Early Termination Visit Visit Month: _____

- Visit Summary (VS-1)
- Monthly Laboratory Results (MLR-1)
- Specimen Storage (SS-1)
- Ring Adherence (RA-1)
- Family Planning (FP-1)
- Ring Collection/Insertion (RCI-1)
- Quarterly Lab Results (QLR-1)
- Abbreviated Physical Exam (APX-1)
- Pelvic Exam (PE-1)
- STI Test Results (STI-1)
- PUEV Laboratory Results (PLR-1)
- Follow-up ACASI Tracking (FAT-1)
- Termination (TM-1)
- End of Study Inventory (ESI-1)
- Pelvic Exam Diagrams (non-DataFax)

Site to add:

- Behavior Assessment (BA-1, -2) – *local-language version*
- Vaginal Practices (VP-1) – *local-language version*
- Ring Worries (RW-1) – *local-language version*
- Follow-up Visit LDMS Specimen Tracking Sheet

This page intentionally left blank.

Visit Month ☐☐.☐ 1

MTN-020 ASPIRE (192) VS-1 (121)

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

Visit Date ☐☐ ☐☐☐ ☐☐ (dd / MMM / yy)

Visit Summary

1. Location of study visit — *clinic* ☐ *home* ☐ *other, specify:* ☐ _____

2. Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV? — *yes* ☐ *no* ☐ → *If yes and currently using PEP, complete Product Hold/Discontinuation Log. Record on Concomitant Medications Log.*

3. Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV? — *yes* ☐ *no* ☐ → *If no, go to item 4.*

   3a. Was oral or topical PrEP used? — *oral* ☐ *topical* ☐ *both* ☐ → *Record on Concomitant Medications Log.*

4. Is this a PUEV, early termination, or scheduled study termination visit? — *yes* ☐ *no* ☐ → *If no, go to item 5.*

   4a. Visit Type *Mark only one.* — *PUEV* ☐ *scheduled termination* ☐ *early termination* ☐ → *Go to item 6.*

5. Is this an interim visit? — *yes* ☐ *no* ☐ → *If no, go to item 6.*

   5a. Reason for interim visit *Mark all that apply.* — *AE report or follow-up* ☐ *return of ring or need for a new ring* ☐ *other, specify:* ☐ _____

   5b. Which forms, besides this form, were newly completed for this interim visit? *Mark "none" or all that apply.*

   - ☐ 5b1. None → *End of form.*
   - ☐ 5b2. Adverse Experience Log
   - ☐ 5b3. Product Hold/Discontinuation Log
   - ☐ 5b4. Ring Collection/Insertion
   - ☐ 5b5. Monthly Laboratory Results
   - ☐ 5b6. Quarterly Laboratory Results
   - ☐ 5b7. STI Test Results
   - ☐ 5b8. Pelvic Exam
   - ☐ 5b9. other, specify: _____

   After completing item 5b, end of form.

6. Were any **new** Adverse Experience Log forms completed for this visit? — *yes* ☐ *no* ☐

7. Were any **new** Product Hold/Discontinuation Log forms completed for this visit? — *yes* ☐ *no* ☐

Visit Summary (VS-1)	
Purpose:	This form is used to summarize information from each follow-up study visit performed for a participant.
General Information/ 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 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 Month:	Record the visit code assigned to the visit. For required visits (Month 1, Month 2, Month 3, etc.), simply record the visit month during which the visit falls (Month 1 = 01.0, Month 2 = 02.0, etc.). For required monthly, quarterly, and semi-annual visits, the Visit Month will end in 0 (XX.0). If the visit is an interim visit/contact, use an interim code for the Visit Month. Start with the Visit Month of the last required visit and add "1" to the right of the decimal point for each interim visit conducted. For example, if the participant's last required visit was Month 8, the interim visit would be assigned a visit code (Visit Month) of 08.1. If the participant has a second interim visit, this would be assigned a code of 08.2. 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 Month (ending in .0). For example, if a participant completes all Month 12 procedures exam pelvic exam procedures on 08-SEP-12, and completes the pelvic procedures on 10-SEP-12, assign a Visit Month of 12.0 to all forms.
Item 1:	If this contact with a participant is over the phone and results in new forms that need to be completed, mark the "other, specify" box and record "phone contact" on the line provided.
Item 2:	If the participant has taken post-exposure prophylaxis (PEP) since her last visit, mark the "yes" box. If the participant is currently using PEP, a Product Hold/Discontinuation (PH) Log must be completed.
Item 3:	Record if the participant has used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV and indicate whether oral or topical PrEP was used. If either or both were used, update the Concomitant Medications (CM) Log.
Item 4:	If the visit completed was a Product Use End Visit (PUEV), early termination, or scheduled study termination visit, mark the "yes" box. If the visit was a typical monthly, quarterly, or semi-annual visit, mark the "no" box. Note that visits where a participant is permanently discontinued from study product for clinical or protocol requirements (HIV seroconversion, for example), this is not a PUEV.
Item 4a:	Mark only one response. If the participant is terminating from the study early (she withdraws consent, for example), this is considered an early termination visit, not a PUEV. Mark scheduled study termination when the visit is the termination/study exit visit, and is being conducted after the completion of a PUEV. Once item 4a is completed, go to item 6 (it is not necessary to complete items 5 or 5a, even if the PUEV/early termination/scheduled study termination visit has an interim visit code).
Item 5b:	Mark the newly-completed forms (in addition to this form) that are being submitted for the interim visit/ contact. If "other, specify" is marked, record the form acronyms in the space provided. End the form after completing this item. Leave items 6 and 7 blank for interim visits.
Item 6:	Mark the "yes" box if at least one Adverse Experience (AE) Log was newly-completed for this visit (Visit Month in item 10 of the AE Log is the same as the Visit Month recorded on this form).
Item 7:	Mark the "yes" box if at least one Product Hold/Discontinuation (PH) Log was newly completed for this visit (Visit Month in item 1 of the PH Log is the same as the Visit Month recorded on this form).

