Subject Case Report Forms

MTN026_version 4.0_PROD_28June2018 - ALL

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

MTN026_version 4.0_PROD_28June2018: ALL
Form: Participant Date of Visit
Generated On: 28 Jun 2018 17:33:37

Date of Visit _____

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Eligibility Criteria
Generated On: 28 Jun 2018 17:33:37

Did the participant meet all eligibility criteria?	Yes ☐ No ☐
Eligibility Status	Ineligible ☐ Eligible and enrolled ☐ Eligible, but participant did not enroll ☐ Incomplete Screening ☐
If eligible and enrolled, end of form.	
If eligible, but participant did not enroll, specify reason	_____
Select inclusion and/or exclusion criteria that contributed to participant's study ineligibility	Age of 18-45 years (inclusive) at Screening ☐ Able and willing to provide written informed consent ☐ HIV-1/2 uninfected at Screening and Enrollment and willing to receive HIV test results ☐ Able and willing to provide adequate locator information ☐ Available to return for all study visits and willing to comply with study participation requirements ☐ In general good health at Screening and Enrollment ☐ Per participant report, a history of consensual RAI at least once in the past calendar year ☐ Willing to not take part in other research studies involving drugs, medical devices, genital or rectal products, or vaccines for the duration of study participation ☐ Willing to be sexually abstinent for 72 hours prior to each study visit, during study product use periods, and for 72 hours after biopsy collection ☐ Willing to abstain from inserting any non-study products into the rectum for 72 hours prior to each study visit and during study product use periods ☐ Women 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 or satisfactory evaluation with no treatment required of Grade 1 or higher Pap result ☐ Willing to be sexually abstinent for 72 hours prior to each study visit and during the study product use periods and for 7 days after biopsy collection ☐

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Form: Eligibility Criteria
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- [ ] Willing to abstain from inserting any non-study products into the vagina for 72 hours prior to each study visit, during study product use periods and for 7 days after biopsy collection
- [ ] Willing to use an effective method of contraception for at least 30 days (inclusive) prior to Enrollment and intending to continue use of effective method for duration of study participation
- [ ] Grade 1 or higher Hemoglobin at Screening
- [ ] Grade 1 or higher Platelet at Screening
- [ ] Grade 2 or higher White blood count at Screening
- [ ] Serum creatinine > 1.3x site ULN at Screening
- [ ] INR >1.5 x site ULN at Screening
- [ ] Grade 1 or higher AST or ALT at Screening
- [ ] Positive for hepatitis C antibody at Screening
- [ ] Positive for hepatitis B surface antigen at Screening
- [ ] History of inflammatory bowel disease per participant report at Screening
- [ ] Anticipated use of and/or unwillingness to abstain from Heparin, including Lovenox during study participation
- [ ] Anticipated use of and/or unwillingness to abstain from Warfarin during study participation
- [ ] Anticipated use of and/or unwillingness to abstain from Plavix (clopidogrel bisulfate), during study participation
- [ ] Anticipated use of and/or unwillingness to abstain from Aspirin (greater than 81 mg) during study participation
- [ ] Anticipated use of and/or unwillingness to abstain from NSAIDS during study participation
- [ ] Anticipated use of and/or unwillingness to abstain any other drugs that are associated with increased likelihood of bleeding during study participation

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- [ ] Anticipated use of and/or unwillingness to abstain from CYP3A inducer(s) and/or inhibitor(s) during study participation
- [ ] Anticipated use of and/or unwillingness to abstain from Hormone-replacement therapy in tablet, injectable, or gel form during study participation
- [ ] Known adverse reaction to any of the components of the study products
- [ ] Use of PEP for potential HIV exposure within 6 months prior to Enrollment
- [ ] Use of PreP for HIV prevention within 6 months prior to Enrollment, and/or anticipated use during trial participation
- [ ] Use of systemic immunomodulatory medications within the 6 months prior to Enrollment, and/or anticipated use during trial participation
- [ ] RAI without a condom and/or penile-vaginal intercourse with a partner who is known to be HIV-positive in the past 6 months
- [ ] Non-therapeutic injection drug use in the 12 months prior to Screening and Enrollment
- [ ] Participation in research studies involving drugs, medical devices, genital or rectal products, or vaccines within 45 days of the Enrollment Visit
- [ ] At Screening, participation report of treatment for anogenital STI within past 3 months
- [ ] At Screening, participant-reported symptoms and/or clinical or laboratory diagnosis of active anorectal or reproductive tract infection requiring treatment per current WHO guidelines
- [ ] At Enrollment, active anorectal or reproductive tract infection requiring treatment per current WHO guidelines or symptomatic UTI

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Form: Eligibility Criteria
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	Has any other condition that, in the opinion of the IoR/designee, could preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving study objectives ☐
	Pregnant or breastfeeding at either Screening or Enrollment or intends to become pregnant or start breastfeeding during study participation ☐
	Last pregnancy outcome 90 days or less prior to Screening ☐
	Has had a hysterectomy ☐
	At enrollment, has clinically apparent Grade 1 or higher pelvic exam finding per FGGT ☐
If other reason, including investigator decision, specify	_____

