

Enrollment Visit Visit 02.0

Required Forms

- Enrollment (ENR)
- Baseline Menstrual History (BMH)
- Pelvic Exam (PE)
- Pelvic Exam Diagrams (non-DataFax)
- Physical Exam (PX)
- Breast Exam (BE)
- Enrollment PK/PD (EPK)
- Laboratory Results (LR)
- Vaginal Specimen Storage (SS)
- Sexual Practices Assessment (SPA)
- Vaginal Practices (VP)

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(MTN 029/IPM 039) DF/Net 015

(ENR) 070

Participant ID

<i>Site Number</i>				<i>Participant Number</i>					<i>Chk</i>

Enrollment

1 Date the participant marked or signed the consent form for study participation:

<i>dd</i>		<i>MMM</i>			<i>yy</i>	

2 Did the participant consent to long-term specimen storage and future testing?

Yes *No*

3 Plasma for archive:

Collection date	<i>stored</i>	<i>not stored</i>	<i>Reason not stored:</i>												
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<i>dd</i>		<i>MMM</i>			<i>yy</i>										

4 Enrollment date and time:

<i>dd</i>			<i>MMM</i>			<i>yy</i>		<i>hr</i>	:	<i>min</i>		<i>24-hr clock</i>

5 Date and time vaginal ring inserted:

<i>dd</i>			<i>MMM</i>			<i>yy</i>		<i>hr</i>	:	<i>min</i>		<i>24-hr clock</i>

Comments:

Purpose:

This form is used to document a participant's study enrollment. This form is completed at the Enrollment Visit.

General Instructions:

Fax this form to DF/Net only if the participant enrolls in the study.

Item-specific Instructions:

Item 2	Consent for long-term specimen storage can be changed if the participant changes her consent decision after enrollment. Update as needed if the participant changes his or her consent during the study.
Item 3	If the specimen for some reason is not stored, mark "not stored" and record the reason on the line provided.
Item 4	Record the date and time that the participant enrolled in the study. In MTN-029, a participant is considered enrolled in the study after completion of the non-DataFax Eligibility Checklist AND final sign-off of items 1a and 1b on the Eligibility Criteria CRF. Refer to the Study-specific Procedures Manual (SSP) for further guidance.

Purpose:

This form is used to document information on the participant's menstrual history at baseline.

General Instructions:

This form is completed at the Enrollment Visit. It is submitted to DF/Net only if the participant enrolls in the study.

Item-specific Instructions:

Item 2	Record the first day of the participant's most recent menstrual period. If the participant is unable to recall the complete date, obtain her best estimate. At a minimum, the month and year are required.
Item 3	If the participant is unable to recall the complete date, obtain her best estimate. At a minimum, the month and year are required. If the participant is currently on her menses, mark "ongoing." In these cases, this item does not need to be updated with a stop date once known at a later visit.
Item 4	During follow-up, occurrences of genital bleeding will be compared to the participant's baseline bleeding pattern (as documented on this form) in order to determine if the episode requires reporting as an AE. With this in mind, use this space to describe as best possible the participant's usual genital bleeding pattern. Include details such as number of sanitary pads typically used, any spotting that is experienced, and any additional details on amount/heaviness of flow.



(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

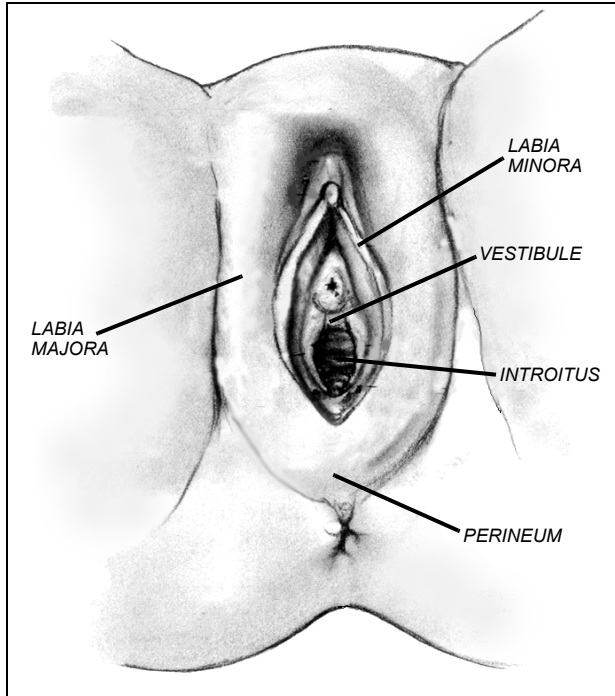
Speculum Type (screening only)

