Subject Case Report Forms

MTN038_Version_3.0_PROD_13FEB2019 - ALL

Signature Prompt: I certify that I have ensured the accuracy and completeness of the data reported in the Case Report Forms.

Screening visit date _____

Did the participant complete this visit?

Yes ☐
No ☐

MTN038_Version_3.0_PROD_13FEB2019: ALL
Form: Follow-up Visit Summary
Generated On: 26 Feb 2019 18:53:29

Visit date	
Was study product permanently discontinued (scheduled or early) at this visit?	Yes ☐ No ☐
Was study product held at this visit?	Yes ☐ No ☐
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit?	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported?	Yes ☐ No ☐
Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV?	Yes ☐ No ☐
Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV?	Yes ☐ No ☐
Were any protocol deviations reported at this visit?	Yes ☐ No ☐
Were any additional study procedures or forms completed outside of the scheduled study visit per protocol?	Yes ☐ No ☐
Source Document Upload	

Visit date	_____
Interim visit code	_____
Was study product held at this visit?	Yes ☐ No ☐
Was study product use permanently discontinued (scheduled or early) at this visit?	Yes ☐ No ☐
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit?	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported?	Yes ☐ No ☐
Were any protocol deviations reported at this visit?	Yes ☐ No ☐
Reason for interim visit (Select all that apply.)	
AE report or follow-up	☐
Return of product or need new product	☐
Completion of missed visit procedures	☐
If completion of missed visit procedures, for which visit are procedures being made up?	Visit 3 ☐ Visit 4 ☐ Visit 5 ☐ Visit 6 ☐ Visit 7 ☐ Visit 8 ☐ Visit 9 ☐ Visit 10 ☐ Visit 11 ☐
Other	☐
If other, specify	_____
What study procedures were completed at this visit? Select all that apply.	
Vital signs	☐
Physical exam	☐
Pelvic exam	☐
Specimen storage	☐
Timed Specimen Storage	☐
Cervical Specimen Storage	☐

Timed Cervical Specimen Storage	☐
Pregnancy Test Results	☐
Hematology	☐
Chemistry Panel	☐
HIV Test Results	☐
STI Test Results	☐
Behavioral Summary	☐
Ring Insertion or Removal	☐
Ring Adherence YN	☐
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MTN038_Version_3.0_PROD_13FEB2019: ALL
Form: Missed Visit
Generated On: 26 Feb 2019 18:53:29

Target Visit Date	
Reason visit was missed	Unable to contact participant ☐ Unable to schedule appointment(s) within window ☐ Participant refused visit ☐ Participant incarcerated ☐ Participant admitted to a health care facility ☐ Participant withdrew from the study ☐ Participant deceased ☐ Other ☐
If other, specify	
Steps taken to address the missed visit (corrective action plan)	
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Is the participant ready to be randomized?	Yes ☐ No ☐
Randomization Date and Time	
Randomization ID	
Source Document Upload	

Did the participant consent to long-term specimen storage and future testing?	Yes ☐ No ☐
Treatment arm	TFV Ring ☐ Placebo Ring ☐
Was the participant randomized to participate in IDI (In Depth Interview)?	Yes ☐ No ☐
Was the participant invited to participate in IDIs?	Yes ☐ No ☐
Will this participant participate in IDIs?	Yes ☐ No ☐
Biopsy schedule assignment	Day 14 and Day 56 ☐ Day 28 and Day 91 ☐
What is the CASI ID assigned to this participant?	_____
Source Document Upload	_____

MTN038_Version_3.0_PROD_13FEB2019: ALL
Form: Additional Study Procedures
Generated On: 26 Feb 2019 18:53:29

What study procedures were completed at this visit:	
CASI and/or IDI	☐
Vital Signs	☐
Physical Exam	☐
Pelvic Exam	☐
Pregnancy Test Results	☐
STI Test results	☐
HIV Test Results	☐
Hematology	☐
Chemistry Panel	☐
Timed Specimen Storage	☐
Cervical Specimen Storage	☐
Timed Cervical Specimen Storage	☐
Ring Insertion and Removal	☐
Specimen Storage	☐
Ring Adherence	☐
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Has the participant experienced an adverse event during the study?	Yes ☐ No ☐

If "Yes", complete the Adverse Event log.

Date AE reported to site	_____
Adverse event (AE)	_____
Onset date	_____
Is the AE still ongoing?	Yes ☐ No ☐
If "No", outcome date	_____
Severity grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Grade 5 (Death) ☐
Relationship to study product	Related ☐ Not related ☐
Action taken with study product	Dose not changed ☐ Dose reduced ☐ Dose increased ☐ Drug withdrawn ☐ Drug interrupted ☐ Not applicable ☐
Other actions Mark "None" or all that apply. None	☐
Medication(s)	☐
Therapeutic procedure/surgery	☐
Diagnostic procedure	☐
Referral	☐
Other	☐
If "Other", specify (max. 200 characters)	_____
Status/outcome	Recovered/resolved ☐ Recovering/resolving ☐ Recovered/resolved with sequelae ☐ Not recovered/not resolved ☐ Fatal ☐ Severity/frequency increased ☐

Is this a serious adverse event according to ICH/GCP or protocol guidelines? If "No", go to "Has or will this AE be reported as an EAE?"..	Yes ☐ No ☐

If "Yes", check all that apply.

Results in death	☐
Is life-threatening	☐
Requires inpatient hospitalization or prolongation of existing hospitalization	☐
Results in persistent or significant disability/incapacity	☐
Is a congenital anomaly/birth defect	☐
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	☐
Has or will this AE be reported as an EAE? If "Yes", provide EAE number below.	Yes ☐ No ☐
EAE number. Begin number with 4-digit year, followed by 6-digit EAE number (no dashes or spaces).	_____
Was this AE a worsening of a baseline medical condition?	Yes ☐ No ☐
Comments (max. 450 characters)	_____
Source Document Upload	_____

Were any concomitant medications taken?	Yes ☐ No ☐

If "Yes", complete the Concomitant Medications log.

