Day 16 / Early Termination Visit 06.0 or varies

Required Forms

- Follow-up Visit Summary (FVS)
- Pelvic Exam (PE)
- Pelvic Exam Diagrams (non-DataFax)
- Breast Exam (BE)
- Follow-up PK/PD (FPK)
- Laboratory Results (LR)
- Vaginal Specimen Storage (SS)
- Sexual Practices Assessment (SPA)
- Vaginal Practices (VP)
- At-home Breast Milk Sampling Log (AHB)
- Termination (TM)

Additional Forms Required for Early Termination Visit only

- Participant Ring Use Log (PRU)
- Ring Insertion and Removal (RIR)

*Note: The PRU and RIR forms can be found and printed from the "**All CRFs**" PDF.*

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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.*

AE report or follow-up	*return of ring or need new ring*	*other, specify:*
☐	☐	☐ _____

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.*

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

Comments:

_____
Staff Initials/Date

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	• 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
☐ *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

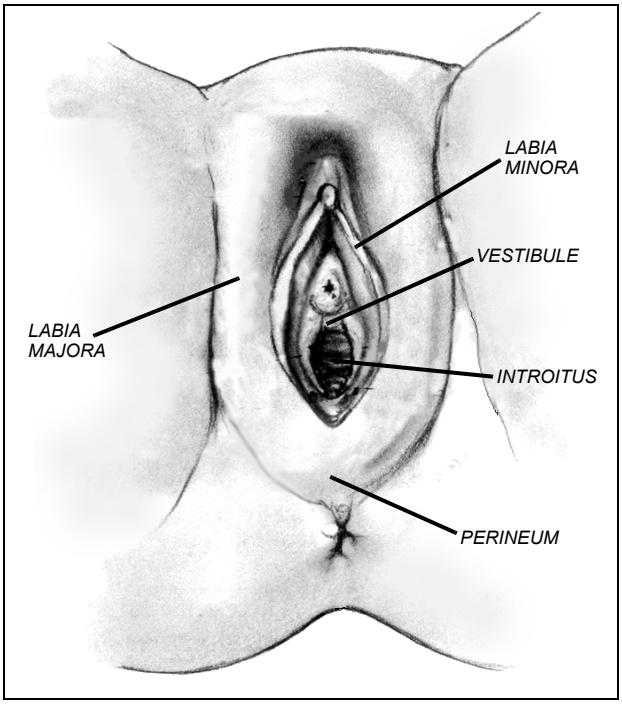
Speculum Type (screening only)

Pederson ☐ *Graves* ☐ *Cusco* ☐

Speculum Size (screening only)

small ☐ *medium* ☐ *large* ☐

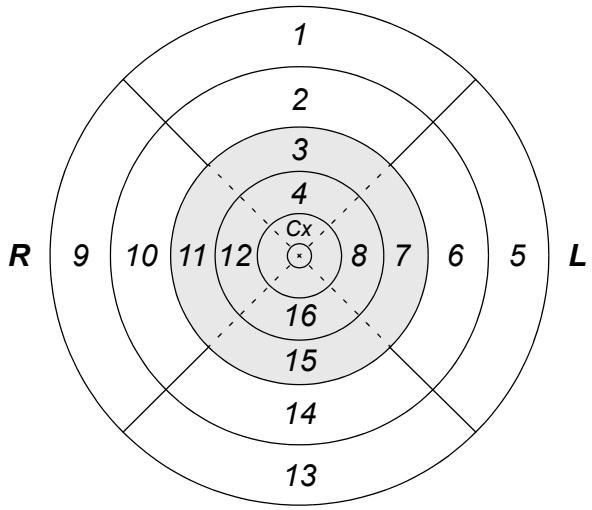
External Genitalia



Legend for Vagina/Cervix

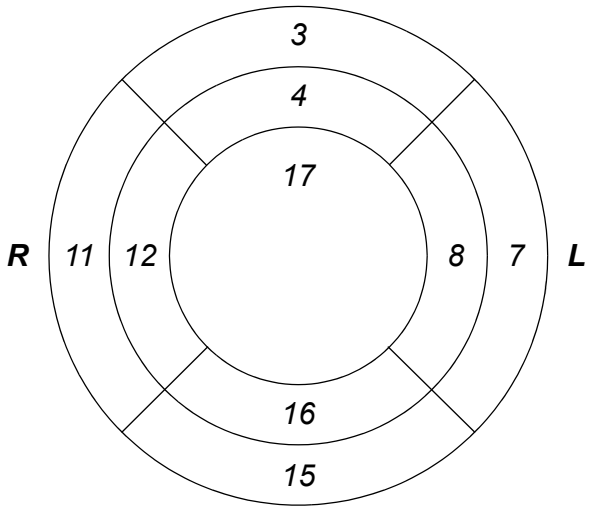
1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina, 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 (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?	☐	☐	
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 (FPK) 161