Pederson Graves Cusco

Speculum Size (screening only)

small medium large

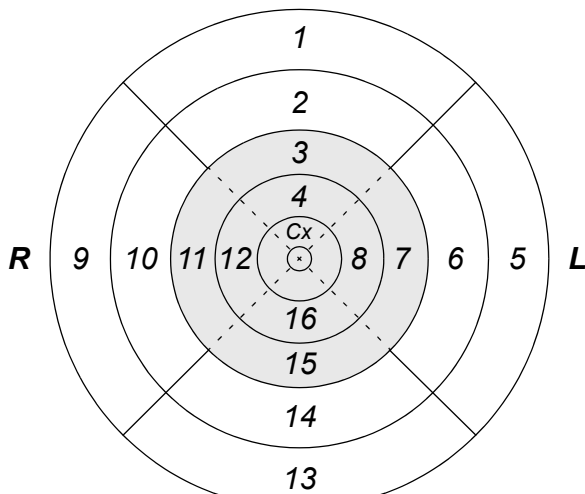
External Genitalia



Legend for Vagina/Cervix

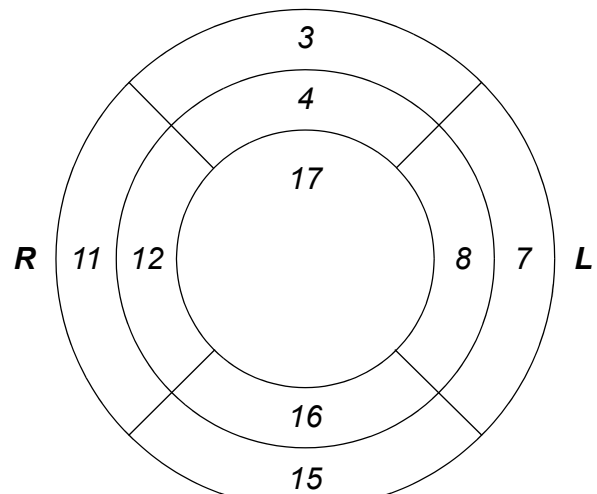
1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina,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

(PX) 036

Visit Code .

Participant ID <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> </tr> <tr> <td colspan="3" style="text-align: center;"><i>Site Number</i></td> <td colspan="6" style="text-align: center;"><i>Participant Number</i></td> <td colspan="3" style="text-align: center;"><i>Chk</i></td> </tr> </table>													<i>Site Number</i>			<i>Participant Number</i>						<i>Chk</i>			Visit Date <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> </tr> <tr> <td colspan="2" style="text-align: center;"><i>dd</i></td> <td colspan="2" style="text-align: center;"><i>MMM</i></td> <td colspan="2" style="text-align: center;"><i>yy</i></td> </tr> </table>							<i>dd</i>		<i>MMM</i>		<i>yy</i>	
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<i>dd</i>		<i>MMM</i>		<i>yy</i>																																	

Physical Exam

Vital Signs		Vital Signs: Initials/Date: _____	
1	Height: <i>not required</i> <input type="checkbox"/> <i>OR</i> <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/> <i>cm</i>	4	Blood Pressure: <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/> / <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/> <i>mmHg</i>
2	Weight: <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/> <i>kg</i>	5	Pulse: <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/> <i>beats per minute</i>
3	Body Temp: <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/> . <input style="width: 40px;" type="text"/> <i>°C</i>	6	Respirations: <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/> <i>breaths per minute</i>

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

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

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

Comments:

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."



(MTN 029/IPM 039) DF/Net 015

(BE) 140

Visit Code .

Participant ID

- -
 Site Number Participant Number Chk

Visit Date

/ /
 dd MMM yy

Breast Exam

		Yes	No	Description
1	Is the skin intact?	<input type="checkbox"/>	<input type="checkbox"/>	_____
2	Was erythema present?	<input type="checkbox"/>	<input type="checkbox"/>	_____
3	Any tenderness to palpation?	<input type="checkbox"/>	<input type="checkbox"/>	_____
4	Swelling?	<input type="checkbox"/>	<input type="checkbox"/>	_____
5	Induration?	<input type="checkbox"/>	<input type="checkbox"/>	_____
6	Mass(es)?	<input type="checkbox"/>	<input type="checkbox"/>	_____
7	Nipple discharge?	<input type="checkbox"/>	<input type="checkbox"/>	_____
8	Other finding(s)?	<input type="checkbox"/>	<input type="checkbox"/>	Specify: _____

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

Comments:

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

(EPK) 061

Participant ID <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center; font-size: small;">Site Number</td> <td colspan="6" style="text-align: center; font-size: small;">Participant Number</td> <td style="text-align: center; font-size: small;">Chk</td> <td colspan="4"></td> </tr> </table>												Site Number	Participant Number						Chk					Specimen Collection Date <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center; font-size: small;">dd</td> <td colspan="2" style="text-align: center; font-size: small;">MMM</td> <td colspan="3" style="text-align: center; font-size: small;">yy</td> </tr> </table>							dd	MMM		yy		
Site Number	Participant Number						Chk																													
dd	MMM		yy																																	

Enrollment PK/PD

Pre-insertion Specimens

		24-hour clock <i>hr min</i>	<i>not collected</i>	<i>stored</i>	<i>not stored</i>	<i>If not stored, specify:</i>
1	Pre-insertion blood draw	□□ : □□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2	Pre-insertion breast milk for PK and lipids	□□ : □□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>If not stored, specify:</i>
3	Pre-insertion breast milk for PD	□□ : □□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>If not stored, specify:</i>
4	Pre-insertion CVF swab	□□ : □□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>If not stored, specify:</i>