MTN026_version 4.0_PROD_28June2018: ALL
Form: Follow-up Yes/No
Generated On: 28 Jun 2018 17:33:37

Did the participant complete this visit?	Yes ☐
	No ☐

MTN026_version 4.0_PROD_28June2018: ALL
Form: Follow-up Visit Summary
Generated On: 28 Jun 2018 17:33:37

Visit date	_____
Was this a PK/PD sampling visit?	Yes ☐ No ☐
Was study product 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 ☐
Have any protocol deviations been reported at this visit?	Yes ☐ No ☐
Were any additional study procedures or forms completed outside of the scheduled study visit per protocol?	Yes ☐ No ☐

_____
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MTN026_version 4.0_PROD_28June2018: ALL
Form: Missed Visit
Generated On: 28 Jun 2018 17:33:37

Target Visit Date	_____
Reason visit was missed	unable to contact participant ☐ unable to schedule appointment(s) within allowable window ☐ participant refused visit ☐ participant incarcerated ☐ participant admitted to a health care facility ☐ participant withdrew from study ☐ participant deceased ☐ other ☐
If other, specify	_____
Steps taken to address the missed visit (corrective action plan)	_____

_____
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MTN026_version 4.0_PROD_28June2018: ALL
Form: CASI Summary
Generated On: 28 Jun 2018 17:33:37

Was a CASI questionnaire and/or an in-depth interview completed at this visit?	Yes ☐ No ☐
If no, please explain:	_____

MTN026_version 4.0_PROD_28June2018: ALL
Form: CASI Tracking
Generated On: 28 Jun 2018 17:33:37

CASI collection date	_____
CASI ID	_____
Which questionnaire was completed?	Baseline - Visit 2 ☐ Follow-up - Visit 3 ☐ Exit - Visit 14 ☐
Were there any problems or issues related to the administration or completion of the questionnaire?	Yes ☐ No ☐
If yes, please describe	_____
Was an in-depth interview completed?	Yes ☐ No ☐ Not required ☐

_____
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MTN026_version 4.0_PROD_28June2018: ALL
Form: Sexual Lubricant
Generated On: 28 Jun 2018 17:33:37

Date of completion:	_____
In the past week, has the participant used a sexual lubricant?	Yes ☐ No ☐
Date of use	_____
Which sexual lubricant(s) were used?	Saliva ☐ Study-provided lubricant ☐ Silicone-based (e.g. Eros, Wet Platinum, Gun Oil Silicone) ☐ Water-based (e.g. KY Jelly, Wet Original, Durex, ForFun, Ministry of Health-provided lubricant, Love Lub, Aquasol, Astroglide, Gun Oil H2O) ☐ Oil-based (e.g. Crisco, lotion or cream, Vaseline, vegetable oil, fish oil, baby oil, yogurt, butter) ☐ Don't know ☐ Other ☐
If other, specify	_____

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Concomitant Medications Summary
Generated On: 28 Jun 2018 17:33:37

Is the participant taking any concomitant medications?	Yes ☐ No ☐

If yes, please complete the Concomitant Medications Log.

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MTN026_version 4.0_PROD_28June2018: ALL
Form: Concomitant Medications
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Medication Name _____

Indication _____

Date Started _____

Date Stopped

Or _____

Continuing at end of study ☐

Frequency

PRN ☐
QD ☐
BID ☐
TID ☐
QID ☐
QHS ☐
ONCE ☐
Other ☐

If other frequency, specify _____

Route

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

If other route, specify _____

Dose _____

Dose Unknown ☐

Dose Units

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

_____
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Form: Concomitant Medications
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	Unknown ☐
	Other ☐
If other dose units, specify	_____
Taken for a reported AE?	Yes ☐
	No ☐
Applicable Adverse Event #1	_____
Applicable Adverse Event #2	_____
Applicable Adverse Event #3	_____
Applicable Adverse Event #4	_____

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Adverse Event Summary
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Has the participant experienced an Adverse Event during the study? If Yes, complete the Adverse Event form.	Yes ☐ No ☐

If yes, please complete the Adverse Event Log.

MTN026_version 4.0_PROD_28June2018: ALL
Form: Adverse Event
Generated On: 28 Jun 2018 17:33:37

Date reported to site	_____
Adverse Event (AE)	_____
Onset date	_____
At which visit was this AE first reported?	V2.0 - Enrollment ☐ V3.0 - Dosing ☐ V4.0 - 24 hr PK ☐ V5.0 - 48 hr PK ☐ V6.0 - 72 hr PK ☐ V7.0 - Dosing ☐ V8.0 - Dosing ☐ V9.0 - Dosing ☐ V10.0 - Dosing ☐ V11.0 - Dosing ☐ V12.0 - Dosing ☐ V13.0 - Final Dosing ☐ V14.0 - 24 hr PK ☐ V15.0 - 48 hr PK ☐ V16.0 - 72 hr PK ☐ V17.0 - Termination ☐ Interim Visit ☐
If 'Interim visit' is chosen, provide interim visit code	_____
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 ☐

