

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

Subject Case Report Forms

MTN039_Version_1.0_PROD_16OCT2019 - ALL

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Screening Date of Visit

Generated On: 16 Oct 2019 22:24:35

Screening visit date

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Demographics

Generated On: 16 Oct 2019 22:24:35

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

How do you identify your sexual orientation? _____ Gay/Lesbian/Homosexual

Bisexual

Queer

Two Spirit

Straight/Heterosexual

Additional category

Not sure

Prefer not to Answer

If "Additional category", specify: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Vital Signs

Generated On: 16 Oct 2019 22:24:35

Were vital signs done? Yes
No

Date of assessment _____ Fixed Unit: cm

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Follow-up Visit Summary
Generated On: 16 Oct 2019 22:24:35

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Additional Study Procedures
Generated On: 16 Oct 2019 22:24:35

Anorectal Exam	<input type="checkbox"/>
CASI	<input type="checkbox"/>
Chemistry Panel	<input type="checkbox"/>
Hematology	<input type="checkbox"/>
HIV Test Results	<input type="checkbox"/>
Pelvic Exam	<input type="checkbox"/>
Physical Examination	<input type="checkbox"/>
Pregnancy Test Results	<input type="checkbox"/>
Specimen Collection and Storage	<input type="checkbox"/>
STI Tests (other than HIV)	<input type="checkbox"/>
Vital Signs	<input type="checkbox"/>
Participant Replacement	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Adverse Event

Generated On: 16 Oct 2019 22:24:35

Date AE reported to site _____

Adverse event (AE) _____

Onset date _____

Visit AE was reported

Screening

Enrollment

Visit 3

Visit 4

Visit 5

Visit 6

Visit 7

Visit 8

Visit 9

Visit 10

Visit 11/Final Contact

Interim Visit

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

Other actions

Mark "None" or all that apply.

None

Medication(s)

Therapeutic procedure/surgery

Diagnostic procedure

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Adverse Event

Generated On: 16 Oct 2019 22:24:35

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? Yes

No

If "No", go to "Has or will this AE be reported as an EAE?". 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

SAE onset date _____

Has or will this AE be reported as an EAE? Yes

No

If "Yes", provide EAE number below.

EAE number _____

Begin number with 4-digit year, followed by 6-digit EAE number
(no dashes or spaces). _____

Study agent(s) _____

Was this AE a worsening of a baseline medical condition? Yes

No

Comments (max. 450 characters): _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Adverse Event Y/N

Generated On: 16 Oct 2019 22:24:35

Has the participant experienced an adverse event during the study? Yes

No

If "Yes", update the Adverse Event log.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Anorectal Exam

Generated On: 16 Oct 2019 22:24:35

Was anorectal exam done? Yes
No

Anorectal exam date _____

PERIANAL EXAMINATION

Perianal examination findings Not done
No abnormal findings
Abnormal findings

If "Abnormal 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

Digital rectal examination findings Not done
No abnormal findings
Abnormal findings

If "Abnormal findings", specify: _____

ANOSCOPY

Rectal mucosa findings Not done
No abnormal findings
Abnormal findings

If "Abnormal findings", select all that apply:

- Erythema

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Anorectal Exam

Generated On: 16 Oct 2019 22:24:35

Abnormal vessels	<input type="checkbox"/>
Ulceration	<input type="checkbox"/>
Friability	<input type="checkbox"/>
Bleeding	<input type="checkbox"/>
Discharge	<input type="checkbox"/>
Polyps	<input type="checkbox"/>
Hemorrhoids	<input type="checkbox"/>
Other abnormal findings	<input type="checkbox"/>

If "Other abnormal findings", specify: _____

SIGMOIDOSCOPY

Sigmoidoscopy findings	Not done <input type="radio"/>
	No abnormal findings <input type="radio"/>
	Abnormal findings <input type="radio"/>

If "Abnormal findings", select all that apply:

Erythema	<input type="checkbox"/>
Abnormal vessels	<input type="checkbox"/>
Ulceration	<input type="checkbox"/>
Friability	<input type="checkbox"/>
Bleeding	<input type="checkbox"/>
Discharge	<input type="checkbox"/>
Polyps	<input type="checkbox"/>
Hemorrhoids	<input type="checkbox"/>
Other abnormal findings	<input type="checkbox"/>

If "Other abnormal findings", specify: _____

Were any new anorectal AE findings reported at this visit?	Yes <input type="radio"/>
	No <input type="radio"/>

Adverse event #1	_____
Adverse event #2	_____
Adverse event #3	_____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Behavioral Assessment

Generated On: 16 Oct 2019 22:24:35

Was a CASI questionnaire or IDI completed at this visit?

Yes

No

If no, please explain: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: CASI Tracking

Generated On: 16 Oct 2019 22:24:35

CASI collection date _____

CASI ID _____

Which questionnaire was completed?

Visit 2 Baseline CASI

Visit 4 Follow-Up CASI

Visit 8 Follow-Up CASI

Visit 10 IDI

Were there any problems or issues related to the administration or completion of the questionnaire? Yes

No

If yes, please describe _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Chemistry Panel

Generated On: 16 Oct 2019 22:24:35

Lab Name: _____

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) adverse event _____

Not reportable as an 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) adverse event _____

Not reportable as an 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 adverse event _____

Not reportable as an adverse event

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Concomitant Medications

Generated On: 16 Oct 2019 22:24:35

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Concomitant Medications
Generated On: 16 Oct 2019 22:24:35

Subcutaneous

Other

If "Other", specify: _____

Taken for a reported AE?

Yes

No

If "Yes", select adverse event. _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Concomitant Medications Y/N
Generated On: 16 Oct 2019 22:24:35

Were any concomitant medications taken?

Yes

No

If "Yes", update the Concomitant Medications log.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Discontinuation of Study Product
Generated On: 16 Oct 2019 22:24:35

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
- Lost to follow-up
- Investigator decision
- Participant refused further study product use
- HIV infection
- Early study closure
- Protocol deviation
- Adverse event
- Pregnancy or breastfeeding
- Study terminated by sponsor
- Anogenital STI
- Use of prohibited medications
- Other, specify

If "Other", specify: _____

If "Adverse event", select applicable adverse event. _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Dose Administration

Generated On: 16 Oct 2019 22:24:35

Visit Number _____ Visit 3

Visit 7

Date insert administered _____

Time insert administered _____

Dosage Administered _____ 1 TAF/EVG insert

2 TAF/EVG inserts

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Enrollment

Generated On: 16 Oct 2019 22:24:35

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

Sample Collection Schedule Assignment

Group 1

Group 2

Is this a replacement participant?

Yes

No

PTID of participant being replaced

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Follow-up Yes/No

Generated On: 16 Oct 2019 22:24:35

Did the participant complete this visit?

Yes

No

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Hematology

Generated On: 16 Oct 2019 22:24:35

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, if applicable

Not reportable as an 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, if applicable

Not reportable as an 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, if applicable

Not reportable as an adverse event

DIFFERENTIAL

Was a differential done? Yes
No

Differential collection date _____

Neutrophils

Neutrophils severity grade
Grade 1 (Mild)
Grade 2 (Moderate)

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Hematology

Generated On: 16 Oct 2019 22:24:35

Lab Name: _____

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

Not gradable

Neutrophils adverse event, if applicable _____

Not reportable as an adverse event

Lymphocytes _____

Lymphocytes severity grade _____

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

Not gradable

Lymphocytes adverse event, if applicable _____

Not reportable as an adverse event

Monocytes _____

Eosinophils _____

Basophils _____

Comments (max. 200 characters): _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: HIV Confirmatory Results

Generated On: 16 Oct 2019 22:24:35

Geenius HIV-1/2 confirmatory test

Was Geenius HIV-1/2 confirmatory test collected for testing? Yes
No

If "No", skip to "Was plasma for confirmatory testing collected?"

Geenius HIV-1/2 confirmatory test collection date _____

Geenius HIV-1/2 confirmatory test HIV 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)

Plasma

Was plasma for confirmatory testing collected? Yes
No

If "No", skip to "Was HIV RNA PCR testing completed?"

Was plasma stored for HIV confirmatory testing? Stored
Not stored

Plasma for HIV confirmatory testing collection date _____

HIV RNA PCR

Was HIV RNA PCR testing completed? Yes
No

If "No", skip to "Were Absolute CD4+ collected for testing?"

HIV RNA PCR collection date _____

HIV RNA PCR =>
=<
==

HIV RNA PCR Fixed Unit: viral copies/mL

Or

Target not detected

HIV RNA PCR kit lower limit of detection

HIV RNA PCR kit Abbott M2000
Roche TaqMan
Gene Xpert

HIV RNA PCR kit lower limit of detection 20
40

OR

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: HIV Confirmatory Results

Generated On: 16 Oct 2019 22:24:35

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

Absolute CD4+ _____
Were Absolute CD4+ collected for testing? Yes
No

If "No", skip to "Final HIV Status".

Absolute CD4+ collection date _____
Absolute CD4+ _____ Fixed Unit: cells/mm³

Or
Unable to analyze

CD4 % _____
CD4 % not available

Or
CD4 % _____ Fixed Unit: %

Final HIV status _____
Final HIV status HIV uninfected
HIV infected
Pending

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: HIV Test Results
Generated On: 16 Oct 2019 22:24:35

HIV test 1

Was an HIV test sample 1 collected for testing? Yes
No

If "No", skip to HIV test 2.

HIV test 1 Kit AlereTM HIV Combo
Oraquick ADVANCE HIV-1/2
Uni-Gold Recombigen HIV-1/2
Alere Determine
Abbott Architect HIV Ag/Ab
Combo
Other

If "Other", specify: _____

HIV test 1 collection date _____

HIV test 1 results Antibody positive
Antigen positive
Antibody and antigen positive
Negative

HIV test 2

Was an HIV test sample 2 collected for testing? Yes
No

If "No", end of form.