Medication name _____

Indication _____

Date started _____

Date stopped _____

OR ☐

Ongoing

Dose _____

Dose units

- ☐ Grams
- ☐ Micrograms
- ☐ Milligrams
- ☐ Milliliters
- ☐ Capsules
- ☐ Drops
- ☐ Puffs
- ☐ Sachets
- ☐ Suppository
- ☐ Tablets
- ☐ Units
- ☐ Unknown
- ☐ Other

If "Other", specify _____

Frequency

- ☐ PRN
- ☐ QD
- ☐ BID
- ☐ TID
- ☐ QID
- ☐ QM
- ☐ QH
- ☐ ONCE
- ☐ Other

If "Other", specify _____

Route

- ☐ Oral
- ☐ Intramuscular
- ☐ Intravenous
- ☐ Topical
- ☐ Inhalation
- ☐ Vaginal
- ☐ Rectal
- ☐ Subcutaneous

	Other ☐
If "Other", specify	
Taken for a reported AE?	Yes ☐ No ☐
If "Yes", select adverse event	
Source Document Upload	

Date of birth	
Age	Fixed Unit: Years
Sex at birth?	Male ○ Female ●
Ethnicity	Hispanic or Latino ○ Not Hispanic or Latino ○

Race
Mark all that apply.

American Indian or Alaska Native	☐
Asian	☐
Black or African American	☐
Native Hawaiian or other Pacific Islander	☐
White	☐
Other	☐
If "Other", specify	

Gender
Mark all that apply.

Male	☐
Female	☐
Transgender Male	☐
Transgender Female	☐
Gender Nonconforming/Gender Variant	☐
Self-identify	☐
If "Self-identify", specify	
Prefer not to answer	☐

In the past 12 months, what was/were the biological sex(es) of the partner(s) with whom the participant had vaginal sex?	Both male and female partners ○ Exclusively female partners ○ Exclusively male partners ○ NA (no sex partners) ○
Source Document Upload	

HEMOGRAM

Was a hematology sample collected? ☐ Yes ☐ No

Hematology collection date

Hemoglobin

Hemoglobin severity grade ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable

Hemoglobin severity grade - calculated ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable

Hemoglobin adverse event, if applicable

Hematocrit

MCV

Platelets

Platelets severity grade ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable

Platelets severity grade - calculated ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable

Platelets adverse event, if applicable

WBC

WBC severity grade ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable

WBC severity grade - calculated	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable ☐
WBC adverse event, if applicable	
DIFFERENTIAL	
Was a differential done?	Yes ☐ No ☐
Differential collection date	
Neutrophils	
Neutrophils severity grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable ☐
Neutrophils severity grade - calculated	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable ☐
Neutrophils adverse event, if applicable	
Lymphocytes	
Lymphocytes severity grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable ☐
Lymphocytes severity grade - calculated	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable ☐
Lymphocytes adverse event, if applicable	
Monocytes	
Eosinophils	
Basophils	

Source Document Upload

Did the participant meet all eligibility criteria?	Yes ☐ No ☐
Informed Consent Date	_____
Eligibility Status	Eligible and Enrolled ☐ Eligible/Not enrolled ☐ Ineligible ☐ Incomplete Screening ☐
If eligible and enrolled or incomplete screening, end of form.	
Select reason(s) why participant is ineligible.	I1 - Assigned female sex at birth ☐ I2 - Age 18 through 45 years (inclusive) at Screening, verified per site SOPs ☐ I3 - Able and willing to provide written informed consent to be screened for and enrolled in MTN-038 ☐ I4 - Able and willing to provide adequate locator information, as defined in site SOPs ☐ I5 - Able to communicate in spoken and written English ☐ I6 - Available for all visits and able and willing to comply with all study procedural requirements ☐ I7 - Willing to abstain from receptive vaginal or anal sexual activities for 72 hours prior to each clinical visit and for 72 hours after biopsy collection ☐ I8 - Willing to use male condoms for penile-vaginal and penile-rectal sexual intercourse for the duration of study participation ☐ I9 -Using an effective method of contraception for at least 30 days (inclusive) prior to Enrollment, and intending to continue use of an effective method for the duration of study participation ☐ I10 - In general good health as determined by the Investigator of Record (IoR)/designee at Screening and Enrollment ☐ I11 - HIV-uninfected based on testing performed at Screening and Enrollment ☐ I12 - Per participant report at Screening, regular menstrual cycles with at least 21 days between menses ☐

I13 - Per participant report at Screening and Enrollment, states a willingness to refrain from inserting any non-study vaginal products or objects into the vagina or rectum for the 24 hours preceding the Enrollment Visit and for the duration of study participation.

I14 - Participants over the age of 21 (inclusive) must have documentation of a satisfactory Pap within the past 3 years prior to Enrollment consistent with Grade 0 according to the Female Genital Grading Table for Use in Microbicide Studies Addendum 1 (Dated November 2007) to the DAIDS Table for Grading Adult and Pediatric Adverse Events, Corrected Version 2.1, JulyMarch 2017, or satisfactory evaluation with no treatment required of Grade 1 or higher Pap result

I15 - At Screening and Enrollment, agrees not to participate in other research studies involving drugs, medical devices, vaginal or rectal products, or vaccines after the Screening Visit and for the duration of study participation

E1 - Pregnant at Screening or Enrollment or plans to become pregnant during the study period

E2 - Diagnosed with a urinary tract infection (UTI) or reproductive tract infection (RTI) at Screening or Enrollment

E3 - Diagnosed with an acute sexually transmitted infection (STI) requiring treatment per current Centers for Disease Control and Prevention (CDC) guidelines at Screening or Enrollment such as gonorrhea, chlamydia, trichomonas, pelvic inflammatory disease, and/or syphilis

E4 - Has a clinically apparent Grade 2 or higher pelvic exam finding (observed by study staff) at Screening or Enrollment, as per the current Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, and/or Addendum 1

	E5a - Known adverse reaction to any of the study products (ever), including polyurethane ☐
	E5b - Chronic and/or recurrent vaginal candidiasis ☐
	E5c - Non-therapeutic injection drug use in the 12 months prior to Enrollment ☐
	E5d - Last pregnancy outcome less than 90 days prior to Enrollment ☐
	E5e - Gynecologic or genital procedure (e.g., tubal ligation, dilation and curettage, piercing) 45 days or less prior to Enrollment ☐
	E5f - Currently breastfeeding or planning to breastfeed during the study ☐
	E5g - Participation in any other research study involving drugs, medical devices, vaginal or rectal products, or vaccines, in the 60 days prior to Enrollment ☐
	E6 - Use of pre-exposure prophylaxis (PrEP) for HIV prevention and/or post-exposure prophylaxis (PEP) for potential HIV exposure within the 3 months prior to Enrollment, and/or anticipated use and/or unwillingness to abstain from PrEP during trial participation ☐
	E7a - Grade 1 or higher Aspartate aminotransferase (AST) or alanine transaminase (ALT) ☐
	E7b - Grade 1 or higher Hemoglobin ☐
	E7c - Calculated creatinine clearance less than 60 mL/min by the Cockcroft-Gault formula ☐
	E7d - Positive Hepatitis B surface antigen result ☐
	E8 - Has any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate the interpretation of study outcome data, or otherwise interfere with achieving the study objectives including any significant uncontrolled active or chronic medical condition ☐
If Eligible/Not enrolled, specify reason:	
If not enrolled due to the decision of the Investigator of Record (IoR)/designee, specify (max. 200 characters):	
Source Document Upload	