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Form: Adverse Event
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Other action(s) taken	☐
None	
Medication	☐
New/prolonged hospitalization	☐
Therapeutic procedure/surgery	☐
Diagnostic procedure	☐
Other	☐
Other, specify	_____
Status/Outcome	recovered/resolved ☐
	recovering/resolving ☐
	resolved with sequelae ☐
	not recovered/resolved ☐
	fatal ☐
Is this a Serious Adverse Event?	Yes ☐
	No ☐
Has or will this AE be reported as an EAE?	Yes ☐
	No ☐
If yes, EAE number	_____
Was this AE a worsening of a baseline medical condition?	Yes ☐
	No ☐
Was this AE related to the flexible sigmoidoscopy procedures?	Yes ☐
	No ☐
Was this AE related to applicator insertion?	Yes ☐
	No ☐
Comments	_____

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MTN026_version 4.0_PROD_28June2018: ALL
Form: Demographics
Generated On: 28 Jun 2018 17:33:37

.What is your date of birth? _____

Age Fixed Unit: Years

_____

.What was your sex at birth?
- Male ☐
- Female ☐

.Are you currently married?
- Yes. ☐
- No. ☐

.Do you currently live with your partner?
- Yes. ☐
- No. ☐

.What is your highest level of education?
- No schooling. ☐
- Primary school, not complete. ☐
- Primary school, complete. ☐
- Secondary school, not complete. ☐
- Secondary school, complete. ☐
- Attended college or university. ☐

.Do you consider yourself to be Latino/a or of Hispanic origin?
- Yes. ☐
- No. ☐

.What is your race? (Select all that apply)

The following should only be selected for US domestic sites.

- American Indian or Alaska Native ☐
- Asian ☐
- Black or African American ☐
- Native Hawaiian or other Pacific Islander ☐
- White ☐
- Other ☐

If other, specify: _____

The following should only be completed for the Bangkok, Thailand site.

- Thai ☐
- Chinese ☐
- Indian ☐
- Other ☐

If other, specify: _____

.Do you earn an income of your own?
- Yes. ☐
- No. ☐

.How do you earn income?
- Formal employment. ☐
- Self-employment. ☐

_____
Staff Initials/Date

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Form: Demographics
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	Other. ☐
.How do you identify your gender?	Male. ☐ Female. ☐ Transgender male (female to male). ☐ Transgender female (male to female). ☐ Additional category. ☐ Decline to state. ☐
.Additional category, specify	_____

MTN026_version 4.0_PROD_28June2018: ALL
Form: Baseline Medical History Summary
Generated On: 28 Jun 2018 17:33:37

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

If yes, complete the Baseline Medical History Log. Please remember to include any abnormal Screening or Enrollment anorectal, pelvic or physical exam findings, and any Screening or Enrollment lab abnormalities.

MTN026_version 4.0_PROD_28June2018: ALL
Form: Baseline Medical History
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Date medical history collected	_____
Description of medical condition/event	_____
Is condition/event gradable?	Yes ☐ No ☐
Toxicity (Severity) Grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Date medical condition/event started	_____
Is the condition ongoing?	Yes ☐ No ☐
Date medical condition/event ended/resolved	_____

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Screening Menstrual History
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Date of assessment	
First day of last menstrual period	
Last day of last menstrual period	
Or	
Ongoing	☐
Provide additional details as needed to describe the participant's baseline menstrual bleeding pattern	

MTN026_version 4.0_PROD_28June2018: ALL
Form: Pregnancy Test
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Was a pregnancy test done?	Yes ☐ No ☐
Date of Pregnancy Test	_____
Time	_____
Test result	Positive ☐ Negative ☐

Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: STI Tests
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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	Postive ☐ Negative ☐ Indeterminate ☐ Not done ☐
Was a urine sample collected for N. gonorrhea testing?	Yes ☐ No ☐
Collection date	_____
N. gonorrhea - URINE test result	Positive ☐ Negative ☐
Was a urine sample collected for C. trachomatis testing?	Yes ☐ No ☐
Collection date	_____
C. trachomatis - URINE test result	Positive ☐ Negative ☐
Was a rectal swab sample collected for N. gonorrhea testing?	Yes ☐ No ☐
Collection date	_____
N. gonorrhea - RECTAL SWAB test result	Positive ☐ Negative ☐
Was a rectal swab sample collected for C. trachomatis testing?	Yes ☐ No ☐
Collection date	_____
C. trachomatis RECTAL SWAB test result	Positive ☐ Negative ☐
Was a blood sample collected for HSV-1 testing?	Yes ☐ No ☐
Collection date	_____
HSV-1 test result	Positive ☐ Negative ☐
Was a blood sample collected for HSV-2 testing?	Yes ☐

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Form: STI Tests
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	No ☐
Collection date	_____
HSV-2 test result	Positive ☐
	Negative ☐
Was a rectal swab collected for HSV-1 testing?	Yes ☐
	No ☐
Collection date	_____
HSV-1 test result	Positive ☐
	Negative ☐
Was a rectal swab collected for HSV-2 testing?	Yes ☐
	No ☐
Collection date	_____
HSV-2 test result	Positive ☐
	Negative ☐

MTN026_version 4.0_PROD_28June2018: ALL
Form: Hematology
Generated On: 28 Jun 2018 17:33:37
Lab Name: _____