HIV test 2 Kit AlereTM HIV Combo
Oraquick ADVANCE HIV-1/2
Uni-Gold Recombigen HIV-1/2
Alere Determine
Abbott Architect HIV Ag/Ab
Combo
Other

If "Other", specify: _____

HIV test 2 collection date _____

HIV test 2 results Antibody positive
Antigen positive
Antibody and antigen positive
Negative

If at least one HIV test result is positive, complete the HIV Confirmatory Results form.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Inclusion Exclusion Criteria
Generated On: 16 Oct 2019 22:24:35

Did the participant meet all eligibility criteria? Yes
No

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. Individuals who are 18 years of age or older at Screening
- I2. Able and willing to provide written informed consent to be screened for and enrolled in MTN-039
- I3. HIV-1/2 uninfected at Screening and Enrollment and willing to receive HIV test results
- I4. Able and willing to provide adequate locator information
- 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. In general good health at Screening and Enrollment, as determined by the site IoR or designee
- I8. At Screening, history of consensual RAI at least once in lifetime per participant report
- I9. Willing not to take part in other research studies involving drugs, medical devices, genital or rectal products, or vaccines for the duration of study participation (including the time between Screening and Enrollment)
- I10. Willing to comply with abstinence and other protocol requirements
- I11. For participants of childbearing potential: a negative pregnancy test at Screening and Enrollment
- I12. For participants of childbearing potential: Per participant report at Enrollment, using an effective method of contraception for at least 30 days (inclusive) prior to Enrollment and intending to use an effective method for the duration of study participation

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Inclusion Exclusion Criteria
Generated On: 16 Oct 2019 22:24:35

- E1a. Hemoglobin Grade 1 or higher
- E1b. Platelet count Grade 1 or higher
- E1c. Aspartate aminotransferase (AST) or alanine transaminase (ALT) Grade 1 or higher
- E1d. Serum creatinine >1.3× the site laboratory upper limit of normal (ULN)
- E1e. International normalized ratio (INR) >1.5× the site laboratory ULN
- E1f. History of inflammatory bowel disease by participant report
- E1g. Positive hepatitis B surface antigen (HBsAg) test result
- E2a. Anticipated use of and/or unwillingness to abstain from anticoagulant medications during study participation
- E2b. Anticipated use of and/or unwillingness to abstain from non-study rectally-administered medications and any products containing N-9 during study participation
- E3. Known adverse reaction to any of the components of the study product
- E4. Use of approved or other investigational pre-exposure prophylaxis (PrEP) for HIV prevention within 3 months prior to Enrollment, and/or anticipated use and/or unwillingness to abstain from PrEP during trial participation
- E5. Use of post-exposure prophylaxis (PEP) for potential HIV exposure within 6 months prior to Enrollment
- E6. Condomless RAI and/or penile-vaginal intercourse with a partner who is known to be HIV-positive or whose status is unknown in the 6 months prior to Enrollment
- E7. History of transactional sex in the 12 months prior to Enrollment
- E8. Non-therapeutic injection drug use or use of non-therapeutic, non-injection stimulant drugs in the 12 months prior to Enrollment

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Inclusion Exclusion Criteria
Generated On: 16 Oct 2019 22:24:35

- E9. Participation in research studies involving drugs, medical devices, genital or rectal products, or vaccines within 30 days of the Enrollment Visit
- E10a. Diagnosis or treatment of an anogenital STI in the 3 months prior to enrollment (including window between Screening and Enrollment).
- E10b. Symptoms, clinical or laboratory diagnosis of active pharyngeal, anorectal, or reproductive tract infection (RTI) requiring treatment per current CDC guidelines
- E10c. Current symptomatic urinary tract infection (UTI).
- E11. For participants of childbearing potential: Pregnant or breastfeeding at either Screening or Enrollment or planning to become pregnant during study participation
- E12. For participants of childbearing potential: Last pregnancy outcome 90 days or less prior to Screening
- E13. 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 "Investigator decision", specify (max. 200 characters): _____

If eligible, but participant declined enrollment, specify reason: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Interim Visit Summary

Generated On: 16 Oct 2019 22:24:35

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

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/Final Contact Interim Visit

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 and Storage

Pregnancy test

Hematology

Chemistry Panel

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Interim Visit Summary

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HIV test(s)	<input type="checkbox"/>
STI test(s) (other than HIV)	<input type="checkbox"/>
CASI	<input type="checkbox"/>
Participant Replacement	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Medical History

Generated On: 16 Oct 2019 22:24:35

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 _____

Comments (max. 200 characters): _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Medical History Y/N

Generated On: 16 Oct 2019 22:24:35

Does the participant have any medical history to report?

Yes

No

If "Yes", update the Medical History log.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Missed Visit

Generated On: 16 Oct 2019 22:24:35

Target visit date _____

- Reason visit was missed
- Unable to contact participant
 - Participant unable to schedule visit within window
 - Participant refused visit
 - Participant incarcerated
 - Participant admitted to healthcare facility
 - Participant withdrew from study
 - Participant deceased
 - Other

If "Other", specify: _____

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Participant Identifier

Generated On: 16 Oct 2019 22:24:35

Participant ID: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Participant Replacement Assessment
Generated On: 16 Oct 2019 22:24:35

Date of assessment _____

Does this participant meet protocol-specified criteria for replacement?

Yes

No

Why is this participant being replaced?

None of the doses administered (e.g., due to non-adherence or permanent discontinuation)

Early termination (e.g., due to participant voluntarily withdrawing from the study, death, lost to follow-up, relocation, or permanent discontinuation)

Other

If other, specify _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Pelvic Exam

Generated On: 16 Oct 2019 22:24:35

Pelvic exam assessment Not done
No abnormal findings
Abnormal findings

Pelvic exam date _____

If "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)

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Pelvic Exam

Generated On: 16 Oct 2019 22:24:35

Cervical motion tenderness	<input type="checkbox"/>
Cervical discharge	<input type="checkbox"/>
Cervical ulcer	<input type="checkbox"/>
Cervical blister	<input type="checkbox"/>
Cervical pustule	<input type="checkbox"/>
Cervical peeling	<input type="checkbox"/>
Cervical ecchymosis	<input type="checkbox"/>
GENERAL/OTHER	
Odor (vaginal)	<input type="checkbox"/>
Condyloma	<input type="checkbox"/>
If "Condyloma", specify location: _____	
Adnexal masses (based on bimanual exam; not pregnancy or infection-related)	<input type="checkbox"/>
Uterine masses (based on bimanual exam)	<input type="checkbox"/>
Uterine tenderness	<input type="checkbox"/>
Adnexal tenderness	<input type="checkbox"/>
Abnormal blood or bleeding	<input type="checkbox"/>
If "Abnormal blood or bleeding", specify: _____	
Other abnormal findings	<input type="checkbox"/>
If "Other abnormal findings", specify: _____	
If "Other abnormal findings", specify 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 <input type="radio"/>
	No <input type="radio"/>
Adverse event #1	_____
Adverse event #2	_____
Adverse event #3	_____
Cervical ectopy (%)	0% <input type="radio"/>
	1-25% <input type="radio"/>
	26-50% <input type="radio"/>
	51-75% <input type="radio"/>
	76-100% <input type="radio"/>
	Not done <input type="radio"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Pharmacy Dispensation

Generated On: 16 Oct 2019 22:24:35

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Physical Exam

Generated On: 16 Oct 2019 22:24:35

Was a physical exam performed? Yes
No

Date of exam _____

BODY SYSTEM

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: _____

Genitourinary Not done
Normal
Abnormal

If "Abnormal", specify: _____

Extremities Not done
Normal
Abnormal

If "Abnormal", specify: _____

Neurological Not done

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Physical Exam
Generated On: 16 Oct 2019 22:24:35

Normal

Abnormal

If "Abnormal", specify: _____

Skin

Not done

Normal

Abnormal

If "Abnormal", specify: _____

Oral Mucosa

Not done

Normal

Abnormal

If "Abnormal", specify: _____

General appearance

Not done

Normal

Abnormal

If "Abnormal", specify: _____

Other system finding

Not done

Normal

Abnormal

If "Other system finding", specify: _____

If "Abnormal", specify: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Pregnancy History

Generated On: 16 Oct 2019 22:24:35

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 (max. 200 characters): _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Pregnancy Outcome Log

Generated On: 16 Oct 2019 22:24:35

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)
If "Stillbirth/intrauterine fetal demise", "Spontaneous abortion", "Ectopic pregnancy" or "Therapeutic/elective abortion" is chosen, go to "Provide a brief narrative of the circumstances:". If "Full term live birth", go to "Method". 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 "Other", specify: _____

Method C-section
If "Full term live birth", go to "Were there any complications related to the pregnancy outcome?" Standard vaginal
Operative vaginal
Vaginal

Provide a brief narrative of the circumstances (max. 400 characters). _____

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

If "No", skip to "Were any fetal/infant congenital anomalies identified?".

Delivery-related complications. Mark "None" or all that apply.

None

Intrapartum hemorrhage

Postpartum hemorrhage

Non-reassuring fetal status

Chorioamnionitis

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Pregnancy Outcome Log

Generated On: 16 Oct 2019 22:24:35

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. Yes

If "No" or "Unknown", go to "Complete the infant items below for live births only." No

Not assessed

Unknown

Central nervous system, cranio-facial

Central nervous system, spinal

Cardiovascular

Renal

Gastrointestinal

Pulmonary

Musculoskeletal/extremities

Physical defect

Skin

Genitourinary

Chromosomal

Cranio-facial (structural)

Hematologic

Infectious

Endocrine/metabolic

Other

Describe congenital anomaly/defect (max. 200 characters). _____

If "Yes", select adverse event. OR Specify congenital anomaly/defect AE.