Visit Month ☐☐.☐ 1

MTN-020 ASPIRE (192) MLR-1 (140)

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

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

Monthly Laboratory Results

1. hCG for pregnancy — Not done/ Not collected ☐ — Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐ — negative ☐ positive ☐ *If newly positive, complete Product Hold/Discontinuation Log and Pregnancy Report.*

2. Rapid HIV test 1 — Not done/ Not collected ☐ — Kit code ☐☐ — Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐ — negative ☐ positive ☐

3. Rapid HIV test 2 — Not done/ Not collected ☐ — Kit code ☐☐ — Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐ — negative ☐ positive ☐

If positive to either, complete HIV Confirmatory Results and Product Hold/Discontinuation Log.

4. Was plasma stored for HIV confirmatory testing? — yes ☐ no ☐ not required ☐ → *If no or not required, go to item 5.*

4a. Plasma for HIV confirmatory testing collection date — dd ☐☐ MMM ☐☐☐ yy ☐☐

5. Self-collected Vaginal fluid swab collection — Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐ — not required ☐ stored ☐ not stored ☐ — *Reason:* _____

If not required or not stored, end of form.

5a. Was blood visible on the swab? — yes ☐ no ☐

5b. Was a used ring in place at the time of swab collection? — yes ☐ — *no – ring removed prior to swab collection* ☐ — *no – ring not in place at start of visit* ☐ — *no – new ring inserted prior to swab collection* ☐

Comments: _____

☐☐☐☒ 26-APR-12

N:\hivnet\forms\MTN_020\forms\m020_MLR.fm

0 1 English

Staff Initials / Date _____

Monthly Laboratory Results (MLR-1)

Purpose: This form is used to document the participant's pregnancy, HIV rapid test results, and self-collected vaginal swab collection at study follow-up visits as specified in the protocol.

General Information/ Instructions: Record test results on this form as they become available. Fax this form into SCHARP DataFax once results for **all** collected specimens are recorded on the form.

- **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 (e.g., swab) 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 on the Comments lines.

Item-specific Instructions:

Items 2 and 3: Record the assigned two-digit rapid test kit code. *Note: More test kit codes may be added to the list as the study proceeds.*

Kit Code	Rapid Test
01	Determine
02	OraQuick
03	Uni-Gold Recombigen
04	StatPak

If item 2 or item 3 is positive (meaning the participant had at least one positive rapid HIV test), complete a new HIV Confirmatory Results form and a Product Hold/Discontinuation (PH) Log.

Item 4: If plasma was required but not stored for HIV confirmatory testing, record the reason on the Comments line.

Item 4a: Record the date the plasma was collected for storage for confirmatory testing.

Item 5: Record whether the vaginal fluid swab required at each monthly/quarterly/semi-annual/Product Use End Visit (PUEV) was collected. If required but not collected or stored, record reason on the line provided.

Visit Month ☐☐.☐ 1

MTN-020 ASPIRE (192) SS-1 (149)

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

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

Specimen Storage

		Alternate Collection Date dd	MMM	yy	not required	stored	not stored	Reason:
1.	Vaginal smear for gram stain:	☐☐	☐☐☐	☐☐	☐	☐	☐ →	
2.	Endocervical swab for biomarkers:	☐☐	☐☐☐	☐☐	☐	☐	☐ →	

If not required or not stored, go to item 3.

2a. Was blood visible on the swab? *yes* ☐ *no* ☐

		Alternate Collection Date dd	MMM	yy	not required	stored	not stored	Reason:
3.	Quarterly/ semi-annual/PUEV/ study exit plasma for PK:	☐☐	☐☐☐	☐☐	☐	☐	☐ →	
4.	Used vaginal ring:	☐☐	☐☐☐	☐☐	☐	☐	☐ →	

Comments: _____

☐☐☐☒ 26-APR-12

N:\hivnet\forms\MTN_020\forms\m020_SS.fm

01 English

Staff Initials / Date

Specimen Storage (SS-1)	
Purpose:	This form is used to document collection and storage of vaginal, cervical and PK specimens and used vaginal rings by the local site laboratory during follow-up.
General Information/ Instructions:	Complete this form at each quarterly, semi-annual, the Product Use End Visit (PUEV), early termination (as applicable), and Termination/Study Exit visits. • Initial Specimen Collection Date: Record the date that the first specimen(s) 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.
Item-specific Instructions:	
Items 1–4:	If the specimen is not required to be collected at this visit, mark the “not required” box. If the specimen is required to be stored, but for some reason it is not stored, mark the “not stored” box and record the reason on the line provided.

Visit Month ☐☐.☐ 1

MTN-020 ASPIRE (192) RA-1 (133)

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

Visit Date ☐☐ ☐☐☐ ☐☐ (dd / MMM / yy)

Ring Adherence

		yes	no	
1.	Did the participant have access to a vaginal ring during the past month?	☐	☐	→ *If no, end of form.*
2.	How many times in the past month has the participant had the vaginal ring out, in total?	☐☐ *times*		→ *If 00, end of form.*
3.	How many of these times was the vaginal ring out for more than 12 hours continuously?	☐☐ *times*		→ *If 00, go to item 5.*
4.	In the past month, what is the longest number of days in a row the vaginal ring was out?	☐☐ *days*		

5. In the past month, why was the vaginal ring out? *Record all codes that apply. See back of form for code listing.*

Reason Code

5a. ☐☐

5b. ☐☐

5c. ☐☐

5d. ☐☐

5e. ☐☐

5f. ☐☐

5g. ☐☐

If there is a reason that is not represented in the Reason Code list, mark item 5h or 5i, as applicable, and record the reason on the adjacent specify lines. Otherwise, leave items 5h and 5i blank.