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 Adverse event _____

Hematocrit _____

MCV _____

Platelets _____

Platelets severity grade: Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ not gradable ☐

Platelets Adverse event _____

WBC _____

WBC severity grade: Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ not gradable ☐

WBC Adverse event _____

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 Adverse event _____

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Hematology
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Lab Name:

Lymphocytes	
Lymphocytes severity grade	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ not gradable ☐
Lymphocytes Adverse event	
Monocytes	
Eosinophils	
Basophils	

Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Local Laboratory Results
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Lab Name: _____

Was a sample collected for serum chemistries?	Yes ☐ No ☐
Collection date	_____
AST (SGOT)	_____
AST (SGOT) severity grade	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ not gradable ☐
AST (SGOT) adverse event	_____
ALT (SGPT)	_____
ALT (SGPT) severity grade	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ not gradable ☐
ALT (SGPT) Adverse event	_____
Creatinine	_____
Creatinine severity grade	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ not gradable ☐
Creatinine Adverse event	_____

_____
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MTN026_version 4.0_PROD_28June2018: ALL
Form: HIV Test Results
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Rapid HIV test 1	
Was a Rapid HIV test 1 sample collected?	Yes ☐ No ☐
Rapid HIV test 1 collection date	_____
Rapid HIV test 1 kit	Alere Determine HIV-1/2 ☐ HIV 1/2 Antigen Antibody ☐ OraQuick Advance Rapid Antibody ☐ Other ☐
If other, specify	_____
Rapid HIV test 1 result	Positive/Reactive ☐ Negative/Non-reactive ☐
Rapid HIV test 2	
Was a Rapid HIV test 2 sample collected?	Yes ☐ No ☐
Rapid HIV test 2 collection date	_____
Rapid HIV test 2 kit	Alere Determine HIV-1/2 ☐ HIV 1/2 Antigen Antibody ☐ OraQuick Advance Rapid Antibody ☐ Other ☐
If other, specify	_____
Rapid HIV test 2 result	Positive/Reactive ☐ Negative/Non-reactive ☐
HIV-EIA	
Was an HIV-EIA test done?	Yes ☐ No ☐
HIV-EIA collection date	_____
HIV-EIA test result	Negative ☐ Positive ☐ Indeterminate ☐

_____
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MTN026_version 4.0_PROD_28June2018: ALL
Form: HIV Confirmatory Results
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HIV Confirmatory Testing

Was a sample collected for HIV Confirmatory testing? Yes ☐ No ☐

Collection date _____

ARCHITECT HIV Ag/Ab Combo Nonreactive ☐ Reactive ☐ Not done ☐

Geenius HIV-1/2 Negative ☐ HIV-1 indeterminate ☐ HIV-2 indeterminate ☐ HIV-1 positive ☐ HIV-2 positive ☐ HIV-2 positive with HIV-1 cross-reactivity ☐ HIV positive undifferentiated (untypeable) ☐ Invalid ☐ Not done ☐

Aptima HIV-1 RNA Qualitative assay Nonreactive ☐ Reactive ☐ Invalid ☐ Not done ☐

HIV RNA

Was HIV RNA PCR testing performed? Yes ☐ No ☐

HIV RNA PCR collection date _____

HIV RNA PCR symbol > ☐ < ☐ = ☐

HIV RNA PCR result Fixed Unit: viral copies/mL _____

Or

HIV RNA PCR target not detected ☐

HIV RNA PCR kit type lower limit of detection Abbott M2000 ☐ Roche Taqman ☐ Gene Xpert ☐ Other ☐

If other, specify _____

HIV RNA PCR kit lower limit of detection Fixed Unit: viral copies/mL

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	20 ☐
	40 ☐
OR	
HIV RNA PCR Kit lower limit of detection	Fixed Unit: viral copies/mL _____
Absolute CD4+	
Was Absolute CD4+ collected?	Yes ☐
	No ☐
Absolute CD4 collection date	_____
Absolute CD4+	Fixed Unit: cells/mm^3 _____
Or	
Unable to analyze	☐
CD4 %	
CD4 % not available	☐
Or	
CD4 %	Fixed Unit: % _____
Was plasma for confirmatory testing collected?	Yes ☐
	No ☐
Plasma for HIV confirmatory testing collection date	_____
Was plasma stored for HIV confirmatory testing?	Stored ☐
	Not Stored ☐
If not stored, specify reason	_____
Final HIV status	
Final HIV status	HIV uninfected ☐
	HIV infected ☐
	Pending ☐

Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Vital Signs
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Date of assessment	
Height	Fixed Unit: centimeters
Weight	Fixed Unit: kilograms
Body Temperature	Fixed Unit: Celsius
Systolic BP	Fixed Unit: mmHg
Diastolic BP	Fixed Unit: mmHg
Pulse	Fixed Unit: beats per minute
Rate of respiration	Fixed Unit: breaths per minute

MTN026_version 4.0_PROD_28June2018: ALL
Form: Physical Exam
Generated On: 28 Jun 2018 17:33:37

Exam date _____

For each organ system or body part evaluated, indicate whether the finding(s) were normal or abnormal. If abnormal, describe the finding(s) in the text field provided. If an organ system or body part is not evaluated, select “Not Done".