MTN038_Version_3.0_PROD_13FEB2019: ALL
Form: Pregnancy Test Results
Generated On: 26 Feb 2019 18:53:29

Was a pregnancy test done?	Yes ☐ No ☐
Collection date	
Pregnancy test result	Positive ☐ Negative ☐
If pregnancy test result is positive, complete a Pregnancy History and Pregnancy Report form.	
Source Document Upload	
Collection time	

Does the participant have any medical history to report?	Yes ☐ No ☐

If "Yes", complete the Medical History form.

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Form: Medical History
Generated On: 26 Feb 2019 18:53:29

Date medical history collected	
Description of medical history condition/event	
Is condition/event gradable?	Yes ☐ No ☐
Severity grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Start date of medical history condition/event	
Is the condition ongoing?	Yes ☐ No ☐
Date medical history/condition ended/resolved	
Source Document Upload	

Was a physical exam performed? Yes ☐ No ☐

Date of exam _____

BODY SYSTEM

General Appearance Not Done ☐ Normal ☐ Abnormal ☐

If abnormal, specify: _____

HEENT Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Neck Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Lymph Nodes Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Heart/Cardiovascular Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Lung/Respiratory Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Abdomen Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Extremities Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Neurological Not Done ☐

	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	
Skin	Not Done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	
Other system finding	Not Done ☐
	Normal ☐
	Abnormal ☐
Other system, specify:	
If "Abnormal", specify:	
Source Document Upload	

MTN038_Version_3.0_PROD_13FEB2019: ALL
Form: Vital Signs
Generated On: 26 Feb 2019 18:53:29

Were vital signs done?	Yes ☐ No ☐
Date of assessment	
Height	Fixed Unit: cm
Weight	Fixed Unit: kg
Body temperature	Fixed Unit: C
Systolic blood pressure	Fixed Unit: mmHg
Diastolic blood pressure	Fixed Unit: mmHg
Pulse	Fixed Unit: beats/min
Rate of respiration	Fixed Unit: breaths/min
Source Document Upload	

Date that study product use ended	_____
Primary reason for ending study product use	☐ Scheduled study product use period completed ☐ Death ☐ Participant refused further participation ☐ Participant is unwilling or unable to comply with required study procedures ☐ Investigator decision ☐ Lost to follow-up ☐ Participant refused further study product use ☐ Unable to contact participant ☐ HIV infection ☐ Early study closure ☐ Protocol deviation ☐ Adverse event ☐ Pregnancy ☐ Withdrawal of consent by participant ☐ Study terminated by sponsor ☐ One or more reactive HIV test results or acute HIV infection suspected ☐ Breastfeeding ☐ Allergic reaction to the IVR ☐ Non-therapeutic injection drug use ☐ Reported use of PEP ☐ Reported use of PrEP ☐ Use of anticoagulant ☐ Other, specify
If "Other", specify:	_____
If "Adverse event", select applicable adverse event	_____
Source Document Upload	_____

Date of study exit	
Primary reason for completion/discontinuation	Scheduled exit visit/end of study ☐ Death ☐ Participant refused further participation ☐ Participant is unwilling or unable to comply with required study procedures ☐ Lost to follow-up ☐ Investigator decision ☐ Participant refused further study product use ☐ Unable to contact participant ☐ HIV infection ☐ Early study closure ☐ Protocol deviation ☐ Adverse event ☐ Pregnancy ☐ Allergic reaction to the IVR ☐ Breastfeeding ☐ Non-therapeutic drug use ☐ Other, specify ☐
If "Participant refused further participation", "Investigator decision", or "Other", specify:	
If "Death", enter date of death	
If "Adverse event", select applicable adverse event	
Source Document Upload	

MTN038_Version_3.0_PROD_13FEB2019: ALL
Form: Pregnancy History
Generated On: 26 Feb 2019 18:53:29

Date pregnancy history collected	
Has the participant ever been pregnant before?	Yes ☐ No ☐
If "No", end of form.	
Number of full term live births (>=37 weeks)	
Number of premature live births (Less than 37 weeks)	
Number of spontaneous fetal deaths and/or still births (>=20 weeks)	
Number of spontaneous abortions (Less than 20 weeks)	
Number of therapeutic/elective abortions	
Number of ectopic pregnancies	
Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?	Yes ☐ No ☐
If "Yes", specify:	
Source Document Upload	

Date pregnancy reported to site	
Visit at which this pregnancy was reported	Screening ☐ Enrollment ☐ V3 - Day 1 ☐ V4 - Day 7 ☐ V5 - Day 14 ☐ V6- Day 28 ☐ V7 - Day 42 ☐ V8 - Day 56 ☐ V9 - Day 91 PUEV ☐ V10 - Day 92 Final Contact ☐ Interim Visit ☐
If Interim visit, specify Interim visit code	
Date of onset of last menstrual period	
Or	
Amenorrheic for past 6 months	☐
Estimated date of delivery	
What primary information was used to estimate the date of delivery?	Last menstrual period ☐ Initial ultrasound <20 weeks ☐ Initial ultrasound >= 20 weeks ☐ Physical examination ☐ Conception date by assisted reproduction ☐ Other ☐
If "Other", specify:	
Is this the participant's first pregnancy since enrollment in this study?	Yes ☐ No ☐
If "Yes", complete Pregnancy History form.	
Source Document Upload	

Was a sample collected for serum chemistries?	Yes ☐ No ☐
Specimen Collection Date	
LIVER FUNCTION TESTS	
AST (SGOT) Result	
AST (SGOT) Severity Grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable ☐
AST (SGOT) severity grade - calculated	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable ☐
AST (SGOT) Adverse Event	
ALT (SGPT) Result	
ALT (SGPT) Severity Grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable ☐
ALT (SGPT) severity grade - calculated	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable ☐
ALT (SGPT) Adverse Event	
RENAL FUNCTION TESTS	
Creatinine Result	
Creatinine Severity Grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable ☐
Creatinine severity grade - calculated	Grade 1 (Mild) ☐