Visit Code ☐☐.☐

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

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

Follow-up PK/PD

		Not collected	Alternate Collection date (dd MMM yy)	Collection time 24-hr clock (hr : min)	stored	not stored
1	Plasma for PK	☐	☐☐ ☐☐☐ ☐☐	☐☐ : ☐☐	☐	☐
						Reason not stored: _____
2	Cervicovaginal fluid swab for PK	☐	☐☐ ☐☐☐ ☐☐	☐☐ : ☐☐	☐	☐
						Reason not stored: _____
3	Breast milk for PK and lipids	☐	☐☐ ☐☐☐ ☐☐	☐☐ : ☐☐	☐	☐
						Reason not stored: _____
4	Breast milk for PD	☐	☐☐ ☐☐☐ ☐☐	☐☐ : ☐☐	☐	☐
						Reason not stored: _____

Comments:

_____
Staff Initials/Date

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.

(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 (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* ☐ Alternate Collection date ☐☐ ☐☐☐ ☐☐ (dd MMM yy) — *stored* ☐ *not stored* ☐

Reason not stored: _____

2 Quantitative vaginal culture — *Not collected* ☐ Alternate Collection date ☐☐ ☐☐☐ ☐☐ (dd MMM yy) — Collection time *24-hr clock* ☐☐ : ☐☐ (hr min) — *stored* ☐ *not stored* ☐

Reason not stored: _____

3 Vaginal swab for biomarkers — *Not collected* ☐ Alternate Collection date ☐☐ ☐☐☐ ☐☐ (dd MMM yy) — Collection time *24-hr clock* ☐☐ : ☐☐ (hr min) — *stored* ☐ *not stored* ☐

Reason not stored: _____

3a. Was blood visible on the swab? ☐ *yes* ☐ *no*

4 Used vaginal ring — *Not collected* ☐ Alternate Collection date ☐☐ ☐☐☐ ☐☐ (dd MMM yy) — *stored* ☐ *not stored* ☐

Reason not stored: _____

Comments:

_____
Staff Initials/Date

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:

Staff Initials/Date

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	☐	☐	1g. vaginal barriers, such as female condoms, diaphragms, or cervical caps	☐	☐
1b. water plus soap	☐	☐	1h. douche, specify: _____	☐	☐
1c. materials such as paper, cloth, or cotton wool	☐	☐	1i. spermicide	☐	☐
1d. fingers to clean or insert something	☐	☐	1j. lubricant, specify: _____	☐	☐
1e. tampons	☐	☐	1k. anything else? _____	☐	☐
1f. sex toys	☐	☐			

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	☐	☐	2g. vaginal barriers, such as female condoms, diaphragms, or cervical caps	☐	☐
2b. water plus soap	☐	☐	2h. douche, specify: _____	☐	☐
2c. materials such as paper, cloth, or cotton wool	☐	☐	2i. spermicide	☐	☐
2d. fingers to clean or insert something	☐	☐	2j. lubricant, specify: _____	☐	☐
2e. tampons	☐	☐	2k. anything else?	☐	☐
2f. sex toys	☐	☐	Specify: _____		

_____
Staff Initials/Date

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.

(MTN 029/IPM 039) DF/Net 015 (AHB-1) 415

Visit Code ☐☐.☐

Participant ID ☐☐☐-☐☐☐☐☐-☐
Site Number *Participant Number* *Chk*

Visit Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

At-home Breast Milk Sampling Log, Page 1 of 2

1 How many total breast milk samples were collected by the participant since the last scheduled visit? ☐☐ → *If 00, go to page 2.*

2 For each breast milk sample collected, complete a row, beginning with item 2a.

Collection Method Codes: *1=hand expression; 2=hand pump; 3=personal electric pump; 4=hospital-grade pump*

	Collection Date (dd/MMM/yy)	Collection Start Time hr: min *(24-hour clock)*	Collection Method Code	Stored	Not Stored	If not stored, specify:
2a.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	
2b.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	
2c.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	
2d.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	
2e.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	
2f.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	
2g.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	
2h.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	
2i.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	
2j.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	
2k.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	
2l.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	
2m.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	
2n.	☐☐ ☐☐☐ ☐☐	☐☐:☐☐	☐	☐	☐	

_____
Staff Initials/Date

Purpose:

This form is used to document participant breast milk samples that are collected at home for study purposes.

General Instructions:

This form is completed at the Day 7, Day 14, and Day 16 Visits. Complete this form using the participant's completed **MTN-029 Participant Breast Milk Collection Log** as a source document, if available; otherwise, transcribe the available information noted on the breast milk collection containers.