General Appearance
Not Done ☐
Normal ☐
Abnormal ☐
If abnormal, specify: _____

Head, Eye, Ear, Nose, and Throat
Not Done ☐
Normal ☐
Abnormal ☐
If abnormal, specify: _____

Oral mucosa
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: _____

Lungs/Respiratory
Not Done ☐
Normal ☐
Abnormal ☐
If abnormal, specify: _____

Abdomen
Not Done ☐
Normal ☐
Abnormal ☐
If abnormal, specify: _____

Extremities
Not Done ☐
Normal ☐

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Form: Physical Exam
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	Abnormal ☐
If abnormal, specify:	_____
Neurological	Not Done ☐
	Normal ☐
	Abnormal ☐
If abnormal, specify:	_____
Skin	Not Done ☐
	Normal ☐
	Abnormal ☐
If abnormal, specify:	_____
Other	Not Done ☐
	Normal ☐
	Abnormal ☐
If Other is abnormal or normal, specify:	_____

MTN026_version 4.0_PROD_28June2018: ALL
Form: Anorectal Exam
Generated On: 28 Jun 2018 17:33:37

At Screening and Enrollment, evaluate any abnormalities for eligibility. Update Baseline Medical History log when applicable. During follow-up, complete or update Adverse Event Log when applicable.

Exam date _____

PERIANAL EXAMINATION

Findings from the perianal examination
- Not done ☐
- No abnormal findings ☐
- Abnormal findings ☐

Abnormal perianal findings:
select all that apply.

- Warts ☐
- Fissure ☐
- Ulceration ☐
- Pigmentation ☐
- Hemorrhoids ☐
- Skin tags ☐
- Leukoplakia ☐
- Fistula ☐
- Petechiae (less than 3 mm) ☐
- Purpura (0.3 to 1 cm) ☐
- Ecchymosis (greater than 1 cm) ☐
- Discharge ☐
- Erythema ☐
- Bleeding ☐
- Other abnormal findings ☐

If other abnormal findings, specify _____

DIGITAL RECTAL EXAMINATION

Findings from the digital rectal examination
- Not done ☐
- No abnormal findings ☐
- Abnormal findings ☐

If abnormal findings, specify _____

ANOSCOPY

Rectal mucosa findings from anoscopy
- Not done ☐
- No abnormal findings ☐
- Abnormal findings ☐

Abnormal anoscopy findings: select all that apply.

- Erythema ☐
- Abnormal vessels ☐

Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Anorectal Exam
Generated On: 28 Jun 2018 17:33:37

Ulceration	☐
Friability	☐
Bleeding	☐
Discharge	☐
Polyps	☐
Hemorrhoids	☐
Other abnormal findings	☐
If other abnormal findings, specify	_____

SIGMOIDOSCOPY

Sigmoidoscopy findings	Not done ☐
	No abnormal findings ☐
	Abnormal findings ☐

Abnormal sigmoidoscopy findings: select all that apply.

Erythema	☐
Abnormal vessels	☐
Ulceration	☐
Friability	☐
Bleeding	☐
Discharge	☐
Polyps	☐
Hemorrhoids	☐
Other abnormal findings	☐
If other abnormal findings, specify	_____

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Pelvic Exam
Generated On: 28 Jun 2018 17:33:37

Pelvic exam assessment	Not done ☐ No abnormal findings ☐ Abnormal findings ☐
Exam date	_____
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	☐

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Pelvic Exam
Generated On: 28 Jun 2018 17:33:37

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 Baseline Medical Conditions 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 ☐

Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Specimen Storage
Generated On: 28 Jun 2018 17:33:37

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/PD 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 _____

4. - Was rectal enema effluent for PD/PK collected? Yes ☐ No ☐

Collection date _____

Collection time _____

Rectal enema effluent for PD/PK - Supernatant Stored ☐ Not Stored ☐

If not stored, specify reason _____

Rectal enema effluent for PD/PK - Cell pellet Stored ☐ Not Stored ☐

If not stored, specify reason _____

5. - Were rectal biopsies for PK collected? Yes ☐ No ☐

Collection date _____

Collection time _____

Rectal biopsies for PK Stored ☐ Not Stored ☐

Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Specimen Storage
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If not stored, specify reason

6. - Were rectal biopsies for PD collected? Yes / No

Collection date

Collection time

Rectal biopsies for PD Stored / Not Stored

If not stored, specify reason

Rectal Mucosal Safety Specimens

7. - Was a rectal sponge for mucosal safety collected? Yes / No

Collection date

Collection time

Rectal sponge for mucosal safety Stored / Not Stored

If not stored, specify reason

8. - Was a rectal swab for microflora /microbiome collected? Yes / No

Collection date

Collection time

Rectal swab for microflora/microbiome Stored / Not Stored

If not stored, specify reason

9. - Were rectal biopsies for mucosal gene expression array collected? Yes / No

Collection date

Collection time

Rectal biopsies for mucosal gene expression array Stored / Not Stored

If not stored, specify reason

10. - Was a rectal biopsy for histology collected? Yes / No

Collection date

Collection time

Rectal biopsy for histology Stored / Not Stored

If not stored, specify reason

11. - Were rectal biopsies for mucosal T cell phenotyping collected? Yes / No

Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Specimen Storage
Generated On: 28 Jun 2018 17:33:37