Complete AE Log and EAE Reporting form. _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Pregnancy Outcome Log

Generated On: 16 Oct 2019 22:24:35

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

Male

Female

Infant sex

Infant birth weight

Fixed Unit: kg

Or

Infant birth weight unavailable

Infant birth length

Fixed Unit: cm

Or

Infant birth length unavailable

Infant birth head circumference

Fixed Unit: cm

Or

Infant birth head circumference unavailable

Infant birth abdominal circumference

Fixed Unit: cm

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 (max. 200 characters): _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Pregnancy Report

Generated On: 16 Oct 2019 22:24:35

Date pregnancy reported to site _____

Visit at which this pregnancy was reported _____

Screening

Enrollment

Visit 3

Visit 4

Visit 5

Visit 6

Visit 7

Visit 8

Visit 9

Visit 10

Visit 11/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. _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Pregnancy Test Results

Generated On: 16 Oct 2019 22:24:35

Was a pregnancy test done? Yes

No

Collection date _____

Pregnancy test result Positive

Negative

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Product Hold Log

Generated On: 16 Oct 2019 22:24:35

Date when study product hold was initiated: _____

Why is study product being held? _____

Reactive HIV test

Adverse Event

Reported use of PEP or PrEP

Pregnancy

Breastfeeding

Participant unable/unwilling to comply with the required study procedures, or otherwise might be put at undue risk to their safety and well-being by continuing product use according to the judgment of IoR/designee

Other

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? Yes

No - hold continuing for another reason

No - early termination

If 'no - permanently discontinued', 'no - early termination' or 'no - hold continuing at scheduled PUEV', complete the Product Discontinuation form.

No - Hold continuing at scheduled PUEV

No - permanently discontinued

Date study product resumed _____

Date study product hold continuing for another reason _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Product Hold Summary

Generated On: 16 Oct 2019 22:24:35

Does the participant have any clinical product holds to be applied?

Yes

No

If Yes, complete the Product Hold Log form

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Protocol Deviations Log

Generated On: 16 Oct 2019 22:24:35

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 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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Protocol Deviations Y/N

Generated On: 16 Oct 2019 22:24:35

Have any protocol deviations been reported?

Yes

No

If "Yes", update the Protocol Deviations log.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Randomization

Generated On: 16 Oct 2019 22:24:35

Is the participant ready to be randomized?

Yes

No

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 4 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs
 - Rectal fluid for PK - 4 hrs
 - Rectal fluid for PK - 6 hrs
 - Rectal fluid for PD
 - Rectal fluid for PD - 2 hrs
 - Rectal fluid for microbiome
 - Rectal fluid for microbiome - 2 hrs
 - Rectal tissue for PK
 - Rectal tissue for PK - 2 hrs
 - Rectal tissue for PD
 - Rectal tissue for PD - 2 hrs
 - Rectal tissue for biomarkers
 - Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters).

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 4 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs
 - Rectal fluid for PK - 4 hrs
 - Rectal fluid for PK - 6 hrs
 - Rectal fluid for PD
 - Rectal fluid for PD - 2 hrs
 - Rectal fluid for microbiome
 - Rectal fluid for microbiome - 2 hrs
 - Rectal tissue for PK
 - Rectal tissue for PK - 2 hrs
 - Rectal tissue for PD
 - Rectal tissue for PD - 2 hrs
 - Rectal tissue for biomarkers
 - Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters).

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

Specimen collection date _____

Specimen collection time _____

Was sample stored?

Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type

Plasma for archive

Blood for PK

Blood for PK - 1 hr

Blood for PK - 2 hrs

Blood for PK - 4 hrs

Blood for PK - 6 hrs

CVF for PK

CVF for PK - 2 hrs

CVF for PK - 4 hrs

CVF for PK - 6 hrs

CVF for PD

CVF for PD - 2 hrs

CVF for microflora

Vaginal gram stain

CVF for microflora - 2 hrs

Vaginal gram stain - 2 hrs

Rectal fluid for PK

Rectal fluid for PK - 2 hrs

Rectal fluid for PK - 4 hrs

Rectal fluid for PK - 6 hrs

Rectal fluid for PD

Rectal fluid for PD - 2 hrs

Rectal fluid for microbiome

Rectal fluid for microbiome - 2 hrs

Rectal tissue for PK

Rectal tissue for PK - 2 hrs

Rectal tissue for PD

Rectal tissue for PD - 2 hrs

Rectal tissue for biomarkers

Rectal tissue for biomarkers - 2 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 4 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs
 - Rectal fluid for PK - 4 hrs
 - Rectal fluid for PK - 6 hrs
 - Rectal fluid for PD
 - Rectal fluid for PD - 2 hrs
 - Rectal fluid for microbiome
 - Rectal fluid for microbiome - 2 hrs
 - Rectal tissue for PK
 - Rectal tissue for PK - 2 hrs
 - Rectal tissue for PD

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

Rectal tissue for PD - 2 hrs
Rectal tissue for biomarkers
Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type

- Plasma for archive
- Blood for PK
- Blood for PK - 1 hr
- Blood for PK - 2 hrs
- Blood for PK - 4 hrs
- Blood for PK - 6 hrs
- CVF for PK
- CVF for PK - 2 hrs
- CVF for PK - 4 hrs
- CVF for PK - 6 hrs
- CVF for PD
- CVF for PD - 2 hrs
- CVF for microflora
- Vaginal gram stain
- CVF for microflora - 2 hrs
- Vaginal gram stain - 2 hrs
- Rectal fluid for PK
- Rectal fluid for PK - 2 hrs
- Rectal fluid for PK - 4 hrs
- Rectal fluid for PK - 6 hrs
- Rectal fluid for PD
- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input checked="" type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 2 hrs	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>
	CVF for PK - 6 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for PD - 2 hrs	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>
	Vaginal gram stain - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 6 hrs	<input type="checkbox"/>
Rectal fluid for PD	<input type="checkbox"/>	

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD
- Rectal tissue for PD - 2 hrs
- Rectal tissue for biomarkers
- Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 4 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
Rectal fluid for PK - 6 hrs	<input type="checkbox"/>
Rectal fluid for PD	<input type="checkbox"/>
Rectal fluid for PD - 2 hrs	<input type="checkbox"/>
Rectal fluid for microbiome	<input type="checkbox"/>
Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
Rectal tissue for PK	<input type="checkbox"/>
Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
Rectal tissue for PD	<input type="checkbox"/>
Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
Rectal tissue for biomarkers	<input type="checkbox"/>
Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored?	Stored <input type="checkbox"/>
	Not stored <input type="checkbox"/>

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive <input type="checkbox"/>
	Blood for PK <input type="checkbox"/>
	Blood for PK - 1 hr <input type="checkbox"/>
	Blood for PK - 2 hrs <input type="checkbox"/>
	Blood for PK - 4 hrs <input type="checkbox"/>
	Blood for PK - 6 hrs <input type="checkbox"/>
	CVF for PK <input type="checkbox"/>
	CVF for PK - 2 hrs <input checked="" type="checkbox"/>
	CVF for PK - 4 hrs <input type="checkbox"/>
	CVF for PK - 6 hrs <input type="checkbox"/>
	CVF for PD <input type="checkbox"/>
	CVF for PD - 2 hrs <input type="checkbox"/>
	CVF for microflora <input type="checkbox"/>
	Vaginal gram stain <input type="checkbox"/>
	CVF for microflora - 2 hrs <input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

- Vaginal gram stain - 2 hrs
- Rectal fluid for PK
- Rectal fluid for PK - 2 hrs
- Rectal fluid for PK - 4 hrs
- Rectal fluid for PK - 6 hrs
- Rectal fluid for PD
- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD
- Rectal tissue for PD - 2 hrs
- Rectal tissue for biomarkers
- Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type Plasma for archive
- Blood for PK
- Blood for PK - 1 hr
- Blood for PK - 2 hrs
- Blood for PK - 4 hrs
- Blood for PK - 6 hrs
- CVF for PK
- CVF for PK - 2 hrs
- CVF for PK - 4 hrs
- CVF for PK - 6 hrs
- CVF for PD
- CVF for PD - 2 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
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- CVF for microflora
- Vaginal gram stain
- CVF for microflora - 2 hrs
- Vaginal gram stain - 2 hrs
- Rectal fluid for PK
- Rectal fluid for PK - 2 hrs
- Rectal fluid for PK - 4 hrs
- Rectal fluid for PK - 6 hrs
- Rectal fluid for PD
- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD
- Rectal tissue for PD - 2 hrs
- Rectal tissue for biomarkers
- Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type
- Plasma for archive
- Blood for PK
- Blood for PK - 1 hr
- Blood for PK - 2 hrs
- Blood for PK - 4 hrs
- Blood for PK - 6 hrs
- CVF for PK
- CVF for PK - 2 hrs
- CVF for PK - 4 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

	CVF for PK - 6 hrs	<input checked="" type="radio"/>
	CVF for PD	<input type="radio"/>
	CVF for PD - 2 hrs	<input type="radio"/>
	CVF for microflora	<input type="radio"/>
	Vaginal gram stain	<input type="radio"/>
	CVF for microflora - 2 hrs	<input type="radio"/>
	Vaginal gram stain - 2 hrs	<input type="radio"/>
	Rectal fluid for PK	<input type="radio"/>
	Rectal fluid for PK - 2 hrs	<input type="radio"/>
	Rectal fluid for PK - 4 hrs	<input type="radio"/>
	Rectal fluid for PK - 6 hrs	<input type="radio"/>
	Rectal fluid for PD	<input type="radio"/>
	Rectal fluid for PD - 2 hrs	<input type="radio"/>
	Rectal fluid for microbiome	<input type="radio"/>
	Rectal fluid for microbiome - 2 hrs	<input type="radio"/>
	Rectal tissue for PK	<input type="radio"/>
	Rectal tissue for PK - 2 hrs	<input type="radio"/>
	Rectal tissue for PD	<input type="radio"/>
	Rectal tissue for PD - 2 hrs	<input type="radio"/>
	Rectal tissue for biomarkers	<input type="radio"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="radio"/>