Item-specific Instructions:

<table>
<tr><td>Items 2a–2n</td><td>Complete one row for each breast milk sample collected (as noted in the item 1 response). When possible, complete items 2a–2n in ascending order by date and time, with item 2a being the earliest sample collected.</td></tr>
<tr><td>Items 2a–2n Collection Method Code</td><td>
<table>
<tr><th>Code</th><th>Description</th></tr>
<tr><td>1</td><td>Hand expression</td></tr>
<tr><td>2</td><td>Hand pump</td></tr>
<tr><td>3</td><td>Personal electric pump</td></tr>
<tr><td>4</td><td>Hospital-grade pump</td></tr>
</table>
</td></tr>
</table>

(MTN 029/IPM 039) DF/Net 015 (AHB-2) 416

Visit Code ☐☐.☐

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number *Participant Number* *Chk*

☐ *No data recorded on this page.*

→ *End of form.*

At-home Breast Milk Sampling Log, Page 2 of 2

Collection Method Codes: *1=hand expression; 2=hand pump; 3=personal electric pump; 4=hospital-grade pump*

	Collection Date (dd/MMM/yy)	Collection Start Time hr: min *(24-hour clock)*	Collection Method Code	Stored	Not Stored	If not stored, specify:
2o.	☐☐☐☐☐☐☐	☐☐:☐☐	☐	☐	☐	
2p.	☐☐☐☐☐☐☐	☐☐:☐☐	☐	☐	☐	
2q.	☐☐☐☐☐☐☐	☐☐:☐☐	☐	☐	☐	
2r.	☐☐☐☐☐☐☐	☐☐:☐☐	☐	☐	☐	
2s.	☐☐☐☐☐☐☐	☐☐:☐☐	☐	☐	☐	
2t.	☐☐☐☐☐☐☐	☐☐:☐☐	☐	☐	☐	
2u.	☐☐☐☐☐☐☐	☐☐:☐☐	☐	☐	☐	
2v.	☐☐☐☐☐☐☐	☐☐:☐☐	☐	☐	☐	
2w.	☐☐☐☐☐☐☐	☐☐:☐☐	☐	☐	☐	
2x.	☐☐☐☐☐☐☐	☐☐:☐☐	☐	☐	☐	

Comments:

_____
Staff Initials/Date

Item-specific Instructions:

<table>
<tr><td>Visit Code</td><td>Record the visit code that is present on page 1 of this form.</td></tr>
<tr><td>No data recorded on this page</td><td>Mark this box only if items 2o–2x and the Comments section are all left blank.</td></tr>
<tr><td>Items 2o–2x</td><td>Complete one row for each breast milk sample collected (as noted in the item 1 response). When possible, complete items 2o–2x in ascending order by date and time, with item 2o being the earliest sample collected and recorded on page 2 of this form.</td></tr>
<tr><td>Items 2o–2x Collection Method Code</td><td>
<table>
<tr><th>Code</th><th>Description</th></tr>
<tr><td>1</td><td>Hand expression</td></tr>
<tr><td>2</td><td>Hand pump</td></tr>
<tr><td>3</td><td>Personal electric pump</td></tr>
<tr><td>4</td><td>Hospital-grade pump</td></tr>
</table>
</td></tr>
</table>

(MTN 029/IPM 039) DF/Net 015 (TM) 490

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number *Participant Number* *Chk*

Termination

1 Termination Date [ ][ ] [ ][ ][ ] [ ][ ] *dd* *MMM* *yy*

Date the site determined that the participant was no longer in the study.

2 Reason for termination. *Mark only one.*

- ☐ 2a. Scheduled exit visit/end of study → *End of form.*
- ☐ 2b. Death
  - 2b1. Date of death [ ][ ] [ ][ ][ ] [ ][ ] *dd* *MMM* *yy* *OR* ☐ date unknown
  - 2b2. Cause of death _____ *OR* ☐ cause unknown

  → *Complete or update Adverse Experience Log.*
- ☐ 2c. Participant refused further participation, specify _____
- ☐ 2d. Participant unable to adhere to visit schedule
- ☐ 2e. Participant relocated, no follow-up planned
- ☐ 2f. Investigator decision, specify _____
- ☐ 2g. Unable to contact participant
- ☐ 2h. HIV infection → *If HIV-1 infection, complete Laboratory Results CRF. End of form.*
- ☐ 2i. Inappropriate enrollment → *End of form.*
- ☐ 2j. Invalid ID due to duplicate screening/enrollment → *End of form.*
- ☐ 2k. Other, specify _____
- ☐ 2l. Early study closure → *End of form.*
- ☐ 2m. Pregnancy

3 Was termination associated with an adverse event? *yes* ☐ *no* ☐ *don't know* ☐ → *If no or don't know, end of form.*

3a. Record AE Log page number *page #* [ ][ ] *OR* Specify _____

Comments:

_____ *Staff Initials/Date*

General Instructions:

This form is completed for every enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.

Item-specific Instructions:

Item 1	A complete date is required.
Item 2	Mark only the primary reason for termination.
Item 2a	Only mark 2a if the participant completes the protocol-defined final visit.
Item 2b1	If date is recorded, at a minimum, the month and year are required.
Item 2l	Only mark 2l when instructed by SCHARP.
Item 3a	Record the page number of the **Adverse Experience Log** on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate. If termination is associated with a non-reportable AE, record the event on the “Specify” line.