic Exam (PE)
- Pelvic Exam Diagrams (non-DataFax)
- Ring Insertion and Removal (RIR)
- Follow-up PK/PD (FPK)
- Vaginal Specimen Storage (SS)
- Sexual Practices Assessment (SPA)
- Vaginal Practices (VP)

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(MTN 029/IPM 039) DF/Net 015

(FVS) 121

Visit Code .

Participant ID

- -
Site Number Participant Number Chk

Visit Date

/ /
dd MMM yy

Follow-up Visit Summary

1 Were any **new** Adverse Experience Logs completed for this visit? *yes* *no*

2 Were any **new** Clinical Product Hold/Discontinuation Logs completed for this visit? *yes* *no*

3 Is this an interim visit? *yes* *no* —————> *If no, end of form.*

3a. Reason for interim visit *Mark all that apply.*

<i>AE report or follow-up</i>	<i>return of ring or need new ring</i>	<i>other, specify: _____</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3b. Which forms, besides this form and the log forms (in items 1 and 2), were newly completed for this interim visit?
Mark "None" or all that apply.

- | | |
|---|--|
| <input type="checkbox"/> None | <input type="checkbox"/> STI Test Results |
| <input type="checkbox"/> Ring Insertion and Removal | <input type="checkbox"/> Laboratory Results |
| <input type="checkbox"/> Follow-up PK/PD | <input type="checkbox"/> Pelvic Exam |
| <input type="checkbox"/> Sexual Practices Assessment | <input type="checkbox"/> Breast Exam |
| <input type="checkbox"/> Vaginal Specimen Storage | <input type="checkbox"/> Physical Exam |
| <input type="checkbox"/> Participant Ring Use Log | <input type="checkbox"/> Other, specify: _____ |
| <input type="checkbox"/> At-home Breast Milk Sampling Log | _____ |

Comments:

Purpose:

This form is used to summarize information from each participant follow-up study visit (including interim visits).

General Instructions:

This form is completed for each scheduled visit. This form is also completed for interim visits/contacts where a new form (other than the Follow-up Visit Summary) is completed. Note that there is no Interim Visit form for this study—instead, this form is completed to document interim visits.

Item-specific Instructions:

Visit Code	<ul style="list-style-type: none"> Record the visit code assigned to the visit. For required visits, the Visit Code will end in 0 (XX.0). If the visit is an interim visit/contact, use an interim code for the Visit Code. Start with the Visit Code of the last required visit and add “1” to the right of the decimal point for each interim visit conducted. If procedures for a required visit are split over 2 or more days, and all days are within the same visit window, assign all forms completed for the split visit the same Visit Code (ending in .0). For more information on visit code assignments, please refer to Section 12 of the SSP manual.
Item 1	Mark “yes” if at least one Adverse Experience Log (AE) was newly completed for this visit (Visit Code in item 3 of the AE Log is the same as the Visit Code recorded on this form).
Item 2	Mark “yes” if at least one Clinical Product Hold/Discontinuation Log (PH) was newly completed for this visit (Visit Code in item 1 of the PH Log is the same as the Visit Code recorded on this form).
Item 3b	Mark the newly completed forms (in addition to this form and the log forms in items 1–2) that are being submitted for the interim visit/contact. If “other, specify” is marked, record the form acronyms in the space provided.