Collection date	_____
Collection time	_____
Rectal biopsies for mucosal T cell phenotyping	Stored ☐ Not Stored ☐
If not stored, specify reason	_____
12. - Was a rectal biopsy for proteomics collected?	Yes ☐ No ☐
Collection date	_____
Collection time	_____
Rectal biopsy for proteomics	Stored ☐ Not Stored ☐
If not stored, specify reason	_____

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Timed Specimen Storage
Generated On: 28 Jun 2018 17:33:37

What time group was the participant assigned to for PK/PD/mucosal safety specimen collection?	30-60 minutes ☐ 120 minutes ☐
Blood	
1. - Was plasma for PK (0 minute pre-dose blood draw) collected?	Yes ☐ No ☐
Collection date	_____
Collection time	_____
Plasma for PK (0 minute pre-dose)	Stored ☐ Not Stored ☐
If not stored, specify reason	_____
2. - Was plasma for PK (assigned time post-dose) collected?	Yes ☐ No ☐
Collection date	_____
Collection time	_____
Plasma for PK (assigned time post-dose)	Stored ☐ Not Stored ☐
If not stored, specify reason	_____
Rectal PK/PD 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	_____
4. - Was rectal enema effluent for PD/PK collected?	Yes ☐ No ☐
Collection date	_____
Collection time	_____
Rectal enema effluent for PD/PK - Supernatant	Stored ☐ Not Stored ☐
If not stored, specify reason	_____
Rectal enema effluent for PD/PK - Cell pellet	Stored ☐ Not Stored ☐
If not stored, specify reason	_____
5. - Were rectal biopsies for PK collected?	Yes ☐ No ☐
Collection date	_____
Collection time	_____

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Timed Specimen Storage
Generated On: 28 Jun 2018 17:33:37

Rectal biopsies for PK	Stored ☐ Not Stored ☐
If not stored, specify reason	
6. - Were rectal biopsies for PD collected?	Yes ☐ No ☐
Collection date	
Collection time	
Rectal biopsies for PD	Stored ☐ Not Stored ☐
If not stored, specify reason	
Rectal Mucosal Safety Specimens	
7. - Was a rectal sponge for mucosal safety collected?	Yes ☐ No ☐
Collection date	
Collection time	
Rectal sponge for mucosal safety	Stored ☐ Not Stored ☐
If not stored, specify reason	
8. - Was rectal swab for microflora/microbiome collected?	Yes ☐ No ☐
Collection date	
Collection time	
Rectal swab for microflora/microbiome	Stored ☐ Not Stored ☐
If not stored, specify reason	
9. - Were rectal biopsies for mucosal gene expression array collected?	Yes ☐ No ☐
Collection date	
Collection time	
Rectal biopsies for mucosal gene expression array	Stored ☐ Not Stored ☐
If not stored, specify reason	
10. - Was a rectal biopsy for histology collected?	Yes ☐ No ☐
Collection date	
Collection time	
Rectal biopsy for histology	Stored ☐ Not Stored ☐
If not stored, specify reason	

MTN026_version 4.0_PROD_28June2018: ALL
Form: Timed Specimen Storage
Generated On: 28 Jun 2018 17:33:37

11. - Were rectal biopsies for mucosal T cell phenotyping collected?	Yes ☐ No ☐
Collection date	_____
Collection time	_____
Rectal biopsies for mucosal T cell phenotyping	Stored ☐ Not Stored ☐
If not stored, specify reason	_____
12. - Was a rectal biopsy for proteomics collected?	Yes ☐ No ☐
Collection date	_____
Collection time	_____
Rectal biopsy for proteomics	Stored ☐ Not Stored ☐
If not stored, specify reason	_____

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Cervical Specimen Storage
Generated On: 28 Jun 2018 17:33:37

Date of last vaginal bleeding	
First day of last menstrual period	_____
Or	
	Amenorrheic for past 6 months ☐
	No menses since participant's last visit ☐
Last day of last menstrual period	_____
Or	
Ongoing	☐
Cervicovaginal lavage (CVL) for PD	
Was CVL for PD collected?	Yes ☐
	No ☐
Collection date	_____
Collection time	_____
Cervicovaginal lavage (CVL) for PD - Supernatant	Stored ☐
	Not Stored ☐
If not stored, specify reason	_____
Cervicovaginal lavage (CVL) for PD - Cell Pellet	Stored ☐
	Not Stored ☐
If not stored, specify reason	_____
Cervicovaginal fluid (CVF) for PK	
Was CVF for PK collected?	Yes ☐
	No ☐
Collection date	_____
Collection time	_____
Cervicovaginal fluid (CVF) for PK	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 biopsies for PK	Stored ☐
	Not Stored ☐
If not stored, specify reason	_____

MTN026_version 4.0_PROD_28June2018: ALL
Form: Randomization
Generated On: 28 Jun 2018 17:33:37