	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
	Not gradable ☐
Creatinine Adverse Event	
Source Document Upload	

Have any protocol deviations been reported?	Yes ☐ No ☐
If "Yes", complete the Protocol Deviations Log.	
If "Yes", complete the Protocol Deviations Log.	
Source Document Upload	

Site awareness date	
Deviation date	
Has or will this deviation be reported to local IRB/EC?	Yes ☐ No ☐
Has or will this deviation be reported to DAIDS as a critical event?	Yes ☐ No ☐
Type of deviation	Inappropriate enrollment ☐ Failure to follow randomization or blinding procedures ☐ Study product management deviation ☐ Study product dispensing error ☐ Study product use/non-use deviation ☐ Study product sharing ☐ Study product not returned ☐ Conduct of non-protocol procedure ☐ Improper AE/EAE ☐ Unreported AE ☐ Unreported EAE ☐ Breach of confidentiality ☐ Physical assessment deviation ☐ Lab assessment deviation ☐ Mishandled lab specimen ☐ Staff performing duties that they are not qualified to perform ☐ Questionnaire administration deviation ☐ Counseling deviation ☐ Use of non-IRB/EC-approved materials ☐ Use of excluded concomitant mediations, devices, or non-study products ☐ Informed consent process deviation ☐ Visit completed outside of window ☐ Other ☐
Description of deviation	
Plans and/or action taken to address the deviation	
Plans and/or action taken to prevent future occurrences of the deviation	
Deviation reported by	
Source Document Upload	

Pelvic exam assessment	Not done ☐ No abnormal findings ☐ Abnormal findings ☐
Exam date	_____
Was the Vaginal Ring in place at the start of the pelvic exam?	Yes ☐ No ☐

Abnormal findings. Select all that apply.

VULVAR	
Vulvar edema	☐
Vulvar erythema	☐
Vulvar rash	☐
Vulvar tenderness	☐
Bartholin's or Skene's gland abnormality	☐
Vulvar ulcer	☐
Vulvar blister	☐
Vulvar pustule	☐
Vulvar peeling	☐
Vulvar ecchymosis	☐
VAGINAL	
Vaginal edema	☐
Vaginal erythema	☐
Vaginal masses (polyps, myomas, possible malignancy)	☐
Vaginal abrasions or lacerations	☐
Vaginal tenderness	☐
Vaginal ulcer	☐
Vaginal blister	☐
Vaginal pustule	☐
Vaginal peeling	☐
Vaginal ecchymosis	☐
Abnormal vaginal discharge	Slight ☐ Moderate ☐ Pooling ☐
CERVICAL	
Cervical edema and/or friability	☐

Cervical erythema	☐
Cervical masses (polyps, myomas, possible malignancy)	☐
Cervical motion tenderness	☐
Cervical discharge	☐
Cervical ulcer	☐
Cervical blister	☐
Cervical pustule	☐
Cervical peeling	☐
Cervical ecchymosis	☐
GENERAL/OTHER	
Odor (vaginal)	☐
Condyloma	☐
If condyloma, specify location	_____
Adnexal masses (based on bimanual exam; not pregnancy or infection-related)	☐
Uterine masses (based on bimanual exam)	☐
Uterine tenderness	☐
Adnexal tenderness	☐
Abnormal blood or bleeding	☐
Abnormal blood or bleeding; describe	_____
Other abnormal findings	☐
If other abnormal findings, specify (include anatomical location)	_____
Complete or update Medical History Log or Adverse Event Log, as applicable.	
Were any new pelvic finding AEs reported at this visit?	Yes ◯ No ◯
Adverse event #1	_____
Adverse event #2	_____
Adverse event #3	_____
Cervical ectopy	0% ◯ 1-25% ◯ 26-50% ◯ 51-75% ◯ 76-100% ◯ Not done ◯
Source Document Upload	_____

Was a CASI questionnaire completed at this visit?	Yes ☐
	No ☐
If no, please explain:	_____
Was an in-depth interview completed at this visit?	Yes ☐
	No ☐
	Not applicable ☐
If no, please explain:	_____

CASI collection date	
Which questionnaire was completed?	Enrollment CASI ☐ Visit 6 (Day 28/Week 4) Follow-Up CASI ☐ Visit 8 (Day 56/Week 8) Follow-Up CASI ☐ PUEV CASI ☐
Were there any problems or issues related to the administration or completion of the questionnaire?	Yes ☐ No ☐
If yes, please describe	
Source Document Upload	

Was sample 1 collected for HIV testing?	Yes ☐ No ☐
Collection date	
Sample 1 HIV test result	Positive ☐ Negative ☐ Indeterminate ☐

If the Rapid test is positive or indeterminate, complete the HIV Confirmatory Test Result form and alert the MTN Laboratory Core.

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Was a sample collected for Syphilis testing?	Yes ☐
	No ☐
Collection date	_____
Syphilis screening test	Non-reactive ☐
	Reactive ☐
	Not reported ☐
Syphilis titer	_____
Syphilis confirmatory test	Positive ☐
	Negative ☐
	Indeterminate ☐
	Not done ☐
Was a vaginal wet prep sample collected?	Yes ☐
	No ☐
Collection date	_____
Vaginal pH	_____
Homogenous vaginal discharge	Positive ☐
	Negative ☐
	Not done ☐
Whiff test	Positive ☐
	Negative ☐
	Not done ☐
Clue cells $\geq$ 20%	Positive ☐
	Negative ☐
	Not done ☐
Trichomonas vaginalis	Positive ☐
	Negative ☐
	Not done ☐
Buds and/or hyphae (yeast)	Positive ☐
	Negative ☐
	Not done ☐
Was a sample collected for NAAT for GC/CT and trichomonas?	Yes ☐
	No ☐
Collection date	_____
N. gonorrhea	Positive ☐
	Negative ☐
	Not done ☐
C. trachomatis	Positive ☐

	Negative ☐
	Not done ☐
Trichomonas	Positive ☐
	Negative ☐
	Not done ☐
Was a sample collected for dipstick urinalysis tests?	Yes ☐
	No ☐
Collection date	_____
Leukocyte esterase (LE)	Positive ☐
	Negative ☐
	Not done ☐
Nitrates	Positive ☐
	Negative ☐
	Not done ☐
Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing?	Yes ☐
	No ☐
Date of collection	_____
Hepatitis B Surface Antigen (HBsAG)	Positive ☐
	Negative ☐
	Not done ☐
Source Document Upload	_____