(MTN 029/IPM 039) DF/Net 015

(PE) 138

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
<input type="checkbox"/> Vulvar edema <input type="checkbox"/> Vulvar erythema <input type="checkbox"/> Vulvar rash <input type="checkbox"/> Vulvar tenderness <input type="checkbox"/> Bartholin's or Skene's gland abnormality Vulvar lesions <input type="checkbox"/> Ulcer <input type="checkbox"/> Blister <input type="checkbox"/> Pustule <input type="checkbox"/> Peeling <input type="checkbox"/> Ecchymosis	<input type="checkbox"/> Vaginal edema <input type="checkbox"/> Vaginal erythema <input type="checkbox"/> Vaginal masses (polyps, myomas, possible malignancy) <input type="checkbox"/> Vaginal abrasions or lacerations <input type="checkbox"/> Vaginal tenderness <input type="checkbox"/> Abnormal vaginal discharge slight moderate pooling → <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Vaginal lesions <input type="checkbox"/> Ulcer <input type="checkbox"/> Blister <input type="checkbox"/> Pustule <input type="checkbox"/> Peeling <input type="checkbox"/> Ecchymosis	<input type="checkbox"/> Cervical edema and/or friability <input type="checkbox"/> Cervical erythema <input type="checkbox"/> Cervical masses (polyps, myomas, possible malignancy) <input type="checkbox"/> Cervical motion tenderness <input type="checkbox"/> Cervical discharge Cervical lesions <input type="checkbox"/> Ulcer <input type="checkbox"/> Blister <input type="checkbox"/> Pustule <input type="checkbox"/> Peeling <input type="checkbox"/> Ecchymosis	<input type="checkbox"/> Odor (vaginal) <input type="checkbox"/> Condyloma, specify location: _____ <input type="checkbox"/> Adnexal masses (based on bimanual exam; not pregnancy or infection-related) <input type="checkbox"/> Uterine masses (based on bimanual exam) <input type="checkbox"/> Uterine tenderness <input type="checkbox"/> Adnexal tenderness <input type="checkbox"/> Abnormal blood or bleeding, describe: _____ _____ _____

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):

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	<ul style="list-style-type: none"> • 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 <i>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)</i>. 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

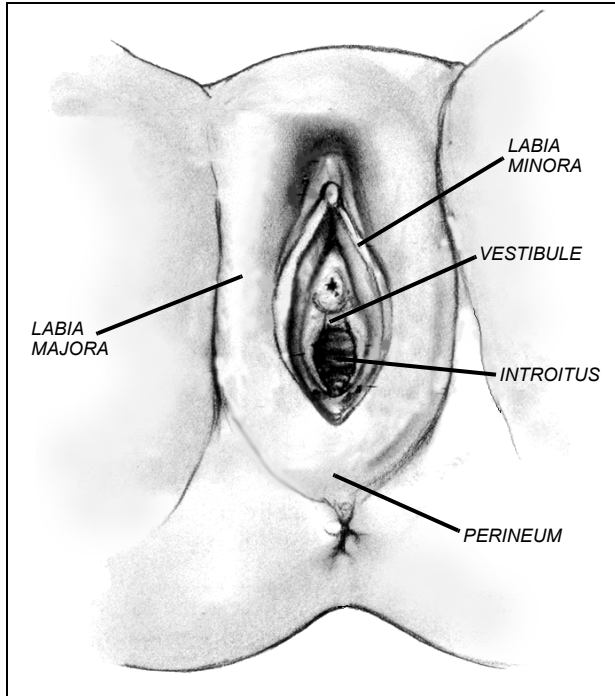
Speculum Type (screening only)

Pederson Graves Cusco

Speculum Size (screening only)

small medium large

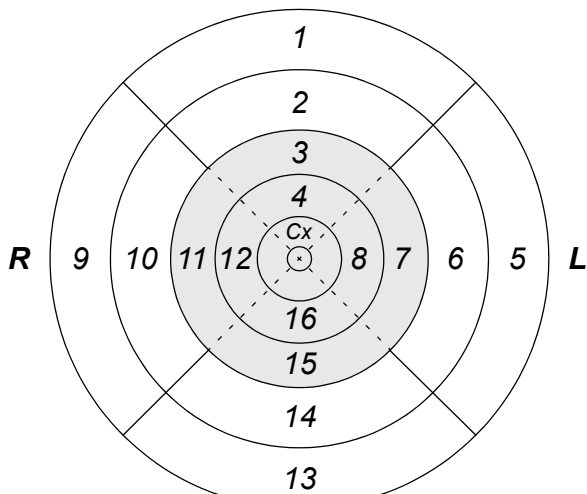
External Genitalia



Legend for Vagina/Cervix

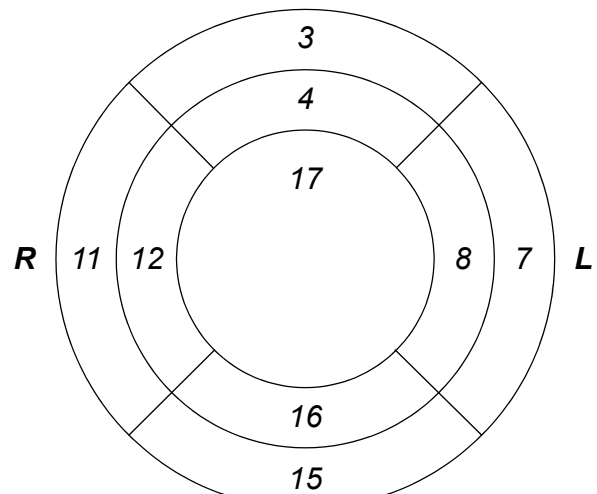
1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina,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

