(MTN 029/IPM 039) DF/Net 015 (AE) 460

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

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

Date AE Reported to Site ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

Adverse Experience Log

1 Adverse Experience (AE) *Record diagnosis (in English) if available. Include anatomical location, if applicable.*

2 Onset date ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

3 At which visit was this AE first reported? ☐☐ . ☐ *visit code*

4 Severity
☐ *Grade 1—mild* ☐ *Grade 2—moderate* ☐ *Grade 3—severe* ☐ *Grade 4—potentially life-threatening* ☐ *Grade 5—death*

5 Relationship to study product ☐ *related* ☐ *not related* *Record rationale or alternative etiology in Comments.*

6 Study product administration ☐ *no change* ☐ *held* ☐ *permanently discontinued* ☐ *N/A*

7 Status or Outcome of AE
☐ *continuing*
☐ *resolved*
☐ *death*
☐ *severity/frequency increased (report as new AE)*
☐ *continuing at end of study participation*

7a. Status/Outcome Date *(Leave blank if item 7 is "continuing" or "continuing at end of study participation.")* ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

7b. If severity/frequency increased, record the new AE Log page # *AE Log page #* ☐☐

8 Treatment *Mark "none" or all that apply.*
☐ *none* → *If none, go to item 9.*
☐ *procedure/surgery* *Comment below.*
☐ *new/prolonged hospitalization* *Comment below.*
☐ *medication(s)* *(Report on CM)*
☐ *other, specify:* _____ *Comment below.*

8a. If medication(s), record the CM Log page #(s): *CM Log page #* ☐☐ ☐☐

9 Is this an SAE according to ICH guidelines? ☐ *yes* ☐ *no*

10 Has or will this AE be reported as an EAE? ☐ *yes* ☐ *no*

11 Was this AE a worsening of a pre-existing condition? ☐ *yes* ☐ *no*

Comments:

_____ *Staff Initials/Date*

Purpose:

To document any Adverse Experience (AE) reported by the participant or clinically observed as defined by the protocol.

General Instructions:

Do not record a condition as an AE if it existed at enrollment as a pre-existing condition, unless it increases in severity or frequency. If a cluster of symptoms reported on separate AE Log pages is later attributed to a single diagnosis, change the earliest reported symptom to the final diagnosis. In addition, mark the AE Log pages for the other symptoms with the words "Delete due to diagnosis on AE page #" (specify page number of diagnosis AE).

Item-specific Instructions:

Page #	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any AE Log pages after faxing, unless instructed by DF/Net.
Item 1	Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate page of the AE Log. 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."
Item 2	At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the AE; if the AE is discovered during the study visit exam, record the date of the study visit exam; if the AE is an abnormal lab result, record the date on which the specimen was collected.
Item 4	To grade the severity of an AE, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse* Events (Version 2.0), Addendum 1: 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).
Item 5	Mark the assessment of the relationship between the AE and the study agent. Mark "related" if there is a reasonable possibility that the AE may be related to the study agent. Mark "not related" if there is not a reasonable possibility that the AE is related to the study agent. Record an alternative etiology, diagnosis, or explanation in Comments. For more information, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2*.
Item 6	no change: Mark if the participant is expected to continue to use study product, as of the date the AE is reported, and the AE does NOT result in a study product hold or permanent discontinuation. held: Mark if the AE results in a study product hold. If multiple AEs are reported at the same visit, mark "held" for the AE(s) that contributed to the product hold. permanently discontinued: Mark if the AE results in permanent discontinuation of study product. If multiple AEs are reported at the same visit, mark "permanently discontinued" for the AE(s) that contributed to the permanent discontinuation. N/A (not applicable): Mark if the AE is reported after the participant had completed all administration of the study product, or the study product is held or permanently discontinued for a different AE or other reason, or the AE is grade 5-death.
Item 7	continuing: AE is continuing at the time it is reported. continuing at end of study participation: Mark this box whenever an AE is continuing at the time of participant study termination. resolved: Condition is no longer present, or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved. death: Mark only if the severity of this AE is grade 5. Any other AEs continuing at the time of death should be changed to "continuing at end of study participation." severity/frequency increased: If an AE increases in severity or frequency after it has been reported on the AE Log, line through the "continuing" box previously marked and mark "severity/frequency increased." Record the date of increase in the "Status/ Outcome Date." Report the increase in severity or frequency as a new AE and record new AE Page # in space provided. If a new AE Page # is completed, an AE Log page with corresponding AE number must be received. For this new AE, the "Onset Date" will be the date that the severity or frequency increased. Update EAE form if applicable. Note that decreases in severity should not be recorded as new AEs.
Item 7a	At minimum, month and year are required. Record one of the following as appropriate: the date on which the participant no longer experienced the AE, or the date of the study visit or specimen collection at which the change in status/outcome is first noted.
Item 8	Indicate all treatments administered for this AE, including treatment provided by a health care professional and participant self-treatment. Do not indicate treatments that were clinically indicated or prescribed but not administered.
Items 9–10	For questions about ICH guidelines and EAE reporting, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2.*