☐ 5h. Other reason ring removed by participant or clinician, specify: _____

_____

☐ 5i. Other reason ring came out on its own, specify: _____

_____

Comments: _____

_____

☐☐☐☒ 30-JUL-13

01 English

Staff Initials / Date

Ring Adherence (RA-1)

Purpose:	This form is used to document the participant's self-reported study ring use during follow-up.
General Information/ Instructions:	Complete this form at each monthly, quarterly and semi-annual follow-up visits, as well as the Product Use End Visit (PUEV), and at an early termination visit, as applicable. Complete at these visits even if the participant has been on product hold or has been permanently discontinued from ring use. All items on this form refer to ring access and use during the past month only, regardless of whether or not the participant missed her last monthly visit.

Item-specific Instructions:

Item 1:	Mark "no" if the participant did not have a ring in her possession during the past month. Mark "yes" if the participant had access to a vaginal ring, regardless of how long ago the ring was dispensed, and regardless of whether or not the participant used the ring. For example, a participant is dispensed a ring at her Month 1 Visit. She misses her Month 2 Visit, but returns for her Month 3 Visit. At her Month 3 Visit, mark "yes" since the participant had in her possession for the past month the ring that was dispensed at her Month 1 Visit.
Item 2:	The purpose of this question is to capture all instances in the past month when the ring was expelled, or was removed other than at regularly scheduled study visits. Do not count instances when the ring was removed at a regularly scheduled visit to insert a new ring.
Item 4:	When determining the longest number of days in a row, include partial days as a day. For example, if a participant reports she removed the ring on a Wednesday and re-inserted it on a Friday, count this as 3 days (Wednesday, Thursday, Friday). This item should be an over-estimate rather than an exact or under-estimate.
Item 5:	Refer to the list of Reason Codes below. Record the two-digit code that corresponds to each reason the vaginal ring was out during the past month (because the participant or clinician removed the ring, or ring expulsion occurred). Up to seven Reason Codes may be recorded (items 5a-5g). A Reason Code is required for item 5a. Record any additional reason codes in items 5b-5g; leave any unused items blank. For example, if three Reason Codes apply, record the codes in items 5a-5c and leave items 5d-5g blank.

REASONS RING REMOVED BY PARTICIPANT OR CLINICIAN

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; includes ring removals at Day 35
31	**Product permanently discontinued:** Participant permanently discontinued from product
32	**Procedure:** Ring removed for clinical procedure (e.g., IUCD insertion, pelvic exam) 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

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

Visit Month ☐☐.☐ 1

MTN-020 ASPIRE (192) FP-1 (155)

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

Visit Date ☐☐ ☐☐☐ ☐☐ (dd / MMM / yy)

Family Planning

1. What method(s) of contraception/family planning has the participant used since her last visit? *Mark "none" or all that apply.*

- ☐ 1a. none
- ☐ 1b. spermicide
- ☐ 1c. diaphragm
- ☐ 1d. sponge
- ☐ 1e. intrauterine device (IUD)
- ☐ 1f. oral contraceptives/birth control pills
- ☐ 1g. injectable contraceptives (such as Depo-Provera)
  - 1g1. Type: ☐ *Depo* ☐ *Depo subq* ☐ *NET-EN* ☐ *Cyclofem* ☐ *other*
- ☐ 1h. (Ortho Evra) The Patch
- ☐ 1i. implants
- ☐ 1j. female condoms
- ☐ 1k. natural methods such as the withdrawal or rhythm method
- ☐ 1l. male condoms
- ☐ 1m. sterilization (tubal ligation/hysterectomy/laparoscopy/other surgical procedure that causes sterilization)
- ☐ 1n. sex with partner who had a vasectomy
- ☐ 1o. other, specify: _____

Update Concomitant Medications Log, as needed.

2. Has the participant had or started her menstrual period since her last visit? ☐ *yes* ☐ *no* → *If no, end of form.*

2a. First day of last menstrual period ☐☐ ☐☐☐ ☐☐ (*dd* / *MMM* / *yy*)

2b. Last day of last menstrual period ☐☐ ☐☐☐ ☐☐ (*dd* / *MMM* / *yy*) OR ☐ *ongoing*

Comments: _____

☐ ☐ ☐ ☒ 26-APR-12

0 1 English

Staff Initials / Date

Family Planning (FP-1)	
Purpose:	This form is used to document the methods of contraception/family planning used by the participant during study follow-up. It is completed at each monthly, quarterly, and semi-annual follow-up visits, as well as at the Product Use End Visit (PUEV), and at an early termination visit, as applicable.
Item-specific Instructions:	
Item 1:	Mark any method(s) of contraception/family planning the participant reports using since her last monthly study visit. If any response boxes for items 1e–1i are marked, update the Concomitant Medications (CM) Log as needed.
Item 1g1.:	Mark the specific type of injectable contraception used by the participant. • Depo for Depo Provera (DMPA, also known as Petogen) injected into the muscle. • Depo subq: mark when the sub-cutaneous route of Depo is used. • NET-EN: also known as Mesigyna. • Cyclofem: also known as Lunelle.
Item 2a:	The first day of the last menstrual period is the first day of bleeding.
Item 2b:	The last day of the last menstrual period is the last day of bleeding.