Is the participant ready to be randomized?	Yes ☐ No ☐
Randomization Date and Time	_____

MTN026_version 4.0_PROD_28June2018: ALL
Form: Enrollment
Generated On: 28 Jun 2018 17:33:37

Date the participant marked or signed the study screening and enrollment consent form	_____
Did the participant consent to long-term specimen storage and future testing?	Yes ☐ No ☐
Is this a replacement participant?	Yes ☐ No ☐
PTID of participant being replaced	_____
PK, PD, and Mucosal Safety Time Assignment	30-60 minutes ☐ 120 minutes ☐
PK/PD Sampling Day Assignment	24 hours ☐ 48 hours ☐ 72 hours ☐

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Participant Replacement Assessment
Generated On: 28 Jun 2018 17:33:37

Date of assessment	_____
Does this participant meet protocol-specified criteria for replacement?	Yes ☐ No ☐
Why is this participant being replaced?	Single dose was not administered at visit 3 (e.g., due to non-adherence) ☐ None of the 7 daily doses administered (e.g., due to non-adherence or permanent discontinuation) ☐ Early termination before visit 7 (e.g., due to participant voluntarily withdrawing from the study, death, lost to follow-up, relocation, or permanent discontinuation) ☐ Other ☐
If other, specify	_____

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Product Dispensation and Returns (For Non-Observed Home Dose)
Generated On: 28 Jun 2018 17:33:37

Was product provided for non-observed home use?	Yes ☐ No ☐
Date product provided for non-observed home use	
Number of applicators provided at this visit for home use	Fixed Unit: applicators
If provided at a visit other than Visit 7, record reason	
Was study product (for home use) returned by participant?	Yes ☐ No ☐
Date study product (for home use) returned by participant	
Number of unused applicators returned	Fixed Unit: unused applicators

Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Pregnancy Report & History
Generated On: 28 Jun 2018 17:33:37

First day 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:	_____
Pregnancy History	
Has the participant ever been pregnant before?	Yes ☐ No ☐
If No, End of form	
Is this the participant's first pregnancy since enrollment in this study?	Yes ☐ No ☐
If No, go to item "Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?"	
Number of full term live births (greater than or equal to 37 weeks)	_____
Number of premature live births (less than 37 weeks)	_____
Number of spontaneous fetal deaths and/or stillbirths (greater than or equal to 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:	_____

MTN026_version 4.0_PROD_28June2018: ALL
Form: Directly Observed Dosing Log
Generated On: 28 Jun 2018 17:33:37

Dose number	Visit 3 - Single Dose Administration Visit ☐
	Visit 7 - Daily dose #1 ☐
	Visit 8 - Daily dose #2 ☐
	Visit 9 - Daily dose #3 ☐
	Visit 10 - Daily dose #4 ☐
	Visit 11 - Daily dose #5 ☐
	Visit 12 - Daily dose #6 ☐
	Visit 13 - Final daily dose #7 ☐
Was the gel application observed?	Not done ☐
	Yes, in clinic ☐
	No, in home not observed ☐
Date gel application observed	_____
Time gel application observed	_____
If dose was inserted at home, is this dosing time an estimate?	Yes ☐
	No ☐

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Enrollment Menstrual History
Generated On: 28 Jun 2018 17:33:37

Date of assessment	_____
Since the Screening Visit, has the participant had her menses?	Yes ☐ No ☐
First day of last menstrual period	_____
Last day of last menstrual period	_____
Or	
Ongoing	☐

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Additional Study Procedures
Generated On: 28 Jun 2018 17:33:37

CASI and/or IDI	☐
Vital Signs	☐
Physical Exam	☐
Pelvic Exam	☐
Anorectal Exam	☐
Pregnancy Test	☐
STI Tests	☐
HIV Tests	☐
HIV Confirmatory Results	☐
CBC with differential and platelets	☐
Serum Creatinine, AST, or ALT	☐
Plasma for archive/storage	☐
Cervicalvaginal specimen collection	☐
Timed specimen collection for PK, PD, and mucosal safety	☐
Pregnancy Report and History	☐
Participant replacement assessment	☐

MTN026_version 4.0_PROD_28June2018: ALL
Form: Protocol Deviations Summary
Generated On: 28 Jun 2018 17:33:37

Have any protocol deviations occurred?	Yes ☐
	No ☐

If yes, please complete the Protocol Deviation Log.

Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Protocol Deviations
Generated On: 28 Jun 2018 17:33:37

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 follow-up ☐
	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 medications, 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	Fixed Unit: Staff code
	_____

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Pregnancy Outcome Summary
Generated On: 28 Jun 2018 17:33:37

Was a pregnancy outcome reported?	Yes ☐ No ☐
Is the outcome of this pregnancy obtainable?	Yes ☐ No ☐

If yes, complete the Pregnancy Outcome Log.