(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 (BMH) 051

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number *Participant Number* *Chk*

Visit Date

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

dd *MMM* *yy*

Baseline Menstrual History

1 Since delivery, has the participant resumed her menses? ☐ *yes* ☐ *no* ☐ *unsure* → *If no or unsure, end of form.*

2 First day of last menstrual period: [ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

3 Last day of menstrual period: [ ][ ] [ ][ ][ ] [ ][ ] *OR* ☐ *ongoing*

dd *MMM* *yy*

4 Provide additional details as needed to describe the participant's baseline menstrual bleeding pattern.

_____

_____

_____

_____

_____

_____

_____

_____

_____

Record usual menstrual symptoms and any irregular bleeding on the Pre-existing Conditions form.

_____

Staff Initials/Date

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.

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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.

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

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number *Participant Number* *Chk*

Clinical Product Hold/Discontinuation Log

1 Date and visit code when study product hold was initiated: dd ☐☐ MMM ☐☐☐ yy ☐☐ *visit code* ☐☐.☐

2 Why is study product being held? *Mark only one per page.*

- ☐ positive HIV test result
- ☐ adverse experience → ☐☐ *AE Log page #*
- ☐ pregnancy
- ☐ provides or intends to provide breast milk to child(ren) or anyone else for consumption/banking/freezing
- ☐ continued use of the vaginal ring would be harmful
- ☐ participant unable/ unwilling to comply with required study procedures, or otherwise might be put at undue risk by continuing product use per judgment of IoR /designee
- ☐ other, specify: _____

3 Date of last study product use: dd ☐☐ MMM ☐☐☐ yy ☐☐

4 Was the participant instructed to resume study product use?

	Date dd	MMM	yy
☐ yes →	☐☐	☐☐☐	☐☐
☐ no—hold continuing for another reason →	☐☐	☐☐☐	☐☐
☐ no—early termination →	☐☐	☐☐☐	☐☐
☐ no—hold continuing at Day 14 Visit →	☐☐	☐☐☐	☐☐
☐ no—permanently discontinued →	☐☐	☐☐☐	☐☐

Comments:

_____
Staff Initials/Date

Purpose:

This log is used to document temporary clinical holds and clinical permanent discontinuations of study product use as instructed by study site staff. Note that the MTN-029 protocol does not include any provisions for temporary clinical holds of study product.

General Instructions:

This log is completed each time a participant is instructed by study staff to temporarily stop (hold) or permanently discontinue study product use. If, at the same visit, a product hold/discontinuation is initiated for more than one reason, complete one **Clinical Product Hold/Discontinuation Log** page for each reason. The same visit code should be used on each Log page.

Do not complete this log in cases where a participant has decided on her own to stop using study product.

Item-specific Instructions:

Page	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any **Clinical Product Hold/Discontinuation Log** pages after faxing, unless instructed by SCHARP.
Item 2	Note that participant decline or refusal of study product is not documented as a product hold. Do not record this as a reason in "other, specify."
Item 3	Record the last date the participant used study product. Use a best estimate if the actual date cannot be determined. ***Note:*** *Do not wait for information about product resumption or permanent discontinuation to fax the form—submit this form to DF/Net as soon as items 1 through 3 have been completed. Resubmit the page once item 4 has been completed.*
Item 4	If "no—hold continuing for another reason" is marked, record the date that the participant would have been instructed to resume study product use based on resolution of the reason indicated in item 2. If "no—permanently discontinued" is marked, record the date the permanent discontinuation was initiated.

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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

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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.

(MTN 029/IPM 039) DF/Net 015 (ECI) 023

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

(MTN 029/IPM 039) DF/Net 015 (ENR) 070

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number *Participant Number* *Chk*

Enrollment

1	Date the participant marked or signed the consent form for study participation:	[ ][ ] [ ][ ][ ] [ ][ ] *dd MMM yy*
2	Did the participant consent to long-term specimen storage and future testing?	☐ *Yes* ☐ *No*
3	Plasma for archive:	Collection date [ ][ ] [ ][ ][ ] [ ][ ] *dd MMM yy* — *stored* ☐ *not stored* ☐ → *Reason not stored:* _____
4	Enrollment date and time:	[ ][ ] [ ][ ][ ] [ ][ ] *dd MMM yy* [ ][ ] : [ ][ ] *hr min* *24-hr clock*
5	Date and time vaginal ring inserted:	[ ][ ] [ ][ ][ ] [ ][ ] *dd MMM yy* [ ][ ] : [ ][ ] *hr min* *24-hr clock*

Comments:

_____
Staff Initials/Date

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.