Blood

1. - Was plasma for archive/storage collected? Yes ☐ No ☐

Collection date _____

Collection time _____

Plasma for archive/storage Stored ☐ Not Stored ☐

If not stored, specify reason _____

2. - Was plasma for PK collected? Yes ☐ No ☐

Collection date _____

Collection time _____

Plasma for PK Stored ☐ Not Stored ☐

If not stored, specify reason _____

Rectal PK Specimens

3. - Was a rectal swab for PK collected? Yes ☐ No ☐

Collection date _____

Collection time _____

Rectal Swab for PK Stored ☐ Not Stored ☐

If not stored, specify reason _____

Was HSV-1/2 for archive/storage collected? Yes ☐ No ☐

Collection date _____

Collection time _____

HSV-1/2 for archive/storage Stored ☐ Not stored ☐

If not stored, specify reason _____

Source Document Upload _____

Did the participant experience any vaginal spotting or bleeding in the past seven days?	Yes ☐ No ☐
On how many of these days did the participant experience heavy bleeding?	_____
Cervicovaginal lavage (CVL) for PD, PK, and Biomarkers	
Was CVL collected?	Yes ☐ No ☐
Collection date	_____
Collection time	_____
Cervicovaginal lavage (CVL) - cell pellet	Stored ☐ Not Stored ☐
If not stored, specify reason	_____
Cervicovaginal lavage (CVL) - supernatant	Stored ☐ Not Stored ☐
If not stored, specify reason	_____
Cervicovaginal fluid (CVF) for anti-HSV activity	
Was CVF for anti-HSV activity collected?	Yes ☐ No ☐
Collection date	_____
Collection time	_____
Cervicovaginal fluid (CVF) for anti-HSV activity	Stored ☐ Not Stored ☐
If not stored, specify reason	_____
Cervicovaginal fluid (CVF) for PK	
Was CVF for PK collected?	Yes ☐ No ☐
Collection date	_____
Collection time	_____
Was blood visible on the swab?	Yes ☐ No ☐
Cervicovaginal fluid (CVF) for PK	Stored ☐ Not stored ☐
If not stored, specify reason	_____
CVF for biomarkers	
Was CVF for biomarkers collected?	Yes ☐ No ☐
Collection date	_____
Collection time	_____
CVF for biomarkers	Stored ☐

	Not stored ☐
If not stored, specify reason	
Cervical tissue for PK	
Were cervical biopsies for PK collected?	Yes ☐
	No ☐
Collection date	
Collection time	
Cervical tissue for PK	Stored ☐
	Not stored ☐
If not stored, specify reason	
Cervical tissue for PD	
Were cervical biopsies for PD collected?	Yes ☐
	No ☐
Collection date	
Collection time	
Cervical tissue for PD	Stored ☐
	Not stored ☐
If not stored, specify reason	
Vaginal swabs for Microbiota	
Were vaginal swabs for microbiota culture collected?	Yes ☐
	No ☐
Collection date	
Vaginal swabs for microbiota culture	Stored ☐
	Not Stored ☐
If not stored, specify reason	
Were vaginal swabs for microbiota q-PCR collected?	Yes ☐
	No ☐
Collection date	
Vaginal swabs for microbiota q-PCR	Stored ☐
	Not stored ☐
If not stored, specify reason	
Vaginal Gram stain	
Was a Vaginal Gram stain collected?	Yes ☐
	No ☐
Collection date	
Vaginal Gram stain	Stored ☐
	Not Stored ☐
If not stored, specify reason	
Source Document Upload	

Since the participant's last adherence assessment (or since the ring was inserted, if currently Visit 6/Day 28), has she ever used a vaginal ring?	Yes ☐ No ☐

Did the participant disclose her ring use to her primary partner?	Yes ☐ No ☐ Not applicable ☐
Since her last adherence assessment (or since the ring was inserted, if currently Visit 6/Day 28), how many times in total has the participant had a vaginal ring out?	
How many of these times since the participant's last adherence assessment (or since the ring was inserted, if currently Visit 6/Day 28) was a vaginal ring out for more than 12 hours continuously?	
Since the participant's last adherence assessment (or since the ring was inserted if currently Visit 6/Day 28), what is the longest number of days in a row the vaginal ring was out?	
Was the ring removed?	Yes ☐ No ☐
Did the ring come out on its own?	Yes ☐ No ☐

For each instance when the ring was out since her last adherence assessment (or since the ring was inserted, if currently Visit 6/Day 28), please add a log line below. Ring removals by site staff for the purpose of clinical examination should not be recorded on this form.

Date ring was removed or came out (estimate if exact date not known):	
Time ring was removed or came out (estimate if exact time not known):	
Was the ring re-inserted?	Yes ☐ No ☐
If the ring was re-inserted, date the ring was re-inserted (estimate if exact date not known):	
If the ring was re-inserted, time the ring was re-inserted (estimate if exact time not known):	
If removed, Reason #1 why vaginal ring was removed:	Discomfort/symptoms: Ring caused discomfort/participant experienced genital or other symptoms ☐ Ring falling out: Ring was partially falling out ☐ Ring placement: Didn't feel the ring was correctly placed ☐ Ring presence: Wanted to look at the ring or see if the ring was still in place ☐ Menses/Bleeding: Had or was expecting menses/any type of genital bleeding or spotting ☐ Cleaned ring: Removed ring to clean it ☐ Cleaned vagina: Removed ring to clean vagina ☐ Felt sick: Felt sick/had non-genital side effects from the ring ☐ Emotional worries: Had emotional worries about the ring ☐

- [ ] Partner ring knowledge: Did not want husband or primary sex partner to know about ring
- [ ] Partner concerns/objections: Husband or any sex partner did not like the ring and/or wanted her to remove/stop using the ring
- [ ] 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
- [ ] Friend or peer concerns/objections: Friend or peer did not like the ring and/or wanted her to remove/stop using the ring
- [ ] Removal for sex: Participant or partner did not want to have vaginal sex with the ring in place
- [ ] Discomfort during sex: The ring feeling uncomfortable or painful during vaginal sex
- [ ] Partner felt ring during sex: The sex partner feeling the ring during sex
- [ ] Showed ring: Removed ring to show it to someone
- [ ] Not having sex: Participant was not having sex so she decided to remove/stop using the ring
- [ ] Interfered with sexual pleasure: The ring interfered with her sexual pleasure
- [ ] Interfered with partner's sexual pleasure: the ring interfered with her partner's sexual pleasure
- [ ] Disliked ring: Removed ring because did not like the ring
- [ ] Partner disliked ring: Removed ring because partner did not like the ring
- [ ] Participant wanted to get pregnant
- [ ] Partner wanted her to get pregnant
- [ ] Product hold: Participant placed on product hold
- [ ] Product permanently discontinued: Participant permanently discontinued from product
- [ ] Procedure: Ring removed for clinical procedure (e.g., IUCD insertion, pelvic exam)