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive	<input type="radio"/>
	Blood for PK	<input type="radio"/>
	Blood for PK - 1 hr	<input type="radio"/>
	Blood for PK - 2 hrs	<input type="radio"/>
	Blood for PK - 4 hrs	<input type="radio"/>
	Blood for PK - 6 hrs	<input type="radio"/>

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	CVF for PK	<input type="checkbox"/>
	CVF for PK - 2 hrs	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>
	CVF for PK - 6 hrs	<input type="checkbox"/>
	CVF for PD	<input checked="" type="checkbox"/>
	CVF for PD - 2 hrs	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>
	Vaginal gram stain - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 6 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for PD - 2 hrs	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

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Blood for PK - 2 hrs

Blood for PK - 4 hrs

Blood for PK - 6 hrs

CVF for PK

CVF for PK - 2 hrs

CVF for PK - 4 hrs

CVF for PK - 6 hrs

CVF for PD

CVF for PD - 2 hrs

CVF for microflora

Vaginal gram stain

CVF for microflora - 2 hrs

Vaginal gram stain - 2 hrs

Rectal fluid for PK

Rectal fluid for PK - 2 hrs

Rectal fluid for PK - 4 hrs

Rectal fluid for PK - 6 hrs

Rectal fluid for PD

Rectal fluid for PD - 2 hrs

Rectal fluid for microbiome

Rectal fluid for microbiome - 2
hrs

Rectal tissue for PK

Rectal tissue for PK - 2 hrs

Rectal tissue for PD

Rectal tissue for PD - 2 hrs

Rectal tissue for biomarkers

Rectal tissue for biomarkers - 2
hrs

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
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Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 2 hrs	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>
	CVF for PK - 6 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for PD - 2 hrs	<input type="checkbox"/>
	CVF for microflora	<input checked="" type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>
	Vaginal gram stain - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 6 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for PD - 2 hrs	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>
Was specimen collected?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? _____ Stored

Participant ID: _____ - _____ - _____

Visit: _____

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Not stored

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type

- Plasma for archive
- Blood for PK
- Blood for PK - 1 hr
- Blood for PK - 2 hrs
- Blood for PK - 4 hrs
- Blood for PK - 6 hrs
- CVF for PK
- CVF for PK - 2 hrs
- CVF for PK - 4 hrs
- CVF for PK - 6 hrs
- CVF for PD
- CVF for PD - 2 hrs
- CVF for microflora
- Vaginal gram stain
- CVF for microflora - 2 hrs
- Vaginal gram stain - 2 hrs
- Rectal fluid for PK
- Rectal fluid for PK - 2 hrs
- Rectal fluid for PK - 4 hrs
- Rectal fluid for PK - 6 hrs
- Rectal fluid for PD
- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD
- Rectal tissue for PD - 2 hrs
- Rectal tissue for biomarkers
- Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters).

Participant ID: _____ - _____ - _____

Visit: _____

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Specimen collection date _____

Specimen collection time _____

Was sample stored? _____

Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type _____

Plasma for archive

Blood for PK

Blood for PK - 1 hr

Blood for PK - 2 hrs

Blood for PK - 4 hrs

Blood for PK - 6 hrs

CVF for PK

CVF for PK - 2 hrs

CVF for PK - 4 hrs

CVF for PK - 6 hrs

CVF for PD

CVF for PD - 2 hrs

CVF for microflora

Vaginal gram stain

CVF for microflora - 2 hrs

Vaginal gram stain - 2 hrs

Rectal fluid for PK

Rectal fluid for PK - 2 hrs

Rectal fluid for PK - 4 hrs

Rectal fluid for PK - 6 hrs

Rectal fluid for PD

Rectal fluid for PD - 2 hrs

Rectal fluid for microbiome

Rectal fluid for microbiome - 2 hrs

Rectal tissue for PK

Rectal tissue for PK - 2 hrs

Rectal tissue for PD

Rectal tissue for PD - 2 hrs

Rectal tissue for biomarkers

Rectal tissue for biomarkers - 2 hrs

Participant ID: _____ - _____ - _____

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Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 4 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs
 - Rectal fluid for PK - 4 hrs
 - Rectal fluid for PK - 6 hrs
 - Rectal fluid for PD
 - Rectal fluid for PD - 2 hrs
 - Rectal fluid for microbiome
 - Rectal fluid for microbiome - 2 hrs
 - Rectal tissue for PK
 - Rectal tissue for PK - 2 hrs
 - Rectal tissue for PD

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

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Rectal tissue for PD - 2 hrs
Rectal tissue for biomarkers
Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type

- Plasma for archive
- Blood for PK
- Blood for PK - 1 hr
- Blood for PK - 2 hrs
- Blood for PK - 4 hrs
- Blood for PK - 6 hrs
- CVF for PK
- CVF for PK - 2 hrs
- CVF for PK - 4 hrs
- CVF for PK - 6 hrs
- CVF for PD
- CVF for PD - 2 hrs
- CVF for microflora
- Vaginal gram stain
- CVF for microflora - 2 hrs
- Vaginal gram stain - 2 hrs
- Rectal fluid for PK
- Rectal fluid for PK - 2 hrs
- Rectal fluid for PK - 4 hrs
- Rectal fluid for PK - 6 hrs
- Rectal fluid for PD
- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

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	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date

Specimen collection time

Was sample stored?	Stored	<input type="checkbox"/>
	Not stored	<input type="checkbox"/>

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 2 hrs	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>
	CVF for PK - 6 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for PD - 2 hrs	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>
	Vaginal gram stain - 2 hrs	<input type="checkbox"/>
Rectal fluid for PK	<input type="checkbox"/>	
Rectal fluid for PK - 2 hrs	<input checked="" type="checkbox"/>	
Rectal fluid for PK - 4 hrs	<input type="checkbox"/>	
Rectal fluid for PK - 6 hrs	<input type="checkbox"/>	
Rectal fluid for PD	<input type="checkbox"/>	

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

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- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD
- Rectal tissue for PD - 2 hrs
- Rectal tissue for biomarkers
- Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 4 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

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Rectal fluid for PK - 4 hrs	<input checked="" type="radio"/>
Rectal fluid for PK - 6 hrs	<input type="radio"/>
Rectal fluid for PD	<input type="radio"/>
Rectal fluid for PD - 2 hrs	<input type="radio"/>
Rectal fluid for microbiome	<input type="radio"/>
Rectal fluid for microbiome - 2 hrs	<input type="radio"/>
Rectal tissue for PK	<input type="radio"/>
Rectal tissue for PK - 2 hrs	<input type="radio"/>
Rectal tissue for PD	<input type="radio"/>
Rectal tissue for PD - 2 hrs	<input type="radio"/>
Rectal tissue for biomarkers	<input type="radio"/>
Rectal tissue for biomarkers - 2 hrs	<input type="radio"/>

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive <input type="radio"/>
	Blood for PK <input type="radio"/>
	Blood for PK - 1 hr <input type="radio"/>
	Blood for PK - 2 hrs <input type="radio"/>
	Blood for PK - 4 hrs <input type="radio"/>
	Blood for PK - 6 hrs <input type="radio"/>
	CVF for PK <input type="radio"/>
	CVF for PK - 2 hrs <input type="radio"/>
	CVF for PK - 4 hrs <input type="radio"/>
	CVF for PK - 6 hrs <input type="radio"/>
	CVF for PD <input type="radio"/>
	CVF for PD - 2 hrs <input type="radio"/>
	CVF for microflora <input type="radio"/>
	Vaginal gram stain <input type="radio"/>
	CVF for microflora - 2 hrs <input type="radio"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

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Vaginal gram stain - 2 hrs	<input type="checkbox"/>
Rectal fluid for PK	<input type="checkbox"/>
Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
Rectal fluid for PK - 6 hrs	<input checked="" type="checkbox"/>
Rectal fluid for PD	<input type="checkbox"/>
Rectal fluid for PD - 2 hrs	<input type="checkbox"/>
Rectal fluid for microbiome	<input type="checkbox"/>
Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
Rectal tissue for PK	<input type="checkbox"/>
Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
Rectal tissue for PD	<input type="checkbox"/>
Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
Rectal tissue for biomarkers	<input type="checkbox"/>
Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive <input type="checkbox"/>
	Blood for PK <input type="checkbox"/>
	Blood for PK - 1 hr <input type="checkbox"/>
	Blood for PK - 2 hrs <input type="checkbox"/>
	Blood for PK - 4 hrs <input type="checkbox"/>
	Blood for PK - 6 hrs <input type="checkbox"/>
	CVF for PK <input type="checkbox"/>
	CVF for PK - 2 hrs <input type="checkbox"/>
	CVF for PK - 4 hrs <input type="checkbox"/>
	CVF for PK - 6 hrs <input type="checkbox"/>
	CVF for PD <input type="checkbox"/>
	CVF for PD - 2 hrs <input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

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- CVF for microflora
- Vaginal gram stain
- CVF for microflora - 2 hrs
- Vaginal gram stain - 2 hrs
- Rectal fluid for PK
- Rectal fluid for PK - 2 hrs
- Rectal fluid for PK - 4 hrs
- Rectal fluid for PK - 6 hrs
- Rectal fluid for PD
- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD
- Rectal tissue for PD - 2 hrs
- Rectal tissue for biomarkers
- Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 4 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