(MTN 029/IPM 039) DF/Net 015 (EPK) 061

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

Specimen Collection Date ___ ___ ___
dd *MMM* *yy*

Enrollment PK/PD

Pre-insertion Specimens

		24-hour clock hr : min	*not collected*	*stored*	*not stored*	*If not stored, specify:*
1	Pre-insertion blood draw	:	☐	☐	☐	*If not stored, specify:*
2	Pre-insertion breast milk for PK and lipids	:	☐	☐	☐	*If not stored, specify:*
3	Pre-insertion breast milk for PD	:	☐	☐	☐	*If not stored, specify:*
4	Pre-insertion CVF swab	:	☐	☐	☐	*If not stored, specify:*

3-hour Post-insertion Specimens

		24-hour clock hr : min	*not collected*	*stored*	*not stored*	*If not stored, specify:*
5	3-hour post-insertion blood draw	:	☐	☐	☐	*If not stored, specify:*
6	3-hour post-insertion breast milk for PK and lipids	:	☐	☐	☐	*If not stored, specify:*
7	3-hour post-insertion breast milk for PD	:	☐	☐	☐	*If not stored, specify:*
8	3-hour post-insertion CVF swab	:	☐	☐	☐	*If not stored, specify:*

6-hour Post-insertion Specimens

		24-hour clock hr : min	*not collected*	*stored*	*not stored*	*If not stored, specify:*
9	6-hour post-insertion blood draw	:	☐	☐	☐	*If not stored, specify:*
10	6-hour post-insertion breast milk for PK and lipids	:	☐	☐	☐	*If not stored, specify:*
11	6-hour post-insertion breast milk for PD	:	☐	☐	☐	*If not stored, specify:*
12	6-hour post-insertion CVF swab	:	☐	☐	☐	*If not stored, specify:*

Comments:

_____
Staff Initials/Date

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 (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 (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 (HCR) 330

Visit Code ☐☐.☐

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number *Participant Number* *Chk*

HIV Confirmatory Results

SAMPLE 1

1 HIV Confirmation Test ☐ Not done/Not collected → *Go to item 2.*

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

1a. Western Blot ☐ *Not done* ☐ *negative* ☐ *positive* ☐ *indeterminate*

1b. HIV EIA ☐ *Not done* ☐☐ *kit code* ☐ *negative/non-reactive* ☐ *positive/reactive* ☐ *invalid*

→ *If negative/non-reactive, go to item 1c.*

1b1. Reactivity *Mark all that apply.* ☐ *HIV-1 Ag reactive* ☐ *HIV-1 Ab reactive* ☐ *HIV-2 Ab reactive* ☐ *HIV-1/2 undifferentiated*

1c. HIV RNA PCR ☐ *Not done* > ☐ = ☐ < ☐ *viral copies/mL* ☐☐☐☐☐☐☐☐ OR ☐ *target not detected*

1c1. RNA PCR kit lower limit of detection *20* ☐ *40* ☐ OR *viral copies/mL* ☐☐☐

SAMPLE 2

2 HIV Confirmation Test ☐ Not done/Not collected → *Go to item 3.*

Specimen Collection Date ☐☐ dd ☐☐☐ MMM ☐☐ yy Visit Code ☐☐.☐

2a. Western Blot ☐ *Not done* ☐ *negative* ☐ *positive* ☐ *indeterminate*

2b. HIV EIA ☐ *Not done* ☐☐ *kit code* ☐ *negative/non-reactive* ☐ *positive/reactive* ☐ *invalid*

→ *If negative/non-reactive, go to item 2c.*

2b1. Reactivity *Mark all that apply.* ☐ *HIV-1 Ag reactive* ☐ *HIV-1 Ab reactive* ☐ *HIV-2 Ab reactive* ☐ *HIV-1/2 undifferentiated*

2c. HIV RNA PCR ☐ *Not done* > ☐ = ☐ < ☐ *viral copies/mL* ☐☐☐☐☐☐☐☐ OR ☐ *target not detected*

2c1. RNA PCR kit lower limit of detection *20* ☐ *40* ☐ OR *viral copies/mL* ☐☐☐

3 Final HIV Status ☐ *HIV-uninfected* ☐ *HIV-infected* ☐ *pending*

Comments:

Staff Initials/Date

Purpose:

This form is used to document results from local lab confirmatory HIV testing once a participant has a newly positive or indeterminate HIV test result.

General Instructions:

Complete this form for each visit where the participant has a newly positive or indeterminate HIV test result.