	Delay in insertion of new ring: Ring removed between study visits and there was a delay in new ring insertion ☐
	Missed visit: Participant removed ring due to missed scheduled visit ☐
	Other ☐
If removed, Reason #2 why vaginal ring was removed:	Discomfort/symptoms: Ring caused discomfort/participant experienced genital or other symptoms ☐
	Ring falling out: Ring was partially falling out ☐
	Ring placement: Didn't feel the ring was correctly placed ☐
	Ring presence: Wanted to look at the ring or see if the ring was still in place ☐
	Menses/Bleeding: Had or was expecting menses/any type of genital bleeding or spotting ☐
	Cleaned ring: Removed ring to clean it ☐
	Cleaned vagina: Removed ring to clean vagina ☐
	Felt sick: Felt sick/had non-genital side effects from the ring ☐
	Emotional worries: Had emotional worries about the ring ☐
	Partner ring knowledge: Did not want husband or primary sex partner to know about ring ☐
	Partner concerns/objections: Husband or any sex partner did not like the ring and/or wanted her to remove/stop using the ring ☐
	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 ☐
	Friend or peer concerns/objections: Friend or peer did not like the ring and/or wanted her to remove/stop using the ring ☐
	Removal for sex: Participant or partner did not want to have vaginal sex with the ring in place ☐
	Discomfort during sex: The ring feeling uncomfortable or painful during vaginal sex ☐
	Partner felt ring during sex: The sex partner feeling the ring during sex ☐

	Showed ring: Removed ring to show it to someone ☐
	Not having sex: Participant was not having sex so she decided to remove/stop using the ring ☐
	Interfered with sexual pleasure: The ring interfered with her sexual pleasure ☐
	Interfered with partner's sexual pleasure: the ring interfered with her partner's sexual pleasure ☐
	Disliked ring: Removed ring because did not like the ring ☐
	Partner disliked ring: Removed ring because partner did not like the ring ☐
	Participant wanted to get pregnant ☐
	Partner wanted her to get pregnant ☐
	Product hold: Participant placed on product hold ☐
	Product permanently discontinued: Participant permanently discontinued from product ☐
	Procedure: Ring removed for clinical procedure (e.g., IUCD insertion, pelvic exam) ☐
	Delay in insertion of new ring: Ring removed between study visits and there was a delay in new ring insertion ☐
	Missed visit: Participant removed ring due to missed scheduled visit ☐
	Other ☐
If removed, Reason #3 why vaginal ring was removed:	Discomfort/symptoms: Ring caused discomfort/participant experienced genital or other symptoms ☐
	Ring falling out: Ring was partially falling out ☐
	Ring placement: Didn't feel the ring was correctly placed ☐
	Ring presence: Wanted to look at the ring or see if the ring was still in place ☐
	Menses/Bleeding: Had or was expecting menses/any type of genital bleeding or spotting ☐
	Cleaned ring: Removed ring to clean it ☐
	Cleaned vagina: Removed ring to clean vagina ☐
	Felt sick: Felt sick/had non-genital side effects from the ring ☐

- [ ] Emotional worries: Had emotional worries about the ring
- [ ] Partner ring knowledge: Did not want husband or primary sex partner to know about ring
- [ ] Partner concerns/objections: Husband or any sex partner did not like the ring and/or wanted her to remove/stop using the ring
- [ ] 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
- [ ] Friend or peer concerns/objections: Friend or peer did not like the ring and/or wanted her to remove/stop using the ring
- [ ] Removal for sex: Participant or partner did not want to have vaginal sex with the ring in place
- [ ] Discomfort during sex: The ring feeling uncomfortable or painful during vaginal sex
- [ ] Partner felt ring during sex: The sex partner feeling the ring during sex
- [ ] Showed ring: Removed ring to show it to someone
- [ ] Not having sex: Participant was not having sex so she decided to remove/stop using the ring
- [ ] Interfered with sexual pleasure: The ring interfered with her sexual pleasure
- [ ] Interfered with partner's sexual pleasure: the ring interfered with her partner's sexual pleasure
- [ ] Disliked ring: Removed ring because did not like the ring
- [ ] Partner disliked ring: Removed ring because partner did not like the ring
- [ ] Participant wanted to get pregnant
- [ ] Partner wanted her to get pregnant
- [ ] Product hold: Participant placed on product hold
- [ ] Product permanently discontinued: Participant permanently discontinued from product
- [ ] Procedure: Ring removed for clinical procedure (e.g., IUCD insertion, pelvic exam)

	Delay in insertion of new ring: Ring removed between study visits and there was a delay in new ring insertion ☐
	Missed visit: Participant removed ring due to missed scheduled visit ☐
	Other ☐
Other reason ring was removed, please specify:	
If the vaginal ring came out on its own, Reason #1:	Urination ☐
	Bowel movement: Having a bowel movement ☐
	Sex: Having sex or just finished sex ☐
	Physical activity: Physical activity (other than sex),including lifting heavy objects ☐
	Body position: Was squatting or sitting or changing body position (i.e., move from lying down to standing up) ☐
	Menses related ☐
	Other ☐
If the vaginal ring came out on its own, Reason #2:	Urination ☐
	Bowel movement: Having a bowel movement ☐
	Sex: Having sex or just finished sex ☐
	Physical activity: Physical activity (other than sex),including lifting heavy objects ☐
	Body position: Was squatting or sitting or changing body position (i.e., move from lying down to standing up) ☐
	Menses related ☐
	Other ☐
If the vaginal ring came out on its own, Reason #3:	Urination ☐
	Bowel movement: Having a bowel movement ☐
	Sex: Having sex or just finished sex ☐
	Physical activity: Physical activity (other than sex),including lifting heavy objects ☐
	Body position: Was squatting or sitting or changing body position (i.e., move from lying down to standing up) ☐
	Menses related ☐
	Other ☐
Other reason ring came out on its own, please specify:	
Source Document Upload	

Does the participant have any clinical product holds to be applied?	Yes ☐ No ☐

If "Yes", complete the Product Hold Log.