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	CVF for PK - 6 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for PD - 2 hrs	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>
	Vaginal gram stain - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 6 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for PD - 2 hrs	<input checked="" type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored?	Stored	<input type="checkbox"/>
	Not stored	<input type="checkbox"/>

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
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	CVF for PK	<input type="checkbox"/>
	CVF for PK - 2 hrs	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>
	CVF for PK - 6 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for PD - 2 hrs	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>
	Vaginal gram stain - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 6 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for PD - 2 hrs	<input type="checkbox"/>
	Rectal fluid for microbiome	<input checked="" type="checkbox"/>
	Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

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- Blood for PK - 2 hrs
- Blood for PK - 4 hrs
- Blood for PK - 6 hrs
- CVF for PK
- CVF for PK - 2 hrs
- CVF for PK - 4 hrs
- CVF for PK - 6 hrs
- CVF for PD
- CVF for PD - 2 hrs
- CVF for microflora
- Vaginal gram stain
- CVF for microflora - 2 hrs
- Vaginal gram stain - 2 hrs
- Rectal fluid for PK
- Rectal fluid for PK - 2 hrs
- Rectal fluid for PK - 4 hrs
- Rectal fluid for PK - 6 hrs
- Rectal fluid for PD
- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD
- Rectal tissue for PD - 2 hrs
- Rectal tissue for biomarkers
- Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
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Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 2 hrs	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>
	CVF for PK - 6 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for PD - 2 hrs	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>
	Vaginal gram stain - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 6 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for PD - 2 hrs	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PK	<input checked="" type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>
Was specimen collected?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? _____ Stored

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

Not stored

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type

- Plasma for archive
- Blood for PK
- Blood for PK - 1 hr
- Blood for PK - 2 hrs
- Blood for PK - 4 hrs
- Blood for PK - 6 hrs
- CVF for PK
- CVF for PK - 2 hrs
- CVF for PK - 4 hrs
- CVF for PK - 6 hrs
- CVF for PD
- CVF for PD - 2 hrs
- CVF for microflora
- Vaginal gram stain
- CVF for microflora - 2 hrs
- Vaginal gram stain - 2 hrs
- Rectal fluid for PK
- Rectal fluid for PK - 2 hrs
- Rectal fluid for PK - 4 hrs
- Rectal fluid for PK - 6 hrs
- Rectal fluid for PD
- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD
- Rectal tissue for PD - 2 hrs
- Rectal tissue for biomarkers
- Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters).

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

Specimen collection date _____

Specimen collection time _____

Was sample stored?

Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type

Plasma for archive

Blood for PK

Blood for PK - 1 hr

Blood for PK - 2 hrs

Blood for PK - 4 hrs

Blood for PK - 6 hrs

CVF for PK

CVF for PK - 2 hrs

CVF for PK - 4 hrs

CVF for PK - 6 hrs

CVF for PD

CVF for PD - 2 hrs

CVF for microflora

Vaginal gram stain

CVF for microflora - 2 hrs

Vaginal gram stain - 2 hrs

Rectal fluid for PK

Rectal fluid for PK - 2 hrs

Rectal fluid for PK - 4 hrs

Rectal fluid for PK - 6 hrs

Rectal fluid for PD

Rectal fluid for PD - 2 hrs

Rectal fluid for microbiome

Rectal fluid for microbiome - 2 hrs

Rectal tissue for PK

Rectal tissue for PK - 2 hrs

Rectal tissue for PD

Rectal tissue for PD - 2 hrs

Rectal tissue for biomarkers

Rectal tissue for biomarkers - 2 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 4 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs
 - Rectal fluid for PK - 4 hrs
 - Rectal fluid for PK - 6 hrs
 - Rectal fluid for PD
 - Rectal fluid for PD - 2 hrs
 - Rectal fluid for microbiome
 - Rectal fluid for microbiome - 2 hrs
 - Rectal tissue for PK
 - Rectal tissue for PK - 2 hrs
 - Rectal tissue for PD

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

Rectal tissue for PD - 2 hrs

Rectal tissue for biomarkers

Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type

Plasma for archive

Blood for PK

Blood for PK - 1 hr

Blood for PK - 2 hrs

Blood for PK - 4 hrs

Blood for PK - 6 hrs

CVF for PK

CVF for PK - 2 hrs

CVF for PK - 4 hrs

CVF for PK - 6 hrs

CVF for PD

CVF for PD - 2 hrs

CVF for microflora

Vaginal gram stain

CVF for microflora - 2 hrs

Vaginal gram stain - 2 hrs

Rectal fluid for PK

Rectal fluid for PK - 2 hrs

Rectal fluid for PK - 4 hrs

Rectal fluid for PK - 6 hrs

Rectal fluid for PD

Rectal fluid for PD - 2 hrs

Rectal fluid for microbiome

Rectal fluid for microbiome - 2 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input checked="" type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 2 hrs	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>
	CVF for PK - 6 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for PD - 2 hrs	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>
	Vaginal gram stain - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 6 hrs	<input type="checkbox"/>
Rectal fluid for PD	<input type="checkbox"/>	

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage
Generated On: 16 Oct 2019 22:24:35

Rectal fluid for PD - 2 hrs	<input type="checkbox"/>
Rectal fluid for microbiome	<input type="checkbox"/>
Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
Rectal tissue for PK	<input type="checkbox"/>
Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
Rectal tissue for PD	<input type="checkbox"/>
Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
Rectal tissue for biomarkers	<input type="checkbox"/>
Rectal tissue for biomarkers - 2 hrs	<input checked="" type="checkbox"/>

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

-
-
- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs
 - Rectal fluid for PK - 6 hrs
 - Rectal fluid for PD
 - Rectal fluid for PD - 2 hrs
 - Rectal fluid for microbiome
 - Rectal fluid for microbiome - 2 hrs
 - Rectal tissue for PK
 - Rectal tissue for PK - 2 hrs
 - Rectal tissue for PD
 - Rectal tissue for PD - 2 hrs
 - Rectal tissue for biomarkers
 - Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive <input type="radio"/>
	Blood for PK <input checked="" type="radio"/>
	Blood for PK - 1 hr <input type="radio"/>
	Blood for PK - 2 hrs <input type="radio"/>
	Blood for PK - 4 hrs <input type="radio"/>
	Blood for PK - 6 hrs <input type="radio"/>
	CVF for PK <input type="radio"/>
	CVF for PK - 2 hrs <input type="radio"/>
	CVF for PK - 6 hrs <input type="radio"/>
	CVF for PD <input type="radio"/>
	CVF for PD - 2 hrs <input type="radio"/>
	CVF for microflora <input type="radio"/>
	Vaginal gram stain <input type="radio"/>
	CVF for microflora - 2 hrs <input type="radio"/>
	Vaginal gram stain - 2 hrs <input type="radio"/>
	Rectal fluid for PK <input type="radio"/>
	Rectal fluid for PK - 2 hrs <input type="radio"/>
	Rectal fluid for PK - 6 hrs <input type="radio"/>
	Rectal fluid for PD <input type="radio"/>
	Rectal fluid for PD - 2 hrs <input type="radio"/>
	Rectal fluid for microbiome <input type="radio"/>
	Rectal fluid for microbiome - 2 hrs <input type="radio"/>
	Rectal tissue for PK <input type="radio"/>
	Rectal tissue for PK - 2 hrs <input type="radio"/>
	Rectal tissue for PD <input type="radio"/>
	Rectal tissue for PD - 2 hrs <input type="radio"/>
	Rectal tissue for biomarkers <input type="radio"/>
	Rectal tissue for biomarkers - 2 hrs <input type="radio"/>

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

Not stored

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type

- Plasma for archive
- Blood for PK
- Blood for PK - 1 hr
- Blood for PK - 2 hrs
- Blood for PK - 4 hrs
- Blood for PK - 6 hrs
- CVF for PK
- CVF for PK - 2 hrs
- CVF for PK - 6 hrs
- CVF for PD
- CVF for PD - 2 hrs
- CVF for microflora
- Vaginal gram stain
- CVF for microflora - 2 hrs
- Vaginal gram stain - 2 hrs
- Rectal fluid for PK
- Rectal fluid for PK - 2 hrs
- Rectal fluid for PK - 6 hrs
- Rectal fluid for PD
- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD
- Rectal tissue for PD - 2 hrs
- Rectal tissue for biomarkers
- Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date

Specimen collection time

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters).

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs
 - Rectal fluid for PK - 6 hrs
 - Rectal fluid for PD
 - Rectal fluid for PD - 2 hrs
 - Rectal fluid for microbiome
 - Rectal fluid for microbiome - 2 hrs
 - Rectal tissue for PK
 - Rectal tissue for PK - 2 hrs
 - Rectal tissue for PD
 - Rectal tissue for PD - 2 hrs
 - Rectal tissue for biomarkers
 - Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

Specimen collection time _____

Was sample stored?

Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type

Plasma for archive

Blood for PK

Blood for PK - 1 hr

Blood for PK - 2 hrs

Blood for PK - 4 hrs

Blood for PK - 6 hrs

CVF for PK

CVF for PK - 2 hrs

CVF for PK - 6 hrs

CVF for PD

CVF for PD - 2 hrs

CVF for microflora

Vaginal gram stain

CVF for microflora - 2 hrs

Vaginal gram stain - 2 hrs

Rectal fluid for PK

Rectal fluid for PK - 2 hrs

Rectal fluid for PK - 6 hrs

Rectal fluid for PD

Rectal fluid for PD - 2 hrs

Rectal fluid for microbiome

Rectal fluid for microbiome - 2 hrs

Rectal tissue for PK

Rectal tissue for PK - 2 hrs

Rectal tissue for PD

Rectal tissue for PD - 2 hrs

Rectal tissue for biomarkers

Rectal tissue for biomarkers - 2 hrs

Was specimen collected?

Yes

No

If "No", record reason why sample was not collected (max. 200 characters).