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	<p>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:</p> <ul style="list-style-type: none"> • 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 <p>If there are no variants of normal or abnormal findings observed mark the "no normal variants or abnormal findings observed" box.</p>
Documenting findings on the cervix:	<p>If helpful, draw the os in the center of the diagram labeled "Cervix" (lower right corner).</p>



(MTN 029/IPM 039) DF/Net 015

(RIR) 135

Visit Code .

Participant ID

- -
Site Number Participant Number Chk

Visit Date

dd MMM yy

Ring Insertion and Removal

1	Did the participant have a ring in place at the start of the visit? <input type="checkbox"/> Yes <input type="checkbox"/> No —————▶ <i>If no, go to item 4.</i>
2	Was the ring removed at this visit? <input type="checkbox"/> Yes <input type="checkbox"/> No —————▶ <i>If no, end of form.</i>
	2a. Time ring was removed: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> (24-hour clock) <i>hh mm</i>
	2b. Who removed the ring? <input type="checkbox"/> Participant <input type="checkbox"/> Study staff
3	Reason ring was removed: <input type="checkbox"/> <i>participant on clinical hold</i> <input type="checkbox"/> <i>participant has been permanently discontinued from product use</i> <input type="checkbox"/> <i>participant declined study ring use, specify: _____</i> <input type="checkbox"/> <i>early termination</i> <input type="checkbox"/> <i>Day 14 Visit</i> <input type="checkbox"/> <i>other, specify: _____</i>
4	Was a ring inserted at this visit? <input type="checkbox"/> Yes—new ring inserted <input type="checkbox"/> Yes—previous ring re-inserted <input type="checkbox"/> No —————▶ <i>If no, end of form.</i>
	4a. Time ring was inserted: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> (24-hour clock) <i>hh mm</i>
	4b. Who inserted the ring? <input type="checkbox"/> Participant <input type="checkbox"/> Study staff

Comments:

Purpose:

This form is used to document participant ring use, as observed at the Day 1, 7 and 14 Visits, as well as any ring insertions or removals that occur during follow-up visits (regularly scheduled or interim).

General Instructions:

This form is completed at the Day 1, Day 7, and Day 14 Visits, as well as any other follow-up visit (regularly scheduled or interim) when a ring is inserted or removed during a visit.

Item-specific Instructions:

Item 3	If the participant declined study ring use due to or associated with an adverse event, document the adverse event on an Adverse Experience Log (AE) and note in the AE Log comments that the participant declined the ring because of the AE.
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Purpose:

This form is used to document collection and timing of collection of pharmacokinetic (PK) and pharmacodynamic (PD) laboratory specimens.

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). 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 collected	Mark this box in the event that a specimen was not collected. If collection of a specimen was required but not done, record the item number and reason in the Comments section.
Stored/ Not stored	Mark "stored" for specimens that are collected and sent to the lab for processing. If specimens are collected but not stored, mark "not stored" and record the reason why on the line provided.



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(SS) 149

Visit Code .

Participant ID

- -
 Site Number Participant Number Chk

Initial Specimen Collection Date

dd MMM yy

Vaginal Specimen Storage

1	Vaginal smear for gram stain Not collected <input type="checkbox"/> Alternate Collection date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy stored <input type="checkbox"/> not stored <input type="checkbox"/> Reason not stored: _____
2	Quantitative vaginal culture Not collected <input type="checkbox"/> Alternate Collection date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy Collection time 24-hr clock <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> hr min stored <input type="checkbox"/> not stored <input type="checkbox"/> Reason not stored: _____
3	Vaginal swab for biomarkers Not collected <input type="checkbox"/> Alternate Collection date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy Collection time 24-hr clock <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> hr min stored <input type="checkbox"/> not stored <input type="checkbox"/> Reason not stored: _____ 3a. Was blood visible on the swab? <input type="checkbox"/> yes <input type="checkbox"/> no
4	Used vaginal ring Not collected <input type="checkbox"/> Alternate Collection date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy stored <input type="checkbox"/> not stored <input type="checkbox"/> Reason not stored: _____

Comments:

Purpose:

This form is used to document collection and storage of vaginal specimens by the local site laboratory.