Visit Month ☐☐.☐ 1

MTN-020 ASPIRE (192) RCI-1 (135)

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

Visit Date ☐☐ ☐☐☐ ☐☐ (dd / MMM / yy)

Ring Collection/Insertion

1. Did the participant have a ring in place at the start of the visit? ☐ yes ☐ no → *If yes, go to item 2.*

   1a. When was the ring last in place? dd ☐☐ MMM ☐☐☐ yy ☐☐ OR ☐ not applicable *(ring not in place since last visit)*

2. Number of used rings collected ☐ none ☐ 1 ☐ 2 ☐ 3 → *If "1," go to item 3.*

   2a. If none, 2, or 3, specify reason: _____

3. Number of unused (never inserted) rings collected ☐ none ☐ 1 ☐ 2 ☐ 3

4. Number of new rings dispensed to participant: ☐ none ☐ 1 ☐ 2 ☐ 3 → *Go to item 5.*

   4a. Reason ring not dispensed
   - ☐ participant on clinical hold
   - ☐ participant has been permanently discontinued from product
   - ☐ participant declined study ring, specify: _____
   - ☐ scheduled PUEV
   - ☐ early termination
   - ☐ other, specify: _____

   → *Go to item 7.*

5. Was a new ring inserted at this visit? ☐ yes ☐ no → *If no, go to item 6.*

   5a. Who inserted the new ring? ☐ participant ☐ study staff

6. Was a ring in place at the end of the visit? ☐ yes ☐ no → *If yes, go to item 7.*

   6a. Reason ring not in place at end of visit
   - ☐ participant declined to have ring inserted
   - ☐ participant had to leave before ring could be inserted
   - ☐ other, specify: _____

7. Appearance of most recently-used ring: ☐ *used* ☐ *not used* ☐ *not sure* ☐ *no ring*

☐ ☐ ☒ ☐ 27-FEB-13

N:\hivnet\forms\MTN_020\forms\m020_RCI.fm

01 English

Staff Initials / Date

Ring Collection/Insertion (RCI-1)	
Purpose:	This form is used to document rings that are inserted and collected for each participant for the duration of the study.
General Information/ Instructions:	Complete this form at each monthly, quarterly, and semi-annual follow-up visits, as well as at the Product Use End Visit (PUEV), and at early termination visit, as applicable. Complete at interim visits as needed. If the participant has been permanently discontinued from study product, this form is not required to be completed at visits following the permanent discontinuation.
Item-specific Instructions:	
Item 1a:	If the vaginal ring was not in place at the start of the visit, record the date the vaginal ring was last in place over the past month. If the participant is unable to recall the exact date, obtain the participant's best estimate. At a minimum, the month and year are required. If the ring was not in place at any time since this form was last completed, mark the “not applicable” box.
Item 2a:	If no rings were collected (returned), specify the reason why (for example, participant forgot, or participant had no dispensed rings to return). If two or three rings were collected, specify reason why (specify why examples include: two rings were dispensed at last visit, or participant returned one recently-dispensed ring along with a ring dispensed at 3 months, but never returned).
Item 4:	Only document ring(s) dispensed and given to the participant.
Item 4a:	If participant declined to have a ring dispensed to her, record a brief reason for her decline on the line provided. If the reason for her decline is due to or associated with an adverse event, document the adverse event on an Adverse Experience (AE) Log and note in the AE Log Comments that the participant declined the ring because of the AE.
Item 7:	Document the clinic staff’s assessment of the appearance of the participant’s most recently-used ring. Base this assessment only on the appearance of the ring, do not factor in the participant’s reported use of the ring or other information when marking a response. If no ring was returned (item 2 of this form is “none”), mark “no ring” to indicate no ring was available for this assessment at this visit. If 2 or more rings are collected, record the appearance of the ring most recently-used by the participant.

Visit Month ___.___ 1

MTN-020 ASPIRE (192) QLR-1 (144)

Participant ID ___ - ___ - ___
Site Number / Participant Number / Chk

Initial Specimen Collection Date ___ ___ ___ ___
dd MMM yy

Quarterly Laboratory Results

1. Hemogram — *Go to item 2.* ← Not done/ Not collected ☐ — Alternate Collection Date *dd* ___ *MMM* ___ *yy* ___

Not reported ☐ 1a. Hemoglobin ___.___ *g/dL* — Severity Grade *(if applicable)* ___ — *AE Log page #* ___ — OR *not reportable as an AE* ☐

Not reported ☐ 1b. Hematocrit ___.___ *%*

Not reported ☐ 1c. MCV ___.___ *fL*

Not reported ☐ 1d. Platelets ___.___ *x10³/mm³* — Severity Grade *(if applicable)* ___ — *AE Log page #* ___ — OR *not reportable as an AE* ☐

Not reported ☐ 1e. WBC ___.___ *x10³/mm³* — ___ — OR ☐

Differential ☐ Not done → *Go to item 2.*

Not reported ☐ 1f. Neutrophils — Absolute Count ___ *cells/mm³* — Severity Grade *(if applicable)* ___ — *AE Log page #* ___ — OR *not reportable as an AE* ☐

Not reported ☐ 1g. Lymphocytes ___ *cells/mm³* — ___ — OR ☐

Not reported ☐ 1h. Monocytes ___ *cells/mm³*

Not reported ☐ 1i. Eosinophils ___ *cells/mm³*

Not reported ☐ 1j. Basophils ___ *cells/mm³*

2. Chemistries — *End of form.* ← Not done/ Not collected ☐ — Alternate Collection Date *dd* ___ *MMM* ___ *yy* ___

Not reported ☐ 2a. AST (SGOT) ___ *U/L* — Severity Grade *(if applicable)* ___ — *AE Log page #* ___ — OR *not reportable as an AE* ☐

Not reported ☐ 2b. ALT (SGPT) ___ *U/L* — ___ — OR ☐

Not reported ☐ 2c. Creatinine ___.___ *mg/dL* OR ___.___ *µmol/L* — Severity Grade *(if applicable)* ___ — *AE Log page #* ___ — OR *not reportable as an AE* ☐