Is the outcome of this pregnancy obtainable? ☐ Yes ☐ No

If no, end of form.

How many pregnancy outcomes resulted from this reported pregnancy? _____

Outcome date _____

Place of delivery/outcome ☐ Home ☐ Hospital ☐ Clinic ☐ Unknown ☐ Other

If "Other", specify: _____

Specify outcome ☐ Full term live birth (greater than or equal to 37 weeks) ☐ Premature live birth (less than 37 weeks) ☐ Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks) ☐ Spontaneous abortion (less than 20 weeks) ☐ Ectopic pregnancy ☐ Therapeutic/elective abortion ☐ Other

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.

If "Other", specify:
If stillbirth/intrauterine fetal demise, spontaneous abortion, ectopic pregnancy or therapeutic/elective abortion is marked, go to "provide a brief narrative of the circumstances ". _____

Method ☐ C-section ☐ Standard vaginal ☐ Operative vaginal

If full term live birth, go to "Were there any complications related to the pregnancy outcome?".

Provide a brief narrative of the circumstances _____

Were there any complications related to the pregnancy outcome? ☐ Yes ☐ No

If there were no complications related to the pregnancy outcome, skip to the "Were any fetal/infant congenital anomalies identified" item.

Delivery-related complications: Mark “None” or all that apply. ☐

None

Intrapartum hemorrhage ☐

Postpartum hemorrhage ☐

Non-reassuring fetal status ☐

Chorioamnionitis ☐

Other ☐

If "Other", specify: _____

Non-delivery related complications: Mark “None” or all that apply. ☐

None

Hypertensive disorders of pregnancy ☐

Gestational diabetes ☐

Other ☐

If "Other", specify: _____

Were any fetal/infant congenital anomalies identified?
Mark all that apply. If No or unknown, go to statement above "infant gender". Complete AE Log and EAE Reporting form.

Yes ☐
No ☐
Unknown ☐

Central nervous system, cranio-facial ☐

Central nervous system, spinal ☐

Cardiovascular ☐

Renal ☐

Gastrointestinal ☐

Pulmonary ☐

Muscoloskeletal/extremities ☐

Physical defect ☐

Skin ☐

Genitourinary ☐

Chromosomal ☐

Cranio-facial (structural) ☐

Hematologic ☐

Infectious ☐

Endocrine/metabolic ☐

Other ☐

Specify congenital anomaly/defect AE _____

Describe the congenital anomaly/defect: _____

Complete the infant items below for live births only. Otherwise, end of form.

Male ☐
Female ☐

Infant gender

Infant birth weight	Fixed Unit: kg
Or	
Infant birth weight unavailable	☐
Infant birth length	Fixed Unit: centimeters
Or	
Infant birth length unavailable	☐
Infant birth head circumference	Fixed Unit: cm
Or	
Infant birth head circumference unavailable	☐
Infant birth abdominal circumference	Fixed Unit: centimeters
OR	
Infant birth abdominal circumference unavailable	☐
Infant gestational age by examination in weeks	Fixed Unit: Weeks
Infant gestational age by examination in days	Fixed Unit: Days
OR	
Infant gestational age by examination unavailable	☐

If unavailable, end of form.

Method used to determine gestational age	Ballard ☐ Dubowitz ☐ Other ☐
If other, specify	
Source Document Upload	

Date when study product hold was initiated	
Visit when study product hold was initiated	Enrollment ☐ V3 - Day 1 ☐ V4 - Day 7 ☐ V5 - Day 14 ☐ V6- Day 28 ☐ V7 - Day 42 ☐ V8 - Day 56 ☐ V9 - Day 91 PUEV ☐ V10 - Day 92 Final Contact ☐ Interim Visit ☐
If 'Interim visit' is chosen, provide interim visit code:	
Why is study product being held?	Reactive rapid HIV test ☐ Adverse Event ☐ Use of anticoagulant ☐ Participant unable/unwilling to comply with required study procedures, or o/w might be put at undue risk to their safety and well-being by continuing product use according to judgment of IoR/designee ☐ Other ☐
If "Other", specify:	
Adverse Event:	
Concomitant Medication:	
Concomitant Medication:	
Concomitant Medication:	
Concomitant Medication:	
Date of last study product use:	
Was the participant instructed to resume study product use? If 'no - permanently discontinued', 'no - early termination' or 'no - hold continuing at scheduled PUEV', complete the Discontinuation of Study Product form.	Yes ☐ No - permanently discontinued ☐ No - early termination ☐ No - Hold continuing at scheduled PUEV ☐ No - hold continuing for another reason ☐
Date study product resumed	
Date study product hold continuing for another reason	
Source Document Upload	

Date of assessment	_____
Did the participant have a ring in place at the start of the visit?	Yes ☐ No ☐
If no, skip to "Was a ring inserted at this visit?"	
Was the ring removed at this visit?	Yes ☐ No ☐
If no, skip to "Was a ring inserted at this visit?"	
Date ring was removed	_____
Time ring was removed	_____
Who removed the ring?	Participant ☐ Study Staff ☐
Reason ring was removed	Participant on clinical hold ☐ Participant has been permanently discontinued from product ☐ Participant declined study ring use ☐ Early termination ☐ Scheduled return of ring ☐ Scheduled PUEV ☐ Other ☐
If participant declined study ring use or other, specify	_____
Ring Storage	Stored ☐ Not stored ☐
If not stored, specify reason	_____
Was a ring inserted at this visit?	Yes ☐ No ☐
If no, end of form	
Date ring was inserted	_____
Time ring was inserted	_____
Did the participant attempt to insert the ring herself?	Yes ☐ No, inserted by study staff ☐
If "Yes", go to "Based on your assessment and her feedback, how easy or difficult was it for the participant to insert the ring?"	
If "No, inserted by study staff," please describe the reason:	_____
If "No, inserted by study staff," End of form.	
Based on your assessment and her feedback, how easy or difficult was it for the participant to insert the ring?	Very difficult ☐ Difficult ☐ Easy ☐ Very easy ☐
If very difficult or difficult, why? (Choose all that apply)	Reluctance to insert herself ☐

	Physical discomfort while inserting ☐ Difficulty folding and gripping ring ☐ Difficulty inserting far enough ☐ Required more than 1 attempt ☐ Other ☐
If other, specify	
Did the participant require any help from the clinican to insert the ring?	Yes ☐ No ☐
If yes, specify	
Did study staff verify that the ring was in place?	Yes ☐ No ☐
If no, explain	
If yes, upon verifying, was the ring correctly inserted by the participant?	Yes ☐ No ☐
If no, explain	
Source Document Upload	

MTN038_Version_3.0_PROD_13FEB2019: ALL
Form: HIV Confirmatory Results
Generated On: 26 Feb 2019 18:53:29

Sample 1 Confirmatory Tests

Was sample 1 collected for HIV Confirmatory testing?	Yes ☐
	No ☐
Collection date	_____
Sample 1 HIV Confirmatory test result	Positive ☐
	Negative ☐
	Indeterminate ☐
	Invalid ☐

If negative, indeterminate, or invalid, contact the MTN LC.
If positive, collect sample 2.