Item-specific Instructions:

<table>
<tr><td>Visit Code</td><td>The visit code recorded on this form should be the same visit code recorded on the Laboratory Results form documenting the positive or indeterminate HIV test result.</td></tr>
<tr><td>Specimen Collection Date</td><td>Record the date the specimen was collected (NOT the date results were reported or recorded on the form).</td></tr>
<tr><td>Item 2</td><td>Record the specimen collection date and visit code which corresponds to Sample 2.</td></tr>
<tr><td>Items 1a, 1b, and 2a, 2b</td><td>If the result is “negative,” “indeterminate,” or “invalid,” consult the Lab Center.</td></tr>
<tr><td>Items 1b and 2b</td><td>Record the assigned two-digit EIA test kit code. Note: More test kit codes may be added to the list as the study proceeds.
<table>
<tr><th>Kit Code</th><th>EIA Test</th></tr>
<tr><td>01</td><td>Multispot</td></tr>
<tr><td>02</td><td>Evolis</td></tr>
<tr><td>03</td><td>BioPlex 2200</td></tr>
<tr><td>04</td><td>Geenius</td></tr>
</table>
</td></tr>
<tr><td>Item 3</td><td>Once a participant’s HIV status has been determined, record the final HIV status. Once all results are available, if the final HIV status is not clearly negative or clearly positive, mark “pending.” If additional testing is done to determine final status, record details in Comments.</td></tr>
</table>

(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 (MV) 463

Visit Code ☐☐.0

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number *Participant Number* *Chk*

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Missed Visit

1 Target Visit Date ☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

2 Reason visit was missed. *Mark only one.*

- ☐ 2a. Unable to contact participant
- ☐ 2b. Unable to schedule appointment(s) within window
- ☐ 2c. Participant refused visit
- ☐ 2d. Participant incarcerated
- ☐ 2e. Participant admitted to a health care facility → *Complete Adverse Experience Log, as applicable.*
- ☐ 2f. Participant withdrew from the study → *Complete Termination form.*
- ☐ 2g. Participant deceased → *Complete Termination form. Complete Adverse Experience Log.*
- ☐ 2h. Other, specify _____

3 Steps taken to address the missed visit (corrective action plan):

_____

_____

_____

_____

Comments:

_____
Staff Initials/Date

Purpose:

Complete this form whenever an enrolled participant misses a required visit according to the visit window outlined in the protocol or Study-specific Procedures (SSP).

General Instructions:

- If the QC Report indicates that a visit is overdue, confirm that the visit was missed before completing a Missed Visit form. Fax this form when it is determined that a visit has been missed and cannot be completed within the visit window. Record the Visit Code of the visit that was missed. Record the date that the form was completed. This will not necessarily be the date of the missed visit.

Item-specific Instructions:

Item 1	Record the target date of the visit. A complete date is required.
Item 2	Record the reason the participant missed the visit.

(MTN 029/IPM 039) DF/Net 015 (PRU) 405

Visit Code ☐☐.☐

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

Visit Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

Participant Ring Use Log

1 Since the last scheduled visit, has the ring been out at any time? ☐ *Yes* ☐ *No* → *If no, end of form.*

2 How many total times has the ring been out since the last scheduled visit? ☐☐ → *If 11 or more, add Comment after completing items 3a–3k.*

3 For each instance when the vaginal ring was out, complete a row below, beginning with item 3a. Ring removals by site staff should not be recorded on this form.

	Date ring was removed or came out (dd/MMM/yy)	Time ring was removed or came out *(24-hour clock)*	Reason Code	Was the ring re-inserted?	If yes, date ring was re-inserted (dd/MMM/yy)	If yes, time ring was re-inserted *(24-hour clock)*
3a.	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*	☐☐	*Yes* ☐ *No* ☐	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*
3b.	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*	☐☐	*Yes* ☐ *No* ☐	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*
3c.	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*	☐☐	*Yes* ☐ *No* ☐	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*
3d.	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*	☐☐	*Yes* ☐ *No* ☐	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*
3e.	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*	☐☐	*Yes* ☐ *No* ☐	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*
3f.	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*	☐☐	*Yes* ☐ *No* ☐	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*
3g.	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*	☐☐	*Yes* ☐ *No* ☐	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*
3h.	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*	☐☐	*Yes* ☐ *No* ☐	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*
3i.	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*	☐☐	*Yes* ☐ *No* ☐	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*
3j.	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*	☐☐	*Yes* ☐ *No* ☐	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*
3k.	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*	☐☐	*Yes* ☐ *No* ☐	☐☐ ☐☐☐ ☐☐ *dd MMM yy*	☐☐:☐☐ *hr min*

Comments:

_____
Staff Initials/Date

Purpose:

This form is used to document participant-reported vaginal ring removals and expulsions between Days 2–6 and Days 8–13. This includes all instances when the ring has not been used, regardless of the reason for non-use.

General Instructions:

This form is completed once at the Day 7 Visit, and again at the Day 14 Visit. Complete this form using the participant's completed MTN-029 Participant Ring Use Log as a source document, if available; otherwise, complete based on participant self-report and note in the Comments that the participant did not complete the log.

Item-specific Instructions:

Item 2	Record how many separate times the participant reports the ring has been out since her last scheduled visit (Day 1 or Day 7).
Items 3a–3k	Complete one row for each separate time the participant reports the ring has been out (as noted in the item 2 response). For example, if the participant reported that the ring has been out for two separate times, complete rows 3a and 3b. When possible, complete items 3a–3k in ascending order by date, with item 3a being the earliest date the ring was out (removed or expelled).
Items 3a–3k Reason Code	Select from the codes below and record the code that best describes why the vaginal ring was removed or came out on its own. If "99" (other), briefly describe the reason why the ring was removed or came out on its own in the Comments section.