☐ ☐ ☐ ☒ 20-SEP-12

0 1 English

Staff Initials / Date

Quarterly Laboratory Results (QLR-1)

Purpose:	This form is used to provide data on the participant's quarterly laboratory test results.
General Information/ Instructions:	Use this form to report the hematology, differential, and liver and renal function test results obtained from specimens collected at quarterly and semi-annual, the Product Use End Visit (PUEV), and early termination (as applicable) visits as they become available. • 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. 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.
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-020 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/μL For creatinine, only record the result in the units listed on the source document. • 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 11.06 g/dL would be recorded as 11.1 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 results. If a value is below severity grade 1, leave the "Severity Grade," "AE Log page #," and "not reportable as an AE" boxes 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 Adverse Experience (AE) Log as applicable.

Visit Month ___.___ 1

MTN-020 ASPIRE (192) APX-1 (136)

Participant ID ___-_____-___ (Site Number – Participant Number – Chk)

Visit Date ___ ___ ___ (dd MMM yy)

Abbreviated Physical Exam

VITAL SIGNS

1. Weight ___ *kg*
2. Body Temp ___.___ °C
3. BP ___ / ___ *mmHg*
4. Pulse ___ *beats per minute*
5. Respirations ___ *breaths per minute*

SYMPTOM-DIRECTED FINDINGS *Items 6 and 7 are required assessments. Other items assessed if clinically indicated.*

		not done	*normal*	*abnormal*	*Notes:*
6.	General appearance	☐	☐	☐	
7.	Abdomen/ Gastrointestinal	☐	☐	☐	
8.	Neck	☐	☐	☐	
9.	Lymph Nodes	☐	☐	☐	
10.	Heart/ Cardiovascular	☐	☐	☐	
11.	Lungs/ Respiratory	☐	☐	☐	
12.	Extremities	☐	☐	☐	
13.	Neurological	☐	☐	☐	
14.	Skin	☐	☐	☐	
15.	Eyes	☐	☐	☐	
16.	Ears, Nose, Throat	☐	☐	☐	
17.	Other	☐	☐	☐	

Record abnormal findings on the Adverse Experience Log or Grade 1 Adverse Experience Log, if applicable.

Abbreviated Physical Exam (APX-1)	
Purpose:	This form is used to document the participant's vital signs and physical exam findings at study follow-up visits as specified in the protocol.
General Information/ Instructions:	Complete this form at quarterly, semi-annual, the Product Use End Visit (PUEV), and at an early termination visit, as applicable.
Item-specific Instructions:	
Vital Signs:	Use leading zeros when needed.
Items 6–7:	These items are required to be assessed at each quarterly, semi-annual, and the PUEV or early termination visit.
Items 8–17:	For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings on the Notes line. If not evaluated, mark the "not done" box.
Item 17:	If abnormal, specify the body system being referenced and describe the findings on the Notes line.

Visit Month ☐☐.☐ 1

MTN-020 ASPIRE (192) PE-1 (138)

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

Exam Date ☐☐ ☐☐☐ ☐☐ (dd MMM yy)

Pelvic Exam

1. Pelvic exam assessment: ☐ not done ☐ abnormal findings ☐ no abnormal findings → *If no abnormal findings, go to item 2.*
   → *If not done, end of form.*

1a. 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)	☐ adnexal masses (based on bimanual exam; not pregnancy or infection-related)
☐ vulvar tenderness	☐ vaginal abrasions or lacerations	☐ cervical motion tenderness	☐ uterine masses (based on bimanual exam)
☐ Bartholin's or Skene's gland abnormality	☐ vaginal tenderness	☐ cervical discharge	☐ uterine tenderness
Vulvar lesions	Abnormal vaginal discharge	Cervical lesions	☐ adnexal tenderness
☐ ulcer	☐ slight	☐ ulcer	☐ observed blood or bleeding; describe:
☐ blister	☐ moderate	☐ blister	_____
☐ pustule	☐ pooling	☐ pustule	_____
☐ peeling	Vaginal lesions	☐ peeling	_____
☐ ecchymosis	☐ ulcer	☐ ecchymosis	_____
	☐ blister		_____
	☐ pustule		
	☐ peeling		
	☐ ecchymosis		

☐ 1b. Other abnormal findings, specify (include anatomical location): _____

Complete or update Adverse Experience Log as applicable.

2. Were any new pelvic finding AEs reported at this visit? ☐ yes ☐ no → *If no, go to item 3.*

2a. AE Log page (#)s: ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

3. Cervical ectopy: ☐ 0% ☐ 1–25% ☐ 26–50% ☐ 51–75% ☐ 76–100%

☐☐☐☒ 26-APR-12

01 English

Staff Initials / Date

Pelvic Exam (PE-1)	
Purpose:	This form is used to document the participant's pelvic exam assessment during study follow-up.
General Information/ Instructions:	Complete this form at each semi-annual visit, the Product Use End Visit (PUEV), at early termination visit (as applicable), and when a as clinically indicated pelvic exam is performed during follow-up. Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to DataFax.
Item-specific Instructions:	
Item 1:	Note that observation of any genital blood or bleeding is considered an abnormal finding, regardless of whether the blood is expected (menstrual blood, for example). If blood or bleeding is observed, mark the "abnormal findings" box and in item 1a, mark the "observed blood or bleeding; describe" box and describe on the lines provided.
Item 1a:	Mark the box to the left of each abnormal finding observed. If an observed abnormal finding is not listed, mark the "other abnormal findings, specify" box 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 1a as AE descriptive text finding (this does not apply to observances of blood or bleeding). Observed blood or bleeding; describe: If 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. Per Study-specific Procedures (SSP) manual section 10.6, all bleeding occurring during follow-up that is different from the participant's baseline bleeding pattern is an AE. This may include unusually heavy or prolonged menses, as well as non-menstrual bleeding different from baseline. Each instance of observed 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 SSP manual section 10.6 for more information/guidance as needed.