Sample 2 Collection

Was sample 2 collected for HIV Confirmatory testing?	Yes ☐
	No ☐
Collection date	_____
Was sample 2 stored?	Stored ☐
	Not stored ☐

Final HIV status

Final HIV status	HIV uninfected ☐
	HIV infected ☐
	pending ☐
Source Document Upload	_____

Blood

Was plasma for archive/storage collected? Yes ☐ No ☐

Collection date _____

Collection time _____

Plasma for archive/storage Stored ☐ Not Stored ☐

If not stored, specify reason _____

Plasma for PK

Was plasma for PK collected prior to ring removal? Yes ☐ No ☐

Collection date _____

Collection time _____

Plasma for PK Stored ☐ Not Stored ☐

If not stored, specify reason _____

Was plasma for PK collected 4 hours following ring removal? Yes ☐ No ☐

Collection date _____

Collection time _____

Plasma for PK Stored ☐ Not stored ☐

If not stored, specify reason _____

Rectal PK Specimens

Was a rectal swab for PK collected prior to ring removal? Yes ☐ No ☐

Collection date _____

Collection time _____

Rectal Swab for PK Stored ☐ Not Stored ☐

If not stored, specify reason _____

Was a rectal swab for PK collected 4 hours following ring removal? Yes ☐ No ☐

Collection date _____

Collection time _____

Rectal Swab for PK Stored ☐ Not stored ☐

If not stored, specify reason _____

Was HSV-1/2 for archive/storage collected? Yes ☐

	No ☐
Collection date	
Collection time	
HSV-1/2 for archive/storage	Stored ☐ Not stored ☐
If not stored, specify reason	
Source Document Upload	

Did the participant experience any vaginal spotting or bleeding in the past seven days?	Yes ☐ No ☐
On how many of these days did the participant experience heavy bleeding?	_____
Cervicovaginal lavage (CVL) for PD, PK, and Biomarkers	
If Visit 2, was CVL collected?	Yes ☐ No ☐
Was sample taken prior to ring insertion?	Yes ☐ No ☐ Not applicable ☐
Collection date	_____
Collection time	_____
Cervicovaginal lavage (CVL) - cell pellet	Stored ☐ Not Stored ☐
If not stored, specify reason	_____
Cervicovaginal lavage (CVL) - supernatant	Stored ☐ Not Stored ☐
If not stored, specify reason	_____
Cervicovaginal fluid (CVF) for anti-HSV activity	
If Visit 2, was CVF for anti-HSV activity collected?	Yes ☐ No ☐
Was sample taken prior to ring insertion?	Yes ☐ No ☐ Not applicable ☐
Collection date	_____
Collection time	_____
Cervicovaginal fluid (CVF) for anti-HSV activity	Stored ☐ Not Stored ☐
If not stored, specify reason	_____
Cervicovaginal fluid (CVF) for PK - Enrollment Visit If Visit 9, skip to Cervicovaginal fluid (CVF) for PK - Visit 9	
Was CVF for PK collected one hour following ring insertion?	Yes ☐ No ☐
Collection date	_____
Collection time	_____
Was blood visible on the swab?	Yes ☐ No ☐
Cervicovaginal fluid (CVF) for PK	Stored ☐ Not stored ☐

If not stored, specify reason _____

Was CVF for PK collected 4 hours following ring insertion? Yes ☐ No ☐

Collection date _____

Collection time _____

Was blood visible on the swab? Yes ☐ No ☐

Cervicovaginal fluid (CVF) for PK Stored ☐ Not stored ☐

If not stored, specify reason _____

Cervicovaginal fluid (CVF) for PK - Visit 9
Do not complete at Visit 2

Was CVF for PK collected immediately prior to ring removal? Yes ☐ No ☐

Collection date _____

Collection time _____

Was blood visible on the swab? Yes ☐ No ☐

Cervicovaginal fluid (CVF) for PK Stored ☐ Not stored ☐

If not stored, specify reason _____

Was CVF for PK collected 4 hours following ring removal? Yes ☐ No ☐

Collection date _____

Collection time _____

Was blood visible on the swab? Yes ☐ No ☐

Cervicovaginal fluid (CVF) for PK Stored ☐ Not stored ☐

If not stored, specify reason _____

CVF for biomarkers

Was CVF for biomarkers collected? Yes ☐ No ☐

If Visit 2, was sample taken prior to ring insertion? Yes ☐ No ☐

Collection date _____

Collection time _____

CVF for biomarkers Stored ☐ Not stored ☐

If not stored, specify reason

Cervical tissue for PK - Visit 9
Do not complete at Visit 2

Were cervical biopsies for PK collected? Yes / No

Collection date

Collection time

Cervical tissue for PK Stored / Not stored

If not stored, specify reason

Cervical tissue for PD - Visit 9
Do not complete at Visit 2

Were cervical biopsies for PD collected? Yes / No

Collection date

Collection time

Cervical tissue for PD Stored / Not stored

If not stored, specify reason

Vaginal swabs for Microbiota

Were vaginal swabs for microbiota culture collected? Yes / No

Collection date

Vaginal swabs for microbiota culture Stored / Not Stored

If not stored, specify reason

Were vaginal swabs for microbiota q-PCR collected? Yes / No

Collection date

Vaginal swabs for microbiota q-PCR Stored / Not stored

If not stored, specify reason

Vaginal Gram stain

Was a Vaginal Gram stain collected? Yes / No

Collection date

Vaginal Gram stain Stored / Not Stored

If not stored, specify reason

Source Document Upload