REASONS RING REMOVED BY PARTICIPANT

Hygienic or Physical Reasons	
Code	Description
10	Discomfort/Symptoms: Ring caused discomfort/participant experienced genital or other symptoms
11	Ring falling out: Ring was partially falling out
12	Ring placement: Didn't feel the ring was correctly placed
13	Ring presence: Wanted to look at the ring or see if the ring was still in place
14	Menses/Bleeding: Had or was expecting menses/any type of genital bleeding or spotting
15	Cleaned ring: Removed ring to clean it
16	Cleaned vagina: Removed ring to clean vagina

Study-related or Procedural Reasons	
Code	Description
30	Product Hold: Participant placed on product hold
31	Product permanently discontinued: Participant permanently discontinued from product
32	Procedure: Ring removed for clinical procedure (e.g., IUCD insertion) that was *not* conducted at a regularly scheduled study visit
33	Inserted new ring: Ring removed to insert new ring between study visits or at an interim visit
34	Missed Visit: Participant removed ring due to missed scheduled visit

Social or Sexual Reasons	
Code	Description
20	Partner ring knowledge: Did not want husband or primary sex partner to know about ring
21	Partner concerns/objections: Husband or any sex partner did not like the ring and/or wanted her to remove/stop using the ring
22	Family concerns/objections: Family member (other than husband/primary sex partner) did not like the ring and/or wanted her to remove/stop using the ring
23	Friend or peer concerns/objections: Friend or peer did not like the ring and/or wanted her to remove/stop using the ring
24	Removal for sex: Participant or partner did not want to have vaginal sex with the ring in place
25	Discomfort during sex: The ring feeling uncomfortable or painful during vaginal sex
26	Partner felt ring during sex: The sex partner feeling the ring during sex
27	Showed ring: Removed ring to show it to someone
28	Not having sex: Participant was not having sex so she decided to remove/stop using the ring
99	Other

REASONS RING CAME OUT ON ITS OWN

Code	Description
40	Urination
41	Bowel movement: Having a bowel movement
42	Sex: Having sex or just finished sex
43	Physical activity: Physical activity (other than sex), including lifting heavy objects
44	Body position: Was squatting or sitting or changing body position (i.e., move from lying down to standing up)
45	Menses: Had her menses

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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

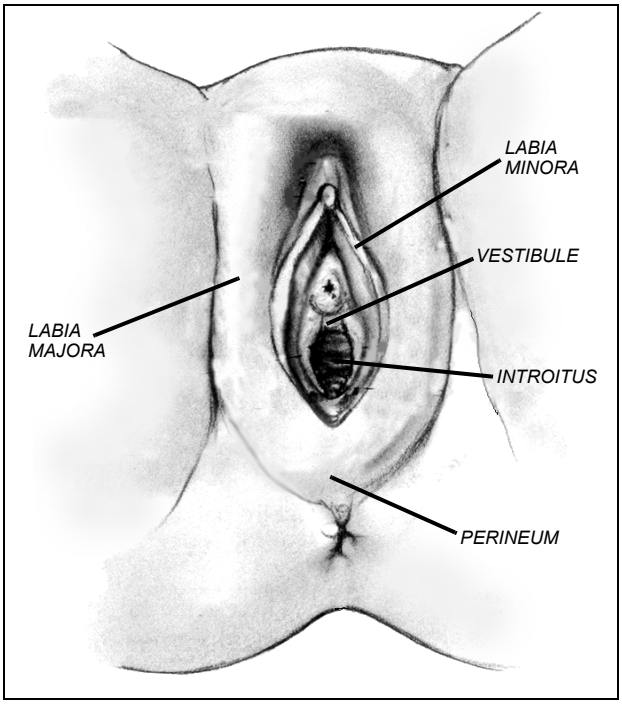
Speculum Type (screening only)

Pederson ☐ *Graves* ☐ *Cusco* ☐

Speculum Size (screening only)