Visit Month ☐☐.☐ 1

MTN-020 ASPIRE (192) STI-1 (190)

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

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

STI Test Results

		Not done/ Not collected	Alternate Collection Date dd MMM yy	negative	positive
1.	Vaginal Wet Prep	☐ *Go to item 2.*	☐☐ ☐☐☐ ☐☐		
☐ Not done	1a. Homogeneous vaginal discharge			☐	☐
☐ Not done	1b. pH ☐.☐ → *If > 4.5, mark as positive.*				☐
☐ Not done	1c. Whiff test			☐	☐
☐ Not done	1d. Clue cells ≥ 20%			☐	☐
☐ Not done	1e. *Trichomonas vaginalis*			☐	☐
☐ Not done	1f. Buds and/or hyphae (yeast)			☐	☐
2.	Trichomonas Rapid Test	☐	☐☐ ☐☐☐ ☐☐	☐	☐
3.	*N. gonorrhoeae*	☐	☐☐ ☐☐☐ ☐☐	☐	☐
4.	*C. trachomatis*	☐	☐☐ ☐☐☐ ☐☐	☐	☐

Complete or update Adverse Experience Log, if applicable.

Comments: _____

☐☐☐☒ 26-APR-12

N:\hivnet\forms\MTN_020\forms\m020_STI.fm

01 English

_____ Staff Initials / Date

STI Test Results (STI-1)	
Purpose:	This form is used to document Vaginal Wet Prep and STI Test Results by the local site laboratory.
General Information/ Instructions:	Complete this form at each semi-annual visit, the Product Use End Visit (PUEV), at early termination (as applicable), and at other visits where these tests are performed during follow-up. • 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. 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 on the Comments lines.
Item-specific Instructions:	
Items 1–4:	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 (AE) Log.
Item 1:	If a vaginal wet prep was performed but not all assays were completed, mark the “Not done/Not collected” box for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason on the Comments lines.
Item 1a:	Mark the “positive” box if homogeneous vaginal discharge was observed.
Item 1b:	Vaginal fluid pH is required at all semi-annual visits and the PUEV.
Item 1d:	Mark the “positive” box if 20% or more of the cells were clue cells.
Item 1e:	Mark the “positive” box if trichomonads were observed.
Item 1f:	Mark the “positive” box if yeast buds and/or hyphae were observed.

Visit Month ☐☐.☐ 1

MTN-020 ASPIRE (192) PLR-1 (193)

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

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

PUEV Laboratory Results

1. PAP SMEAR — Not done/ Not collected ☐ → *Go to item 2.*

Alternate Collection Date: *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

- ☐ negative for intraepithelial lesion or cancer (malignancy)
- ☐ ASCUS
- ☐ ASC-H
- ☐ SIL-low grade (LSIL)
- ☐ SIL-high grade (HSIL)
- ☐ AGC
- ☐ AGC-favor neoplastic
- ☐ cancer

2. SYPHILIS SEROLOGY — *Go to item 3.* Not done/ Not collected ☐

Alternate Collection Date: *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

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

2a1. Syphilis titer — **1:** ☐☐☐☐

2b. Syphilis confirmatory test — *negative* ☐ *positive* ☐ *indeterminate* ☐

3. Were any new AE Log pages completed based on results recorded on this form? — *yes* ☐ *no* ☐ → *If no, end of form.*

3a. AE Log page number(s) ☐☐☐ ☐☐☐

Complete or update Adverse Experience Log, if applicable.

PUEV Laboratory Results (PLR-1)	
Purpose:	This form is used to document results of Pap specimens and Syphilis serology collected during the Product Use End Visit (PUEV).
General Information/ Instructions:	This form is completed at the PUEV. It is also completed at an early termination visit, if applicable. Record test results on this form as they become available. If the Pap test result indicates that the participant has a condition requiring further evaluation, record the result on the Adverse Experience (AE) Log. Do not use this Pap smear to diagnose STIs, such as Trichomoniasis. • Initial Specimen Collection Date: Record the date that the first specimen(s) 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.
Item-specific Instructions:	
Item 1:	Record the Pap Smear result. Mark only one box. • Negative for intraepithelial lesion or cancer (malignancy): Includes all normal findings and any findings of infection (trichomonas, candida, etc.), reactive changes/inflammation, glandular changes due to hysterectomy, or atrophic changes. • ASCUS: Mark this box when abnormal/atypical squamous cells of undetermined significance are reported. • ASC-H: Mark this box when abnormal/atypical squamous cells that cannot exclude high-grade squamous intraepithelial lesions (HSIL) are reported. • SIL-low grade (LSIL): Mark this box when low-grade squamous interepithelial lesions are reported. This category includes presence of human papillomavirus (HPV) infection, mild dysplasia, and cervical interepithelial neoplasia (CIN 1). • SIL-high grade (HSIL): Mark this box when high-grade squamous interepithelial lesions are reported. This category includes the presence of moderate to severe dysplasia, carcinoma in situ (CIS), CIN 2, and CIN 3, or changes suspicious for invasive cancer. • AGC: Mark this box when atypical/abnormal glandular cells are reported. This category includes endocervical (from cervical canal) atypical cells; endometrial atypical cells; glandular atypical cells. • AGC-favor neoplastic: Mark this box when atypical/abnormal glandular cells that favor cell growth (neoplastic changes) are reported. This category includes endocervical cells and glandular cells. • Cancer: Mark this box when cancer or adenocarcinoma is reported. This includes endocervical, endometrial, extrauterine, and other (not specified) cancers/adenocarcinomas.
Item 2:	If the syphilis screening test is reactive, items 2a1 and 2b must be completed.
Item 2a1:	Use leading zeros when recording a syphilis titer level. For example, a titer level of 1:16 would be recorded on the form as “1:0016.”
Item 2b:	If a result is positive, provide treatment according to WHO guidelines, and report the relevant infection on the AE Log.

