

Subject Case Report Forms

MTN042_C3_1.0_PROD_AM_31MAY2022 - V144W_COMCRF

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

MTN042_C3_1.0_PROD_AM_31MAY2022: V144W_COMCRF

Folder: V14.0 - Week 12 4w Visit

Form: Follow-up Visit Summary

Generated On: 27 Jun 2022 19:56:58

Visit date _____

Was study product permanently discontinued (scheduled or early) at this visit? Yes
No

Was study product held at this visit? Yes
No

Did the participant exit/terminate the study at this visit? Yes
No

Were any new adverse events (AEs) reported at this visit? Yes
No

Is the participant taking any concomitant medications that have not been previously reported? Yes
No

Were any protocol deviations reported at this visit? Yes
No

Since her last visit, has the participant inserted anything in her vagina? Please include non-medicated gels, water, soap, dry materials (such as paper, ashes, or powders), and any other materials inserted vaginally. Yes
No

Note: all medicated vaginal products (including prescription medications, over-the-counter preparations, vitamins and nutritional supplements, and herbal preparations) should be recorded as concomitant medications.

Were any additional study procedures or forms completed outside of the scheduled study visit per protocol? Yes
No

Rapid HIV test 1

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

If "No", skip to Rapid HIV test 2.

Rapid HIV test 1 Kit Alere/Abbot HIV Combo/Ultra
Oraquick ADVANCE HIV-1/2
Uni-Gold Recombigen HIV-1/2
Alere/Abbot Determine
Other

If "Other", specify: _____

Rapid HIV test 1 collection date _____

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

Rapid HIV test 2

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

If "No", end of form.

Rapid HIV test 2 Kit Alere/Abbot HIV Combo/Ultra
Oraquick ADVANCE HIV-1/2
Uni-Gold Recombigen HIV-1/2
Alere/Abbot Determine
Other

If "Other", specify: _____

Rapid HIV test 2 collection date _____

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

If at least one Rapid HIV tests is positive, complete the HIV Confirmatory Test Result form.

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Form: Specimen Storage

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| | | |
|---------------|---|----------------------------------|
| Specimen type | Plasma for DPV drug levels | <input checked="" type="radio"/> |
| | Dried blood spot for TFV-DP and FTC-TP drug levels | <input type="radio"/> |
| | Gram Stain of vaginal smear | <input type="radio"/> |
| | Vaginal Swabs for biomarkers | <input type="radio"/> |
| | Vaginal Swabs for microbiota | <input type="radio"/> |
| | Plasma for archive | <input type="radio"/> |
| | Used vaginal ring #1 | <input type="radio"/> |
| | Used vaginal ring #2 | <input type="radio"/> |

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

Specimen collection date

| | | |
|--------------------|------------|-----------------------|
| 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 DPV drug levels | <input type="radio"/> |
| | Dried blood spot for TFV-DP and FTC-TP drug levels | <input checked="" type="radio"/> |
| | Gram Stain of vaginal smear | <input type="radio"/> |
| | Vaginal Swabs for biomarkers | <input type="radio"/> |
| | Vaginal Swabs for microbiota | <input type="radio"/> |
| | Plasma for archive | <input type="radio"/> |
| | Used vaginal ring #1 | <input type="radio"/> |
| | Used vaginal ring #2 | <input type="radio"/> |

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

Specimen collection date

| | | |
|--------------------|------------|-----------------------|
| 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 DPV drug levels | <input type="radio"/> |
| | Dried blood spot for TFV-DP and FTC-TP drug levels | <input type="radio"/> |
| | Gram Stain of vaginal smear | <input checked="" type="radio"/> |
| | Vaginal Swabs for biomarkers | <input type="radio"/> |
| | Vaginal Swabs for microbiota | <input type="radio"/> |

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Plasma for archive

Used vaginal ring #1

Used vaginal ring #2

Was specimen collected? Yes

No

Specimen collection date _____

Was sample stored? Stored

Not stored

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

Specimen type

Plasma for DPV drug levels

Dried blood spot for TFV-DP and FTC-TP drug levels

Gram Stain of vaginal smear

Vaginal Swabs for biomarkers

Vaginal Swabs for microbiota

Plasma for archive

Used vaginal ring #1

Used vaginal ring #2

Was specimen collected? Yes

No

Specimen collection date _____

Was sample stored? Stored

Not stored

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

Specimen type

Plasma for DPV drug levels

Dried blood spot for TFV-DP and FTC-TP drug levels

Gram Stain of vaginal smear

Vaginal Swabs for biomarkers

Vaginal Swabs for microbiota

Plasma for archive

Used vaginal ring #1

Used vaginal ring #2

Was specimen collected? Yes

No

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Specimen collection date

Was sample stored? Stored
Not stored

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

Specimen type Plasma for DPV drug levels
Dried blood spot for TFV-DP and
FTC-TP drug levels
Gram Stain of vaginal smear
Vaginal Swabs for biomarkers
Vaginal Swabs for microbiota
Plasma for archive
Used vaginal ring #1
Used vaginal ring #2

Was specimen collected? Yes
No

Specimen collection date

Was sample stored? Stored
Not stored

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

Specimen type Plasma for DPV drug levels
Dried blood spot for TFV-DP and
FTC-TP drug levels
Gram Stain of vaginal smear
Vaginal Swabs for biomarkers
Vaginal Swabs for microbiota
Plasma for archive
Used vaginal ring #1
Used vaginal ring #2

Was specimen collected? Yes
No

Specimen collection date

Was sample stored? Stored
Not stored

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

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Form: Specimen Storage

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| | | |
|---------------|---|-------------------------------------|
| Specimen type | Plasma for DPV drug levels | <input type="checkbox"/> |
| | Dried blood spot for TFV-DP and FTC-TP drug levels | <input type="checkbox"/> |
| | Gram Stain of vaginal smear | <input type="checkbox"/> |
| | Vaginal Swabs for biomarkers | <input type="checkbox"/> |
| | Vaginal Swabs for microbiota | <input type="checkbox"/> |
| | Plasma for archive | <input type="checkbox"/> |
| | Used vaginal ring #1 | <input type="checkbox"/> |
| | Used vaginal ring #2 | <input checked="" type="checkbox"/> |

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

Specimen collection date

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

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

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Form: Obstetric abdominal exam

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Was an obstetric abdominal exam performed? Yes
No

Date of exam _____
Appearance Not done
Normal
Abnormal

If abnormal, specify: _____
Palpation of abdomen Not done
Normal
Abnormal

If abnormal, specify: _____
Fundal height Fixed Unit: cm

Was auscultation of fetal heart tones performed? Yes
No

If "No", explain:

If "No", end of form. _____
Method Doppler
Fetoscope
Ultrasound

Rate per minute Fixed Unit: bpm

Was a physical exam performed? Yes
No

Date of exam _____

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

HEENT Not done
Normal
Abnormal

If "Abnormal", specify: _____

Neck Not done
Normal
Abnormal

If "Abnormal", specify: _____

Lymph Nodes Not done
Normal
Abnormal

If "Abnormal", specify: _____

Heart/Cardiovascular Not done
Normal
Abnormal

If "Abnormal", specify: _____

Lung/Respiratory Not done
Normal
Abnormal

If "Abnormal", specify: _____

Abdomen Not done
Normal
Abnormal

If "Abnormal", specify: _____

Extremities Not done
Normal
Abnormal

If "Abnormal", specify: _____

Neurological Not done
Normal
Abnormal

If "Abnormal", specify: _____

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Form: Physical Examination

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Skin 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: _____

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Form: Vital Signs

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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