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

Specimen collection date _____

Specimen collection time _____

Was sample stored? _____

Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type _____

Plasma for archive

Blood for PK

Blood for PK - 1 hr

Blood for PK - 2 hrs

Blood for PK - 4 hrs

Blood for PK - 6 hrs

CVF for PK

CVF for PK - 2 hrs

CVF for PK - 6 hrs

CVF for PD

CVF for PD - 2 hrs

CVF for microflora

Vaginal gram stain

CVF for microflora - 2 hrs

Vaginal gram stain - 2 hrs

Rectal fluid for PK

Rectal fluid for PK - 2 hrs

Rectal fluid for PK - 6 hrs

Rectal fluid for PD

Rectal fluid for PD - 2 hrs

Rectal fluid for microbiome

Rectal fluid for microbiome - 2 hrs

Rectal tissue for PK

Rectal tissue for PK - 2 hrs

Rectal tissue for PD

Rectal tissue for PD - 2 hrs

Rectal tissue for biomarkers

Rectal tissue for biomarkers - 2 hrs

Was specimen collected? _____

Yes

No

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date

Specimen collection time

Was sample stored?

Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type

Plasma for archive

Blood for PK

Blood for PK - 1 hr

Blood for PK - 2 hrs

Blood for PK - 4 hrs

Blood for PK - 6 hrs

CVF for PK

CVF for PK - 2 hrs

CVF for PK - 6 hrs

CVF for PD

CVF for PD - 2 hrs

CVF for microflora

Vaginal gram stain

CVF for microflora - 2 hrs

Vaginal gram stain - 2 hrs

Rectal fluid for PK

Rectal fluid for PK - 2 hrs

Rectal fluid for PK - 6 hrs

Rectal fluid for PD

Rectal fluid for PD - 2 hrs

Rectal fluid for microbiome

Rectal fluid for microbiome - 2 hrs

Rectal tissue for PK

Rectal tissue for PK - 2 hrs

Rectal tissue for PD

Rectal tissue for PD - 2 hrs

Rectal tissue for biomarkers

Rectal tissue for biomarkers - 2 hrs

Was specimen collected?

Yes

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

No

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date

Specimen collection time

Was sample stored?

Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type

Plasma for archive

Blood for PK

Blood for PK - 1 hr

Blood for PK - 2 hrs

Blood for PK - 4 hrs

Blood for PK - 6 hrs

CVF for PK

CVF for PK - 2 hrs

CVF for PK - 6 hrs

CVF for PD

CVF for PD - 2 hrs

CVF for microflora

Vaginal gram stain

CVF for microflora - 2 hrs

Vaginal gram stain - 2 hrs

Rectal fluid for PK

Rectal fluid for PK - 2 hrs

Rectal fluid for PK - 6 hrs

Rectal fluid for PD

Rectal fluid for PD - 2 hrs

Rectal fluid for microbiome

Rectal fluid for microbiome - 2 hrs

Rectal tissue for PK

Rectal tissue for PK - 2 hrs

Rectal tissue for PD

Rectal tissue for PD - 2 hrs

Rectal tissue for biomarkers

Rectal tissue for biomarkers - 2 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs
 - Rectal fluid for PK - 6 hrs
 - Rectal fluid for PD
 - Rectal fluid for PD - 2 hrs
 - Rectal fluid for microbiome
 - Rectal fluid for microbiome - 2 hrs
 - Rectal tissue for PK
 - Rectal tissue for PK - 2 hrs
 - Rectal tissue for PD
 - Rectal tissue for PD - 2 hrs
 - Rectal tissue for biomarkers

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs
 - Rectal fluid for PK - 6 hrs
 - Rectal fluid for PD
 - Rectal fluid for PD - 2 hrs
 - Rectal fluid for microbiome
 - Rectal fluid for microbiome - 2 hrs
 - Rectal tissue for PK
 - Rectal tissue for PK - 2 hrs
 - Rectal tissue for PD
 - Rectal tissue for PD - 2 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

Rectal tissue for biomarkers
Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type

- Plasma for archive
- Blood for PK
- Blood for PK - 1 hr
- Blood for PK - 2 hrs
- Blood for PK - 4 hrs
- Blood for PK - 6 hrs
- CVF for PK
- CVF for PK - 2 hrs
- CVF for PK - 6 hrs
- CVF for PD
- CVF for PD - 2 hrs
- CVF for microflora
- Vaginal gram stain
- CVF for microflora - 2 hrs
- Vaginal gram stain - 2 hrs
- Rectal fluid for PK
- Rectal fluid for PK - 2 hrs
- Rectal fluid for PK - 6 hrs
- Rectal fluid for PD
- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

Rectal tissue for PD - 2 hrs

Rectal tissue for biomarkers

Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type

Plasma for archive

Blood for PK

Blood for PK - 1 hr

Blood for PK - 2 hrs

Blood for PK - 4 hrs

Blood for PK - 6 hrs

CVF for PK

CVF for PK - 2 hrs

CVF for PK - 6 hrs

CVF for PD

CVF for PD - 2 hrs

CVF for microflora

Vaginal gram stain

CVF for microflora - 2 hrs

Vaginal gram stain - 2 hrs

Rectal fluid for PK

Rectal fluid for PK - 2 hrs

Rectal fluid for PK - 6 hrs

Rectal fluid for PD

Rectal fluid for PD - 2 hrs

Rectal fluid for microbiome

Rectal fluid for microbiome - 2 hrs

Rectal tissue for PK

Rectal tissue for PK - 2 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

Rectal tissue for PD
Rectal tissue for PD - 2 hrs
Rectal tissue for biomarkers
Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type

Plasma for archive
Blood for PK
Blood for PK - 1 hr
Blood for PK - 2 hrs
Blood for PK - 4 hrs
Blood for PK - 6 hrs
CVF for PK
CVF for PK - 2 hrs
CVF for PK - 6 hrs
CVF for PD
CVF for PD - 2 hrs
CVF for microflora
Vaginal gram stain
CVF for microflora - 2 hrs
Vaginal gram stain - 2 hrs
Rectal fluid for PK
Rectal fluid for PK - 2 hrs
Rectal fluid for PK - 6 hrs
Rectal fluid for PD
Rectal fluid for PD - 2 hrs
Rectal fluid for microbiome
Rectal fluid for microbiome - 2 hrs
Rectal tissue for PK

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

Rectal tissue for PK - 2 hrs

Rectal tissue for PD

Rectal tissue for PD - 2 hrs

Rectal tissue for biomarkers

Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type

Plasma for archive

Blood for PK

Blood for PK - 1 hr

Blood for PK - 2 hrs

Blood for PK - 4 hrs

Blood for PK - 6 hrs

CVF for PK

CVF for PK - 2 hrs

CVF for PK - 6 hrs

CVF for PD

CVF for PD - 2 hrs

CVF for microflora

Vaginal gram stain

CVF for microflora - 2 hrs

Vaginal gram stain - 2 hrs

Rectal fluid for PK

Rectal fluid for PK - 2 hrs

Rectal fluid for PK - 6 hrs

Rectal fluid for PD

Rectal fluid for PD - 2 hrs

Rectal fluid for microbiome

Rectal fluid for microbiome - 2 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
Generated On: 16 Oct 2019 22:24:35

	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date

Specimen collection time

Was sample stored?	Stored	<input type="checkbox"/>
	Not stored	<input type="checkbox"/>

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 2 hrs	<input type="checkbox"/>
	CVF for PK - 6 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for PD - 2 hrs	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>
	Vaginal gram stain - 2 hrs	<input checked="" type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
Rectal fluid for PK - 6 hrs	<input type="checkbox"/>	
Rectal fluid for PD	<input type="checkbox"/>	
Rectal fluid for PD - 2 hrs	<input type="checkbox"/>	
Rectal fluid for microbiome	<input type="checkbox"/>	

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- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD
- Rectal tissue for PD - 2 hrs
- Rectal tissue for biomarkers
- Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs
 - Rectal fluid for PK - 6 hrs
 - Rectal fluid for PD
 - Rectal fluid for PD - 2 hrs

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Rectal fluid for microbiome	<input type="checkbox"/>
Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
Rectal tissue for PK	<input type="checkbox"/>
Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
Rectal tissue for PD	<input type="checkbox"/>
Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
Rectal tissue for biomarkers	<input type="checkbox"/>
Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date

Specimen collection time

Was sample stored?	Stored <input type="checkbox"/>
	Not stored <input type="checkbox"/>

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive <input type="checkbox"/>
	Blood for PK <input type="checkbox"/>
	Blood for PK - 1 hr <input type="checkbox"/>
	Blood for PK - 2 hrs <input type="checkbox"/>
	Blood for PK - 4 hrs <input type="checkbox"/>
	Blood for PK - 6 hrs <input type="checkbox"/>
	CVF for PK <input type="checkbox"/>
	CVF for PK - 2 hrs <input type="checkbox"/>
	CVF for PK - 6 hrs <input type="checkbox"/>
	CVF for PD <input type="checkbox"/>
	CVF for PD - 2 hrs <input type="checkbox"/>
	CVF for microflora <input type="checkbox"/>
	Vaginal gram stain <input type="checkbox"/>
	CVF for microflora - 2 hrs <input type="checkbox"/>
	Vaginal gram stain - 2 hrs <input type="checkbox"/>
	Rectal fluid for PK <input type="checkbox"/>
	Rectal fluid for PK - 2 hrs <input checked="" type="checkbox"/>
	Rectal fluid for PK - 6 hrs <input type="checkbox"/>
	Rectal fluid for PD <input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
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- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD
- Rectal tissue for PD - 2 hrs
- Rectal tissue for biomarkers
- Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs
 - Rectal fluid for PK - 6 hrs

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	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for PD - 2 hrs	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored?	Stored	<input type="checkbox"/>
	Not stored	<input type="checkbox"/>