Visit Month ☐☐.☐ 1

MTN-020 ASPIRE (192) FAT-1 (153)

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

Visit Date ☐☐ ☐☐☐ ☐☐ (dd / MMM / yy)

Follow-up ACASI Tracking

1. Was an ACASI questionnaire completed at this visit? *yes* ☐ *no* ☐ → *If no, record reasons in Comments. End the form.*

1a. Which questionnaire was completed? *Month 3* ☐ *PUEV/Discontinuers* ☐ → *If Month 3, go to item 2.*

1b. Reason PUEV/Discontinuers ACASI questionnaire was completed: *scheduled PUEV* ☐ *early termination* ☐ *permanent product discontinuation prior to PUEV/early termination* ☐

2. Were there any problems or issues related to the administration or completion of the questionnaire? *yes* ☐ *no* ☐ → *If no, end of form.*

2a. Describe:

_____

_____

_____

Comments: _____

_____

_____

☐☐☐☒ 26-APR-12

N:\hivnet\forms\MTN_020\forms\m020_FAT.fm

0 1 English

Staff Initials / Date

Follow-up ACASI Tracking (FAT-1)	
Purpose:	This form is used to document participant completion of the Audio Computer-assisted Self Interview (ACASI) computerized questionnaires during follow-up.
General Information/ Instructions:	Complete this form at the Month 3 Visit. Also complete this form at the participant's Product Use End Visit (PUEV) or early termination visit. Additionally, complete this form (and the PUEV/Discontinuers ACASI questionnaire) if participant is permanently discontinued from study product (as documented by a Product Hold/Discontinuation Log).
Item-specific Instructions:	
Item 2a:	Use this space to describe when and why multiple ACASI questionnaires are completed for a participant at a visit. If there were any unusual details related to the ACASI questionnaire administration or completion, describe them here.

MTN-020 ASPIRE (192) TM-1 (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, *indicate date and cause if known*
  - 2b1. date of death: dd MMM yy — *date unknown* OR ☐
  - 2b2. cause of death: _____ — *cause unknown* OR ☐
  - → *Complete or update Adverse Experience Log.*
- ☐ 2c. participant refused further participation, specify: _____
- 2d. NOT APPLICABLE FOR THIS PROTOCOL.
- ☐ 2e. participant relocated, no follow-up planned
- ☐ 2f. investigator decision, specify: _____
- ☐ 2g. unable to contact participant
- 2h. NOT APPLICABLE FOR THIS PROTOCOL.
- ☐ 2i. inappropriate enrollment → *End of form.*
- ☐ 2j. invalid ID due to duplicate screening/enrollment → *End of form.*
- ☐ 2k. other, specify: _____
- ☐ 2l. early study closure

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

3a. Record AE Log page number *AE Log page #* ___ OR Specify: _____

Comments: _____

☐ ☐ ☐ ☒ 26-APR-12

0 1
English

Staff Initials / Date

Termination (TM-1)	
Purpose:	This form should be 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:	Scheduled exit visit/end of study: Only mark 2a if the participant completes the protocol-defined final visit.
Item 2b1:	At a minimum, the month and year are required.
Item 2l:	Early study closure: 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.

MTN-020 ASPIRE (192) ESI-1 (489)

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

Form Completion Date ___ ___ ___
dd MMM yy

End of Study Inventory

1. Did the participant complete her scheduled study exit (4-week post-product use) visit? ☐ *yes* ☐ *no*

2. What is the **highest** visit month (scheduled or interim) for this participant, recorded on a form submitted via DataFax? ___.___ *visit month*

3. How many interim visits were conducted for this participant during the study and recorded on a form submitted via DataFax? ___ *# of interim visits*

4. Indicate the **highest** page number submitted for this participant for each of the following forms:

4a.	Adverse Experience Log (AE)	___ *page #*	OR	☐	*no pages submitted*
4b.	Concomitant Medications Log (CM)	___ *page #*			
4c.	Pre-existing Conditions (PRE)	___ *page #*			
4d.	Product Hold/Discontinuation Log (PH)	___ *page #*	OR	☐	*no pages submitted*
4e.	Social Impact Log (SIL)	___ *page #*	OR	☐	*no pages submitted*
4f.	Protocol Deviations Log (PDL)	___ *page #*	OR	☐	*no pages submitted*
4g.	Grade 1 Adverse Experience Log (GAE) *Record highest page number completed.*	___ *page #*	OR	☐	*no pages completed*

Comments: _____

☐ ☐ ☐ ☒ 26-APR-12

0 1
English

Staff Initials / Date

End of Study Inventory (ESI-1)	
Purpose:	This form is used to confirm that SCHARP has received all study data for a given participant.
General Information/ Instructions:	Complete this form once for each enrolled participant after the participant has terminated from the study (as documented by a Termination form).
Item-specific Instructions:	
Form Completion Date:	A complete date is required.
Item 2:	Record the highest visit month (last visit for which DataFax forms were submitted). If the participant's last visit was missed (as documented by a Missed Visit form), record the visit month of the missed visit.
Item 3:	Record the total number of interim visits documented on the Visit Summary DataFax forms submitted for this participant. If no interim visits were completed for the participant, record "000" in the boxes.
Item 4a, 4d, and 4e:	Record the highest page number of the Adverse Experience Log, Product Hold/Discontinuation Log, Protocol Deviations Log, and Social Impact Log submitted for this participant, even if that page was marked for deletion.
Item 4g:	Record the highest page number completed for the Grade 1 Adverse Experience Log. Complete this item even though these forms are not faxed to SCHARP.