small ☐ *medium* ☐ *large* ☐

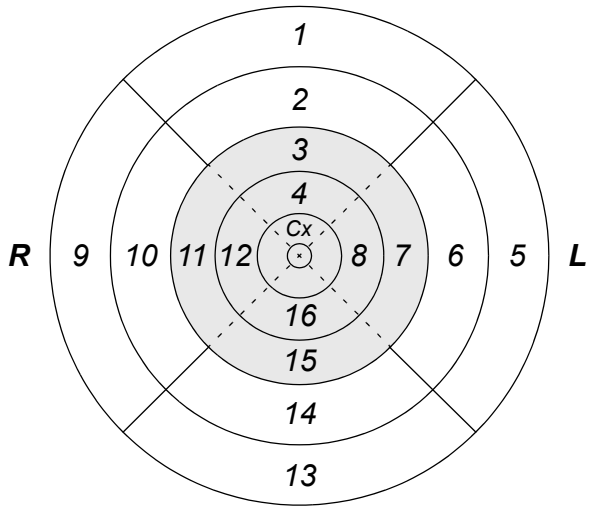
External Genitalia



Legend for Vagina/Cervix

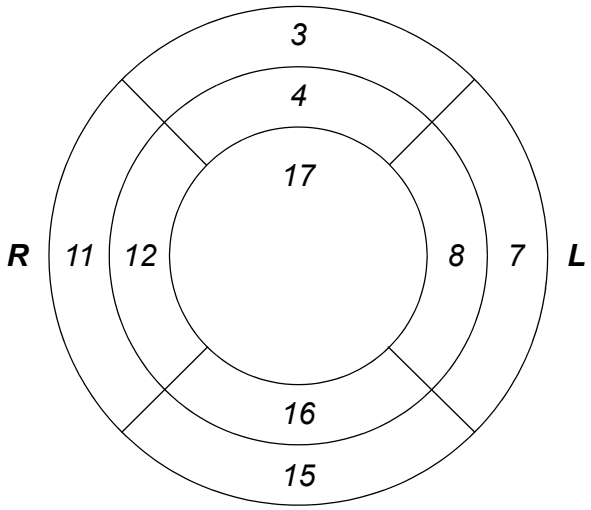
1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina,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

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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 (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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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.

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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 ☐☐.☐ Outcome Number ☐

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number *Participant Number* *Chk*

☐ Outcome unobtainable → *Go to page 2.*

Pregnancy Outcome, page 1 of 2

1 How many pregnancy outcomes resulted from this reported pregnancy? ☐

2 Outcome Date dd ☐☐ MMM ☐☐☐ yy ☐☐

3 Place of delivery/outcome

- ☐ home
- ☐ hospital
- ☐ clinic
- ☐ unknown
- ☐ other, specify: _____

4 Specify outcome. *Mark only one.*

Items 4a–4f: If the pregnancy or outcome was associated with maternal complications or symptoms that would otherwise be reported as an AE, report these on an AE Log. Complete an EAE Reporting form, if applicable.

- ☐ 4a. full term live birth (>= 37 weeks) → 4a1. Method: ☐ C-section ☐ standard vaginal ☐ operative vaginal
- ☐ 4b. premature term live birth (< 37 weeks)
- ☐ 4c. stillbirth/intrauterine fetal demise (>= 20 weeks)
- ☐ 4d. spontaneous abortion (< 20 weeks)
- ☐ 4e. ectopic pregnancy
- ☐ 4f. therapeutic/elective abortion

If full term live birth, go to item 6.

- ☐ 4g. other, specify: _____

5 Provide a brief narrative of the circumstances: _____

6 Were there any complications related to the pregnancy outcome? *yes* ☐ *no* ☐ → *If no, go to item 7 on page 2.*

6a. Delivery-related complications. *Mark "none" or all that apply.*

- ☐ 6a1. none
- ☐ 6a2. intrapartum hemorrhage
- ☐ 6a3. postpartum hemorrhage
- ☐ 6a4. non-reassuring fetal status
- ☐ 6a5. chorioamnionitis
- ☐ 6a6. other, specify: _____

6b. Non-delivery-related complications. *Mark "none" or all that apply.*

- ☐ 6b1. none
- ☐ 6b2. hypertensive disorders of pregnancy
- ☐ 6b3. gestational diabetes
- ☐ 6b4. other, specify: _____

Staff Initials/Date

Purpose

This form is used to report pregnancy outcome information for a pregnancy reported post-enrollment. Complete this form when information about a pregnancy outcome becomes available to study staff or when it is determined that pregnancy outcome is unobtainable.

General Instructions:

A **Pregnancy Outcome** form is required for each **Pregnancy Report** form that is completed for a participant.

Item-specific Instructions:

Visit Code	Record the visit code of the participant's corresponding **Pregnancy Report** form.
Outcome Number	A pregnancy outcome can be an infant or fetus. The conception of twins, for example, will result in reporting of two outcomes. For a pregnancy resulting in one outcome, record "1" here. For a pregnancy with multiple outcomes, record the outcome number corresponding to the outcome data recorded on the form.
Outcome unobtainable	If it is determined that an outcome is unobtainable (i.e., the participant refuses further contact), mark the "Outcome unobtainable" box at the top of the page and fax both pages of this form to DF/Net.
Item 1	If the pregnancy results in two or more outcomes, complete a **Pregnancy Outcome** form for each outcome. Each **Pregnancy Outcome** form will have the same visit code, but different outcome numbers (for example, one **Pregnancy Outcome** form will have an outcome number =1 and the second form will have an outcome number =2, and so on).
Item 4	If the outcome is spontaneous fetal death, still birth, spontaneous abortion, therapeutic/elective abortion, or ectopic pregnancy, the outcome itself is not an adverse experience (AE). If a therapeutic/elective abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an **Adverse Experience Log** (AE), if prior to termination, with "procedure/surgery" marked under item 8, "Treatment." If there are any maternal complications as a result of the pregnancy outcome, refer to the protocol, Study-specific Procedures (SSP) manual, and *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2* for guidance on AE and expedited AE reporting requirements.
Item 4a1	"Operative vaginal" delivery includes delivery with forceps and/or vacuum.
Item 5	Include information on medical conditions associated with the outcome, including early contractions, rupture of membranes, and cramping, along with actions taken as a result of these conditions.