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 2 hrs	<input type="checkbox"/>
	CVF for PK - 6 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for PD - 2 hrs	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>
	Vaginal gram stain - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
Rectal fluid for PK - 2 hrs	<input type="checkbox"/>	

Participant ID: _____ - _____ - _____

Visit: _____

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Rectal fluid for PK - 6 hrs	<input type="radio"/>
Rectal fluid for PD	<input checked="" type="radio"/>
Rectal fluid for PD - 2 hrs	<input type="radio"/>
Rectal fluid for microbiome	<input type="radio"/>
Rectal fluid for microbiome - 2 hrs	<input type="radio"/>
Rectal tissue for PK	<input type="radio"/>
Rectal tissue for PK - 2 hrs	<input type="radio"/>
Rectal tissue for PD	<input type="radio"/>
Rectal tissue for PD - 2 hrs	<input type="radio"/>
Rectal tissue for biomarkers	<input type="radio"/>
Rectal tissue for biomarkers - 2 hrs	<input type="radio"/>

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive	<input type="radio"/>
	Blood for PK	<input type="radio"/>
	Blood for PK - 1 hr	<input type="radio"/>
	Blood for PK - 2 hrs	<input type="radio"/>
	Blood for PK - 4 hrs	<input type="radio"/>
	Blood for PK - 6 hrs	<input type="radio"/>
	CVF for PK	<input type="radio"/>
	CVF for PK - 2 hrs	<input type="radio"/>
	CVF for PK - 6 hrs	<input type="radio"/>
	CVF for PD	<input type="radio"/>
	CVF for PD - 2 hrs	<input type="radio"/>
	CVF for microflora	<input type="radio"/>
	Vaginal gram stain	<input type="radio"/>
	CVF for microflora - 2 hrs	<input type="radio"/>
	Vaginal gram stain - 2 hrs	<input type="radio"/>
	Rectal fluid for PK	<input type="radio"/>

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Visit: _____

Visit Date: _____

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	Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 6 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for PD - 2 hrs	<input checked="" type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date

Specimen collection time

Was sample stored?	Stored	<input type="checkbox"/>
	Not stored	<input type="checkbox"/>

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 2 hrs	<input type="checkbox"/>
	CVF for PK - 6 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for PD - 2 hrs	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>
	Vaginal gram stain - 2 hrs	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
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	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 6 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for PD - 2 hrs	<input type="checkbox"/>
	Rectal fluid for microbiome	<input checked="" type="checkbox"/>
	Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 2 hrs	<input type="checkbox"/>
	CVF for PK - 6 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for PD - 2 hrs	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

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Form: Specimen Collection and Storage (Group 1)
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Vaginal gram stain - 2 hrs	<input type="checkbox"/>
Rectal fluid for PK	<input type="checkbox"/>
Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
Rectal fluid for PK - 6 hrs	<input type="checkbox"/>
Rectal fluid for PD	<input type="checkbox"/>
Rectal fluid for PD - 2 hrs	<input type="checkbox"/>
Rectal fluid for microbiome	<input type="checkbox"/>
Rectal fluid for microbiome - 2 hrs	<input checked="" type="checkbox"/>
Rectal tissue for PK	<input type="checkbox"/>
Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
Rectal tissue for PD	<input type="checkbox"/>
Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
Rectal tissue for biomarkers	<input type="checkbox"/>
Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive <input type="checkbox"/>
	Blood for PK <input type="checkbox"/>
	Blood for PK - 1 hr <input type="checkbox"/>
	Blood for PK - 2 hrs <input type="checkbox"/>
	Blood for PK - 4 hrs <input type="checkbox"/>
	Blood for PK - 6 hrs <input type="checkbox"/>
	CVF for PK <input type="checkbox"/>
	CVF for PK - 2 hrs <input type="checkbox"/>
	CVF for PK - 6 hrs <input type="checkbox"/>
	CVF for PD <input type="checkbox"/>
	CVF for PD - 2 hrs <input type="checkbox"/>
	CVF for microflora <input type="checkbox"/>
	Vaginal gram stain <input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
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-
- CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs
 - Rectal fluid for PK - 6 hrs
 - Rectal fluid for PD
 - Rectal fluid for PD - 2 hrs
 - Rectal fluid for microbiome
 - Rectal fluid for microbiome - 2 hrs
 - Rectal tissue for PK
 - Rectal tissue for PK - 2 hrs
 - Rectal tissue for PD
 - Rectal tissue for PD - 2 hrs
 - Rectal tissue for biomarkers
 - Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

-
- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

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- Vaginal gram stain
- CVF for microflora - 2 hrs
- Vaginal gram stain - 2 hrs
- Rectal fluid for PK
- Rectal fluid for PK - 2 hrs
- Rectal fluid for PK - 6 hrs
- Rectal fluid for PD
- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD
- Rectal tissue for PD - 2 hrs
- Rectal tissue for biomarkers
- Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs

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	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>
	Vaginal gram stain - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 6 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for PD - 2 hrs	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input checked="" type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 2 hrs	<input type="checkbox"/>
	CVF for PK - 6 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

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Form: Specimen Collection and Storage (Group 1)
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- CVF for PD - 2 hrs
- CVF for microflora
- Vaginal gram stain
- CVF for microflora - 2 hrs
- Vaginal gram stain - 2 hrs
- Rectal fluid for PK
- Rectal fluid for PK - 2 hrs
- Rectal fluid for PK - 6 hrs
- Rectal fluid for PD
- Rectal fluid for PD - 2 hrs
- Rectal fluid for microbiome
- Rectal fluid for microbiome - 2 hrs
- Rectal tissue for PK
- Rectal tissue for PK - 2 hrs
- Rectal tissue for PD
- Rectal tissue for PD - 2 hrs
- Rectal tissue for biomarkers
- Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

- Specimen type
- Plasma for archive
 - Blood for PK
 - Blood for PK - 1 hr
 - Blood for PK - 2 hrs
 - Blood for PK - 4 hrs
 - Blood for PK - 6 hrs
 - CVF for PK
 - CVF for PK - 2 hrs
 - CVF for PK - 6 hrs

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 1)
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	CVF for PD	<input type="checkbox"/>
	CVF for PD - 2 hrs	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	CVF for microflora - 2 hrs	<input type="checkbox"/>
	Vaginal gram stain - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 2 hrs	<input type="checkbox"/>
	Rectal fluid for PK - 6 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for PD - 2 hrs	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal fluid for microbiome - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PK - 2 hrs	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for PD - 2 hrs	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input checked="" type="checkbox"/>
	Rectal tissue for biomarkers - 2 hrs	<input type="checkbox"/>

Was specimen collected?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored?	Stored	<input type="checkbox"/>
	Not stored	<input type="checkbox"/>

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 2 hrs	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

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-
- CVF for PK - 6 hrs
 - CVF for PD
 - CVF for PD - 2 hrs
 - CVF for microflora
 - Vaginal gram stain
 - CVF for microflora - 2 hrs
 - Vaginal gram stain - 2 hrs
 - Rectal fluid for PK
 - Rectal fluid for PK - 2 hrs
 - Rectal fluid for PK - 6 hrs
 - Rectal fluid for PD
 - Rectal fluid for PD - 2 hrs
 - Rectal fluid for microbiome
 - Rectal fluid for microbiome - 2 hrs
 - Rectal tissue for PK
 - Rectal tissue for PK - 2 hrs
 - Rectal tissue for PD
 - Rectal tissue for PD - 2 hrs
 - Rectal tissue for biomarkers
 - Rectal tissue for biomarkers - 2 hrs

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 2)
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Specimen type	Plasma for archive <input checked="" type="radio"/>
	Blood for PK <input type="radio"/>
	Blood for PK - 1 hr <input type="radio"/>
	Blood for PK - 2 hrs <input type="radio"/>
	Blood for PK - 4 hrs <input type="radio"/>
	Blood for PK - 6 hrs <input type="radio"/>
	CVF for PK <input type="radio"/>
	CVF for PK - 4 hrs <input type="radio"/>
	CVF for PD <input type="radio"/>
	CVF for microflora <input type="radio"/>
	Vaginal gram stain <input type="radio"/>
	Rectal fluid for PK <input type="radio"/>
	Rectal fluid for PK - 4 hrs <input type="radio"/>
	Rectal fluid for PD <input type="radio"/>
	Rectal fluid for microbiome <input type="radio"/>
	Rectal tissue for PK <input type="radio"/>
	Rectal tissue for PD <input type="radio"/>
	Rectal tissue for biomarkers <input type="radio"/>

Was specimen collected?	Yes <input type="radio"/>
	No <input type="radio"/>

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored?	Stored <input type="radio"/>
	Not stored <input type="radio"/>

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive <input type="radio"/>
	Blood for PK <input checked="" type="radio"/>
	Blood for PK - 1 hr <input type="radio"/>
	Blood for PK - 2 hrs <input type="radio"/>
	Blood for PK - 4 hrs <input type="radio"/>
	Blood for PK - 6 hrs <input type="radio"/>
	CVF for PK <input type="radio"/>
	CVF for PK - 4 hrs <input type="radio"/>
	CVF for PD <input type="radio"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 2)
Generated On: 16 Oct 2019 22:24:35

	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input checked="" type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
Rectal tissue for PK	<input type="checkbox"/>	
Rectal tissue for PD	<input type="checkbox"/>	
Rectal tissue for biomarkers	<input type="checkbox"/>	

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 2)
Generated On: 16 Oct 2019 22:24:35