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Form: Pregnancy Outcome Log
Generated On: 28 Jun 2018 17:33:37

Visit Code that this pregnancy was reported	V2.0 - Enrollment ☐ V3.0 - Dosing ☐ V4.0 - 24 hr PK ☐ V5.0 - 48 hr PK ☐ V6.0 - 72 hr PK ☐ V7.0 - Dosing ☐ V8.0 - Dosing ☐ V9.0 - Dosing ☐ V10.0 - Dosing ☐ V11.0 - Dosing ☐ V12.0 - Dosing ☐ V13.0 - Final Dosing ☐ V14.0 - 24 hr PK ☐ V15.0 - 48 hr PK ☐ V16.0 - 72 hr PK ☐ V17.0 - Termination ☐ Interim Visit ☐
If interim visit, specify interim visit code	_____
Outcome number	_____
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 (>= 37 weeks) ☐ Premature term live birth (<37 weeks) ☐ Stillbirth/intrauterine fetal demise (>= 20 weeks) ☐ Spontaneous abortion (< 20 weeks) ☐ Ectopic pregnancy ☐ Therapeutic/elective abortion ☐ Other ☐
If other, specify	_____
Method	C-section ☐

Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Pregnancy Outcome Log
Generated On: 28 Jun 2018 17:33:37

	Standard vaginal ☐
	Operative Vaginal ☐
Provide a brief narrative of the circumstances	_____
Were there any complications related to the pregnancy outcome?	Yes ☐
	No ☐
Delivery-related complications Select "none" or all that apply.	☐
None	
Intrapartum hemorrhage	☐
Postpartum hemorrhage	☐
Non-reassuring fetal status	☐
Chorioamnionitis	☐
Other	☐
If other, specify	_____
Non-delivery related complications Select "none" or all that apply.	☐
None	
Hypertensive disorders of pregnancy	☐
Gestational diabetes	☐
Other	☐
If other, specify	_____
Were any fetal/infant congenital anomalies identified?	Yes ☐
	No ☐
Congenital anomalies identified. Select all that apply. Complete AE Log and EAE Reporting form.	Unknown ☐
Central nervous system, cranio-facial	☐
Central nervous system, spinal	☐
Cardiovascular	☐
Renal	☐
Gastrointestinal	☐
Pulmonary	☐
Muscoloskeletal/extremities	☐
Physical defect	☐
Skin	☐
Genitourinary	☐

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Pregnancy Outcome Log
Generated On: 28 Jun 2018 17:33:37

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.	
Infant gender	Male ☐ Female ☐
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	☐

Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Pregnancy Outcome Log
Generated On: 28 Jun 2018 17:33:37

Method used to determine gestational age	Ballard ☐ Dubowitz ☐ Other ☐
If other, specify	_____

MTN026_version 4.0_PROD_28June2018: ALL
Form: Treatment Discontinuation
Generated On: 28 Jun 2018 17:33:37

When was study product use permanently discontinued?	
Date of last study product use	
Did the participant complete study product use through Visit 13 (Last Study Product Administration Visit)?	Yes ☐ No ☐
Select "No" if the participant permanently discontinued study product use early (i.e. prior to Visit 13)	
Primary reason for ending study product use early	Acquisition of HIV infection ☐ Adverse Event ☐ Reported use of prohibited medications ☐ Pregnancy ☐ Breastfeeding ☐ Anorectal STIs ☐ Participant unable/unwilling to comply with required study procedures, or otherwise 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	
If adverse event, select applicable adverse event	
If reported use of prohibited medication, select applicable concomitant medication	

Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Study Discontinuation
Generated On: 28 Jun 2018 17:33:37

Date of study exit	_____
Did the participant complete the study?	Yes ☐ No ☐
If participant completed the study, end of form.	
Primary reason for non-completion	Death ☐ Withdrawal of consent by participant ☐ Lost to follow-up ☐ Investigator decision ☐ Study terminated by sponsor ☐ Pregnancy ☐ HIV infection ☐ Permanent study product discontinuation ☐ Other ☐
If withdrawal of consent by participant, investigator decision, or other, specify:	_____
If death, enter date of death	_____
Was termination associated with an adverse event?	Yes ☐ No ☐ Don't know ☐
If yes, select applicable Adverse Event	_____

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Interim Visit Summary
Generated On: 28 Jun 2018 17:33:37

Visit date	_____
Interim visit code	_____
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 ☐
Have any protocol deviations been 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 7 ☐ Visit 13 ☐ Visit 14 ☐ Visit 16 ☐
Other	☐
If other, specify	_____
What study procedures were completed at this visit? Select all that apply.	
Vital signs	☐
Physical exam	☐
Pelvic exam	☐
Anorectal exam	☐
Specimen collection for PK, PD and mucosal safety	☐
Cervicalvaginal specimen collection	☐
Timed specimen collection for PK, PD, and mucosal safety	☐
Pregnancy test	☐
CBC testing (includes platelets and differential)	☐
Serum creatinine, AST, or ALT	☐
HIV test(s)	☐

_____
Staff Initials/Date

MTN026_version 4.0_PROD_28June2018: ALL
Form: Interim Visit Summary
Generated On: 28 Jun 2018 17:33:37

HIV confirmatory test(s)	☐
STI test(s) (other than HIV)	☐
CASI and/or IDI	☐
Participant replacement	☐
Pregnancy report and history	☐

MTN026_version 4.0_PROD_28June2018: ALL
Form: Participant Identifier
Generated On: 28 Jun 2018 17:33:37

Participant ID: _____