(MTN 029/IPM 039) DF/Net 015 (PO-2) 443

Visit Code ☐☐.☐ Outcome Number ☐

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

☐ No data recorded on this page. → *End of form.*

Pregnancy Outcome, page 2 of 2

7 Were any fetal/infant congenital anomalies identified? ☐ *yes* ☐ *no* ☐ *unknown* → *If no or unknown, go to the statement above item 8.*

7a. Congenital anomalies identified. *Mark all that apply. Complete AE Log and EAE Reporting form.*

- ☐ central nervous system, cranio-facial
- ☐ central nervous system, spinal
- ☐ cardiovascular
- ☐ renal
- ☐ gastrointestinal
- ☐ pulmonary
- ☐ musculoskeletal/extremities
- ☐ physical defect
- ☐ skin
- ☐ genitourinary
- ☐ chromosomal
- ☐ cranio-facial (structural)
- ☐ hematologic
- ☐ infectious
- ☐ endocrine/metabolic
- ☐ other

7b. Describe the congenital anomaly/defect: _____

_____

7c. Record AE Log page # *AE Log page #* ☐☐ OR ☐ *outcome occurred after termination*

Complete items 8–13 for live births only. Otherwise, end of form.

8 Infant gender ☐ *male* ☐ *female*

9 Infant birth weight ☐☐.☐ *kg* OR ☐ *unavailable*

10 Infant birth length ☐☐.☐ *cm* OR ☐ *unavailable*

11 Infant birth head circumference ☐☐.☐ *cm* OR ☐ *unavailable*

12 Infant birth abdominal circumference ☐☐.☐ *cm* OR ☐ *unavailable*

13 Infant gestational age by examination *weeks* ☐☐ *days* ☐ OR *unavailable* ☐ → *If unavailable, end of form.*

13a. Method used to determine gestational age: ☐ *Ballard* ☐ *Dubowitz* ☐ *other* *specify:* _____

Comments:

_____
Staff Initials/Date

Item-specific Instructions:

Visit Code	Record the visit code that is present on page 1 of this form.
No data recorded on this page:	This box should only be marked if the "outcome unobtainable" box is marked on page 1. This box must only be marked if all items on the page are left blank.
Outcome Number	Record the outcome number that is present on page 1 of this form.
Item 7a	If a woman on study has a baby with a congenital anomaly, report the event on an **Adverse Experience Log** (AE), if prior to termination. On the **AE Log**, record "Congenital Anomaly in Offspring" on item 1, record the Outcome Date as the Onset Date, and record the specific anomaly in Comments. Also submit an Expedited Adverse Event (EAE) Reporting form.
Items 9–12	Record the information as documented in medical records. If no medical record documentation of the information is available, complete this item based on participant report. Mark "unavailable" if no medical record documentation is available and the participant does not know the information.
Item 13	Record the infant's gestational age at birth. If the infant's gestational age is determined using the Ballard method, please record "0" in the "days" box. Mark "unavailable" if no medical record documentation of the infant's gestational age is available.

(MTN 029/IPM 039) DF/Net 015 (PR) 440

Visit Code ☐☐.☐

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number *Participant Number* *Chk*

Pregnancy Report

1	First day of last menstrual period: ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)	*OR* ☐ *amenorrhoeic for past 6 months*
2	Estimated date of delivery: ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)	
3	What information was used to estimate the date of delivery?	
	3a. last menstrual period	☐ *yes* ☐ *no*
	3b. initial ultrasound < 20 weeks	☐ *yes* ☐ *no*
	3c. initial ultrasound ≥ 20 weeks	☐ *yes* ☐ *no*
	3d. physical examination	☐ *yes* ☐ *no*
	3e. conception date by assisted reproduction	☐ *yes* ☐ *no*
	3f. other, specify: _____	☐ *yes* ☐ *no*

_____
Staff Initials/Date

General Instructions:

- Complete this form when reporting a pregnancy of a study participant post-enrollment through termination.
- A **Pregnancy Report** form is required for each new pregnancy that the participant experiences during the study.
- Record the visit code at which study staff became aware that the participant is/was pregnant.

Item-specific Instructions:

Item 1	A complete date is required. Record best estimate if date not known.
Item 2	A complete date is required.
Item 3d	Physical examination includes fundal height, uterine size by pelvic exam, and/or fetal heart rate.