3-hour Post-insertion Specimens

		24-hour clock <i>hr min</i>	<i>not collected</i>	<i>stored</i>	<i>not stored</i>	<i>If not stored, specify:</i>
5	3-hour post-insertion blood draw	□□ : □□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6	3-hour post-insertion breast milk for PK and lipids	□□ : □□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>If not stored, specify:</i>
7	3-hour post-insertion breast milk for PD	□□ : □□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>If not stored, specify:</i>
8	3-hour post-insertion CVF swab	□□ : □□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>If not stored, specify:</i>

6-hour Post-insertion Specimens

		24-hour clock <i>hr min</i>	<i>not collected</i>	<i>stored</i>	<i>not stored</i>	<i>If not stored, specify:</i>
9	6-hour post-insertion blood draw	□□ : □□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10	6-hour post-insertion breast milk for PK and lipids	□□ : □□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>If not stored, specify:</i>
11	6-hour post-insertion breast milk for PD	□□ : □□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>If not stored, specify:</i>
12	6-hour post-insertion CVF swab	□□ : □□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>If not stored, specify:</i>

Comments:

Purpose:

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

General Instructions:

Complete this form at Enrollment.

Item-specific Instructions:

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 by the lab, mark "not stored" and record the reason why in the space provided.



(MTN 029/IPM 039) DF/Net 015

(LR) 144

Visit Code .

Participant ID <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <small>Site Number Participant Number Chk</small>	Initial Specimen Collection Date <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <small>dd MMM yy</small>
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Laboratory Results

1	hCG FOR PREGNANCY	<i>Not done/ Not collected</i> <input type="checkbox"/>	<i>negative</i> <input type="checkbox"/>	<i>positive</i> <input type="checkbox"/>	<i>not required</i> <input type="checkbox"/>	If newly positive, complete Clinical Product Hold/ Discontinuation Log and Pregnancy Report form.
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2	HIV	<i>Not done/ Not collected</i> <input type="checkbox"/>	<i>negative</i> <input type="checkbox"/>	<i>positive</i> <input type="checkbox"/>	<i>indeterminate</i> <input type="checkbox"/>	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.
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3	DIPSTICK URINALYSIS TESTS	<i>Not done/ Not collected</i> <input type="checkbox"/>	<i>Go to item 4.</i>	Alternate Collection Date dd MMM yy <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	
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	3a. Leukocyte esterase (LE)	<i>Not done</i> <input type="checkbox"/>	<i>negative</i> <input type="checkbox"/>	1+ <input type="checkbox"/>	2+ <input type="checkbox"/>	3+ <input type="checkbox"/>					
	3b. Nitrites	<i>Not done</i> <input type="checkbox"/>	<i>negative</i> <input type="checkbox"/>	<i>positive</i> <input type="checkbox"/>							
	3c. Protein	<i>Not done</i> <input type="checkbox"/>	<i>negative</i> <input type="checkbox"/>	<i>trace</i> <input type="checkbox"/>	1+ <input type="checkbox"/>	2+ <input type="checkbox"/>	3+ <input type="checkbox"/>	4+ <input type="checkbox"/>	Severity Grade If applicable <input type="checkbox"/>	AE Log Page # <input type="text"/> <input type="text"/>	Not reportable as an AE OR <input type="checkbox"/>
	3d. Glucose	<i>Not done</i> <input type="checkbox"/>	<i>negative</i> <input type="checkbox"/>	<i>trace</i> <input type="checkbox"/>	1+ <input type="checkbox"/>	2+ <input type="checkbox"/>	3+ <input type="checkbox"/>	4+ <input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	OR <input type="checkbox"/>
	3e. Culture	<i>Not done</i> <input type="checkbox"/>	<i>negative</i> <input type="checkbox"/>	<i>positive</i> <input type="checkbox"/>			Complete Adverse Experience Log when applicable.				

4	SERUM CHEMISTRIES	<i>Not done/ Not collected</i> <input type="checkbox"/>	<i>End of form.</i>	Alternate Collection Date dd MMM yy <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>					
	4a. AST (SGOT)	<i>Not done</i> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> U/L			Severity Grade If applicable <input type="checkbox"/>	AE Log Page # <input type="text"/> <input type="text"/>	Not reportable as an AE OR <input type="checkbox"/>	
	4b. ALT (SGPT)	<i>Not done</i> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> U/L			<input type="checkbox"/>	<input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	

Comments:

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	<ul style="list-style-type: none"> 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: $IU/L = U/L$ $I/I \times 100 = \%$ $10^9/L = 10^3/mm^3 = 10^3/mL$ 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. <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> If any values meet the criteria for severity grade 1 or greater, according to the appropriate <i>DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events</i>, 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. <ul style="list-style-type: none"> 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

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