General Instructions:

Complete this form at Enrollment and all scheduled follow-up visits.

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.
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. A complete date is required.
Not collected	Mark "Not collected" in the event that a specimen was not collected. If collection of a specimen was required but not done, record the item number and reason in the Comments section.
Stored/ Not Stored	Mark "stored" for specimens that are collected and sent to the lab for processing. If specimens are collected but not stored by the lab, mark "not stored" and record the reason why on the line provided.



(MTN 029/IPM 039) DF/Net 015

(SPA) 175

Visit Code .

Participant ID

- -

Site Number

Participant Number

Chk

Visit Date

dd

MMM

yy

Sexual Practices Assessment

1 Have you had vaginal sex within the past 24 hours? *yes* *no*

Comments:

Purpose:

This form is used to document whether a participant had vaginal sex in the 24 hours prior to Enrollment and all scheduled follow-up visits.

General Instructions:

This is an interviewer-administered form.



(MTN 029/IPM 039) DF/Net 015

(VP) 185

Visit Code .

Participant ID

- -
 Site Number Participant Number Chk

Visit Date

/ /
 dd MMM yy

Vaginal Practices

Please tell me about things that you have put in your vagina since your last study visit. These are things other than normal washing of the external vagina. Even though we ask participants not to put certain things in the vagina while they are in the study, and within 24 hours of a study visit, we know that this is not possible for all women. For example, things may be inserted inside the vagina to prepare for sex, to clean inside the vagina before or after sex, to manage vaginal bleeding/spotting, or to treat or heal the vagina. Please feel free to answer openly. I'll read a list and ask you to tell me what you used.

1 Since your last study visit, have you put any of the following inside your vagina?

	yes	no		yes	no
1a. water only	<input type="checkbox"/>	<input type="checkbox"/>	1g. vaginal barriers, such as female condoms, diaphragms, or cervical caps	<input type="checkbox"/>	<input type="checkbox"/>
1b. water plus soap	<input type="checkbox"/>	<input type="checkbox"/>	1h. douche, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>
1c. materials such as paper, cloth, or cotton wool	<input type="checkbox"/>	<input type="checkbox"/>	1i. spermicide	<input type="checkbox"/>	<input type="checkbox"/>
1d. fingers to clean or insert something	<input type="checkbox"/>	<input type="checkbox"/>	1j. lubricant, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>
1e. tampons	<input type="checkbox"/>	<input type="checkbox"/>	1k. anything else? _____	<input type="checkbox"/>	<input type="checkbox"/>
1f. sex toys	<input type="checkbox"/>	<input type="checkbox"/>			

If "no" to all, end of form.

2 In the past 24 hours, what have you put inside your vagina?

	yes	no		yes	no
2a. water only	<input type="checkbox"/>	<input type="checkbox"/>	2g. vaginal barriers, such as female condoms, diaphragms, or cervical caps	<input type="checkbox"/>	<input type="checkbox"/>
2b. water plus soap	<input type="checkbox"/>	<input type="checkbox"/>	2h. douche, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>
2c. materials such as paper, cloth, or cotton wool	<input type="checkbox"/>	<input type="checkbox"/>	2i. spermicide	<input type="checkbox"/>	<input type="checkbox"/>
2d. fingers to clean or insert something	<input type="checkbox"/>	<input type="checkbox"/>	2j. lubricant, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>
2e. tampons	<input type="checkbox"/>	<input type="checkbox"/>	2k. anything else?	<input type="checkbox"/>	<input type="checkbox"/>
2f. sex toys	<input type="checkbox"/>	<input type="checkbox"/>	Specify: _____		

Purpose:

This form is used to document a participant's vaginal practices during the study.

General Instructions:

This form is completed at the Enrollment Visit, and at each scheduled study follow-up visit. It is an interviewer-administered form. Read each item aloud and record the participant's response.