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number *Participant Number* *Chk*

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Protocol Deviation Log

1	Site awareness date: ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*
2	Deviation date: ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*
3	Has or will this deviation be reported to local IRB/EC? ☐ *yes* ☐ *no*
4	Has or will this deviation be reported to DAIDS as a critical event? ☐ *yes* ☐ *no*
5	Type of deviation: ☐☐ *deviation code (See back of form for code listing.)*
6	Description of deviation: _____
7	Plans and/or action taken to address the deviation: _____
8	Plans and/or action taken to prevent future occurrences of the deviation: _____
9	Deviation reported by: ☐☐☐☐ *staff code*

_____
Staff Initials/Date

Purpose:
This form documents and reports protocol deviations identified for study participants.
General Instructions:
Complete this form each time a protocol deviation is identified. Consult the MTN Regulatory Team (mtnregulatory@mtnstopshiv.org) and the Study Management Team if you are unsure if an event requires reporting as a deviation.
Item-specific Instructions:

Page

Number pages sequentially for each participant, starting with 01. Do not re-assign page numbers if a form is marked for deletion.

Item 2

Record the date the event occurred (start date).

Item 5

Record the two-digit category code that best describes the type of deviation. Use "99" (other) if none of the listed categories match. Describe the specifics of the deviation in item 6.

Code	Description
01	Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met.
02	Failure to follow trial randomization or blinding procedures: Include instances where randomization procedures were not followed by site staff, or product blinding procedures were not followed by pharmacy staff.
03	Study product management deviation: The site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements.
04	Study product dispensing error: The wrong study product was dispensed to a participant, or study product was dispensed to a participant on product hold. Do not include any information related to study product assignment (product codes) on this form. Pharmacy staff must follow up with the MTN Pharmacist separately.
05	Study product use/non-use deviation: Participant did not use the study product (including refusals) or used it incorrectly (i.e., not in accordance with protocol requirements).
06	Study product sharing: Participant has shared study product with another person or study participant.
07	Study product not returned: Study product was not returned by the participant per protocol requirements.
08	Conduct of non-protocol procedure: A clinical or administrative procedure was performed that was not specified in the protocol, and was not covered under local standard of care practice.
09	Improper AE/EAE follow-up: Use when an AE or EAE is not followed per protocol. For example, a clinical finding/lab result is not re-assessed as outlined in the protocol.
10	Unreported AE: Site staff become aware of an AE, but do not report it per protocol requirements.
11	Unreported EAE: Site staff become aware of an EAE, but do not report it per protocol and DAIDS EAE Manual requirements.

NOT APPLICABLE FOR THIS PROTOCOL.

Code	Description
12	Breach of confidentiality: Include potential and actual cases where participant confidentiality is breached. For example, a staff member puts a participant's name on a case report form.
13	Physical assessment deviation: Include missed or incomplete physical/pelvic/breast exam assessments.
14	Lab assessment deviation: Include missed, or incomplete lab specimen collection.
15	Mishandled lab specimen: Include errors in the labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens.
16	Staff performing duties that they are not qualified to perform: Use for any instance when any study procedure, including clinical and administrative procedures, is completed by a staff member who is not adequately qualified AND delegated to perform the procedure.
17	Questionnaire administration deviation: A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed.
18	Counseling deviation: Protocol-required counseling was not done and/or not documented correctly.
19	Use of non-IRB/EC-approved materials: Include use of ANY study-related material that requires IRB or EC approval for use per site requirements.
20	Use of excluded concomitant medications, devices or non-study products
21	Informed consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process.
22	Visit completed outside of window: Use when visit procedures for a visit are done within the wrong window or not in a designated visit window. For example, use if Visit 3.0 procedures are done in the Visit 4.0 window.
99	Other

Item 6

Briefly describe the specific details of the deviation.

Item 9

Record staff code of the site staff person who completed the form. Sites will need to assign a four-digit staff code to each site staff person who will be completing this form. This list is created, maintained, and kept at the study site.

(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? ☐ *Yes* ☐ *No* → *If no, go to item 4.*

2 Was the ring removed at this visit? ☐ *Yes* ☐ *No* → *If no, end of form.*

2a. Time ring was removed: ☐☐ : ☐☐ *(24-hour clock)* (hh : mm)

2b. Who removed the ring? ☐ *Participant* ☐ *Study staff*

3 Reason ring was removed:

☐ *participant on clinical hold*

☐ *participant has been permanently discontinued from product use*

☐ *participant declined study ring use, specify:* _____

☐ *early termination*

☐ *Day 14 Visit*

☐ *other, specify:* _____

4 Was a ring inserted at this visit?

☐ *Yes–new ring inserted*

☐ *Yes–previous ring re-inserted*

☐ *No* → *If no, end of form.*

4a. Time ring was inserted: ☐☐ : ☐☐ *(24-hour clock)* (hh : mm)

4b. Who inserted the ring? ☐ *Participant* ☐ *Study staff*

Comments:

_____ *Staff Initials/Date*

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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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 (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.

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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.

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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.

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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.