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type

- Plasma for archive
- Blood for PK
- Blood for PK - 1 hr
- Blood for PK - 2 hrs
- Blood for PK - 4 hrs
- Blood for PK - 6 hrs
- CVF for PK
- CVF for PK - 4 hrs
- CVF for PD
- CVF for microflora
- Vaginal gram stain
- Rectal fluid for PK
- Rectal fluid for PK - 4 hrs
- Rectal fluid for PD
- Rectal fluid for microbiome
- Rectal tissue for PK
- Rectal tissue for PD
- Rectal tissue for biomarkers

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 2)
Generated On: 16 Oct 2019 22:24:35

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive <input type="radio"/>
	Blood for PK <input type="radio"/>
	Blood for PK - 1 hr <input type="radio"/>
	Blood for PK - 2 hrs <input type="radio"/>
	Blood for PK - 4 hrs <input checked="" type="radio"/>
	Blood for PK - 6 hrs <input type="radio"/>
	CVF for PK <input type="radio"/>
	CVF for PK - 4 hrs <input type="radio"/>
	CVF for PD <input type="radio"/>
	CVF for microflora <input type="radio"/>
	Vaginal gram stain <input type="radio"/>
	Rectal fluid for PK <input type="radio"/>
	Rectal fluid for PK - 4 hrs <input type="radio"/>
	Rectal fluid for PD <input type="radio"/>
	Rectal fluid for microbiome <input type="radio"/>
	Rectal tissue for PK <input type="radio"/>
	Rectal tissue for PD <input type="radio"/>
	Rectal tissue for biomarkers <input type="radio"/>

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive <input type="radio"/>
	Blood for PK <input type="radio"/>
	Blood for PK - 1 hr <input type="radio"/>
	Blood for PK - 2 hrs <input type="radio"/>
	Blood for PK - 4 hrs <input type="radio"/>
	Blood for PK - 6 hrs <input checked="" type="radio"/>
	CVF for PK <input type="radio"/>
	CVF for PK - 4 hrs <input type="radio"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 2)
Generated On: 16 Oct 2019 22:24:35

	CVF for PD	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>

Was specimen collected?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date

Specimen collection time

Was sample stored?	Stored	<input type="checkbox"/>
	Not stored	<input type="checkbox"/>

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input checked="" type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
Rectal fluid for microbiome	<input type="checkbox"/>	
Rectal tissue for PK	<input type="checkbox"/>	
Rectal tissue for PD	<input type="checkbox"/>	

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

**MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 2)
Generated On: 16 Oct 2019 22:24:35**

Rectal tissue for biomarkers

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type

- Plasma for archive
- Blood for PK
- Blood for PK - 1 hr
- Blood for PK - 2 hrs
- Blood for PK - 4 hrs
- Blood for PK - 6 hrs
- CVF for PK
- CVF for PK - 4 hrs
- CVF for PD
- CVF for microflora
- Vaginal gram stain
- Rectal fluid for PK
- Rectal fluid for PK - 4 hrs
- Rectal fluid for PD
- Rectal fluid for microbiome
- Rectal tissue for PK
- Rectal tissue for PD
- Rectal tissue for biomarkers

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
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If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive	<input type="radio"/>
	Blood for PK	<input type="radio"/>
	Blood for PK - 1 hr	<input type="radio"/>
	Blood for PK - 2 hrs	<input type="radio"/>
	Blood for PK - 4 hrs	<input type="radio"/>
	Blood for PK - 6 hrs	<input type="radio"/>
	CVF for PK	<input type="radio"/>
	CVF for PK - 4 hrs	<input type="radio"/>
	CVF for PD	<input checked="" type="radio"/>
	CVF for microflora	<input type="radio"/>
	Vaginal gram stain	<input type="radio"/>
	Rectal fluid for PK	<input type="radio"/>
	Rectal fluid for PK - 4 hrs	<input type="radio"/>
	Rectal fluid for PD	<input type="radio"/>
	Rectal fluid for microbiome	<input type="radio"/>
	Rectal tissue for PK	<input type="radio"/>
	Rectal tissue for PD	<input type="radio"/>
	Rectal tissue for biomarkers	<input type="radio"/>

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive	<input type="radio"/>
	Blood for PK	<input type="radio"/>
	Blood for PK - 1 hr	<input type="radio"/>
	Blood for PK - 2 hrs	<input type="radio"/>
	Blood for PK - 4 hrs	<input type="radio"/>
	Blood for PK - 6 hrs	<input type="radio"/>
	CVF for PK	<input type="radio"/>
	CVF for PK - 4 hrs	<input type="radio"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 2)
Generated On: 16 Oct 2019 22:24:35

	CVF for PD	<input type="checkbox"/>
	CVF for microflora	<input checked="" type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input checked="" type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 2)
Generated On: 16 Oct 2019 22:24:35

Rectal tissue for biomarkers

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type

- Plasma for archive
- Blood for PK
- Blood for PK - 1 hr
- Blood for PK - 2 hrs
- Blood for PK - 4 hrs
- Blood for PK - 6 hrs
- CVF for PK
- CVF for PK - 4 hrs
- CVF for PD
- CVF for microflora
- Vaginal gram stain
- Rectal fluid for PK
- Rectal fluid for PK - 4 hrs
- Rectal fluid for PD
- Rectal fluid for microbiome
- Rectal tissue for PK
- Rectal tissue for PD
- Rectal tissue for biomarkers

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
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Generated On: 16 Oct 2019 22:24:35

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input checked="" type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 2)
Generated On: 16 Oct 2019 22:24:35

	CVF for PD	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input checked="" type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>

Was specimen collected? Yes

No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for microbiome	<input checked="" type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

**MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 2)
Generated On: 16 Oct 2019 22:24:35**

Rectal tissue for biomarkers

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Specimen type

- Plasma for archive
- Blood for PK
- Blood for PK - 1 hr
- Blood for PK - 2 hrs
- Blood for PK - 4 hrs
- Blood for PK - 6 hrs
- CVF for PK
- CVF for PK - 4 hrs
- CVF for PD
- CVF for microflora
- Vaginal gram stain
- Rectal fluid for PK
- Rectal fluid for PK - 4 hrs
- Rectal fluid for PD
- Rectal fluid for microbiome
- Rectal tissue for PK
- Rectal tissue for PD
- Rectal tissue for biomarkers

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 2)
Generated On: 16 Oct 2019 22:24:35

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>
	CVF for PD	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PD	<input checked="" type="checkbox"/>
	Rectal tissue for biomarkers	<input type="checkbox"/>

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters).

Specimen type	Plasma for archive	<input type="checkbox"/>
	Blood for PK	<input type="checkbox"/>
	Blood for PK - 1 hr	<input type="checkbox"/>
	Blood for PK - 2 hrs	<input type="checkbox"/>
	Blood for PK - 4 hrs	<input type="checkbox"/>
	Blood for PK - 6 hrs	<input type="checkbox"/>
	CVF for PK	<input type="checkbox"/>
	CVF for PK - 4 hrs	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL
Form: Specimen Collection and Storage (Group 2)
Generated On: 16 Oct 2019 22:24:35

	CVF for PD	<input type="checkbox"/>
	CVF for microflora	<input type="checkbox"/>
	Vaginal gram stain	<input type="checkbox"/>
	Rectal fluid for PK	<input type="checkbox"/>
	Rectal fluid for PK - 4 hrs	<input type="checkbox"/>
	Rectal fluid for PD	<input type="checkbox"/>
	Rectal fluid for microbiome	<input type="checkbox"/>
	Rectal tissue for PK	<input type="checkbox"/>
	Rectal tissue for PD	<input type="checkbox"/>
	Rectal tissue for biomarkers	<input checked="" type="checkbox"/>

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: STI Tests

Generated On: 16 Oct 2019 22:24:35

Was a pharyngeal sample collected for N. gonorrhoea and C. trachomatis testing? Yes
No

Collection date _____
N. gonorrhoea - Pharyngeal test result Positive
Negative

C. trachomatis - Pharyngeal test result Positive
Negative

Was a pelvic sample collected for N. gonorrhoea, C. trachomatis, and trichomonas vaginalis testing? Yes
No

Collection date _____
N. gonorrhoea - Pelvic test result Positive
Negative

C. trachomatis - Pelvic test result Positive
Negative

trichomonas vaginalis - Pelvic test result Positive
Negative

Was a urine sample collected for N. gonorrhoea and C. trachomatis testing? Yes
No

Collection date _____
N. gonorrhoea - URINE test result Positive
Negative

C. trachomatis - URINE test result Positive
Negative

Was a rectal swab sample collected for N. gonorrhoea and C. trachomatis testing? Yes
No

Collection date _____
N. gonorrhoea - RECTAL SWAB test result Positive
Negative

C. trachomatis - RECTAL SWAB test result Positive
Negative

Was a sample collected for Syphilis testing? Yes
No

Collection date _____
Syphilis screening test Non-reactive
Reactive
Not reported

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: STI Tests

Generated On: 16 Oct 2019 22:24:35

Syphilis titer	
Syphilis confirmatory test	Positive <input type="radio"/>
	Negative <input type="radio"/>
	Indeterminate <input type="radio"/>
	Not done <input type="radio"/>

Was the participant diagnosed with asymptomatic BV?	Yes <input type="radio"/>
	No <input type="radio"/>

Was the participant diagnosed with asymptomatic candida?	Yes <input type="radio"/>
	No <input type="radio"/>

Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing?	Yes <input type="radio"/>
	No <input type="radio"/>

Date of collection	
Hepatitis B Surface Antigen (HBsAG)	Positive <input type="radio"/>
	Negative <input type="radio"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN039_Version_1.0_PROD_16OCT2019: ALL

Form: Study Termination

Generated On: 16 Oct 2019 22:24:35

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

HIV infection

Early study closure

Protocol deviation

Adverse event

Pregnancy

Study terminated by sponsor

Other, specify

If "Other", specify (max. 200 characters): _____

If "Death", enter date of death. _____

If "Adverse event", select applicable adverse event. _____