Not a DataFax form. Do not fax to DataFax.

MTN-020 ASPIRE (192)

Pelvic Exam Diagrams

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

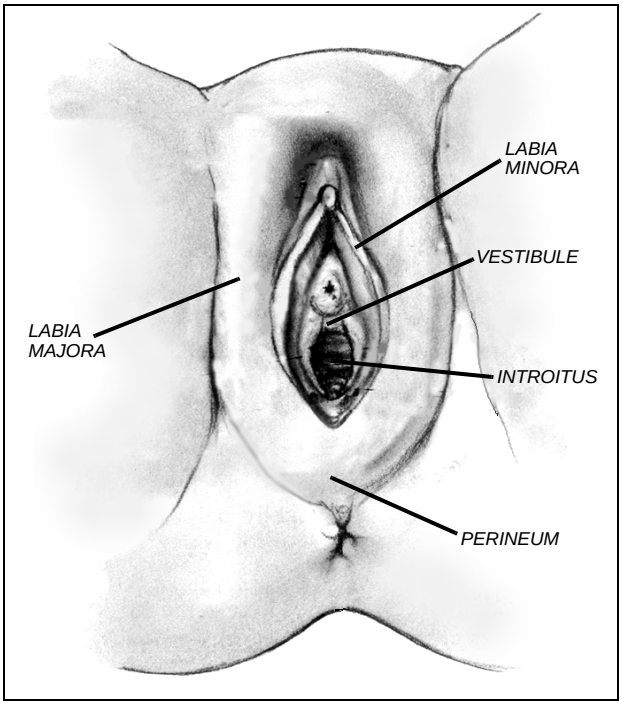
Exam Date ___ ___ ___ (dd MMM yy)

☐ no normal variants or abnormal findings observed

Speculum Type (screening only) *Pederson* ☐ *Graves* ☐ *Cusco* ☐

Speculum Size (screening only) *small* ☐ *medium* ☐ *large* ☐

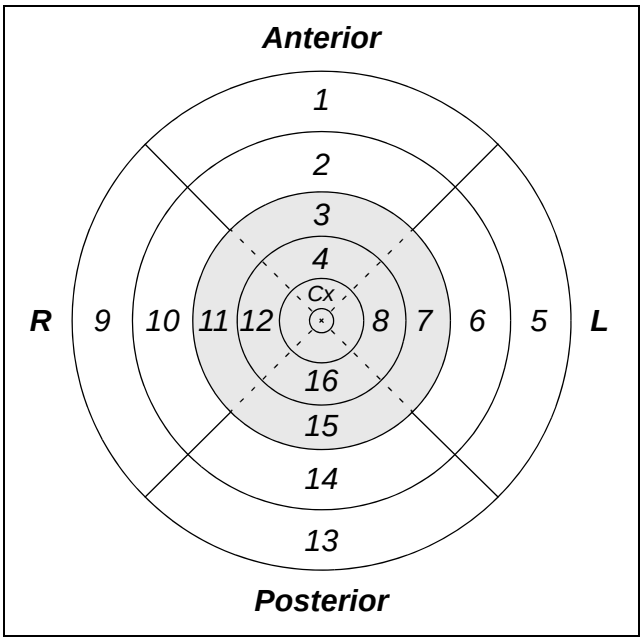
External Genitalia



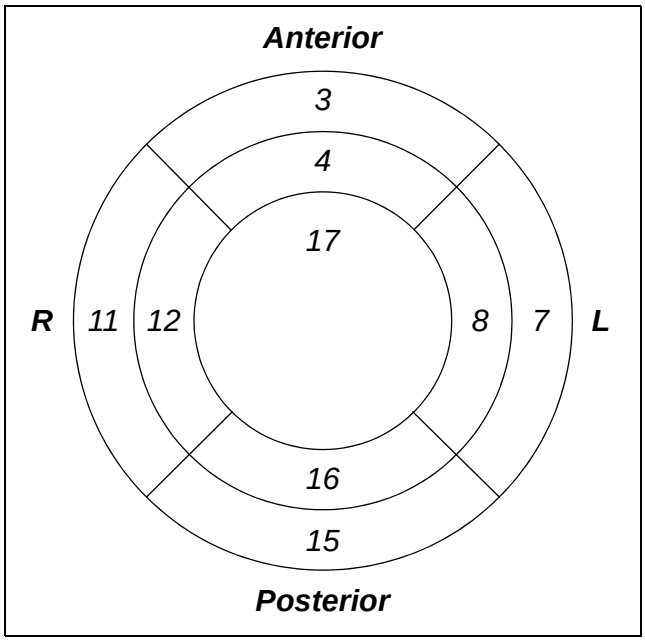
Legend for Vagina/Cervix

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



Cervix



☐ ☐ ☐ ☒ 26-APR-12

N:\hivnet\forms\MTN_020\forms\m020_nonDF_PE_diagrams.fm

0 1 English

Staff Initials / Date

Pelvic Exam Diagrams (non-DataFax)	
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 Information/ Instructions:	This form is completed at the Screening Visit, each semi-annual visit, at the Product Use End Visit (PUEV), and whenever a pelvic exam is clinically indicated during the study. This is a non-DataFax form and should not be faxed to SCHARP 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: • anatomic variants • gland openings • Nabothian cysts • mucus retention cysts • Gartner's duct cysts • blood vessel changes other than disruption • skin tags • scars 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).