**Instructions:** Complete staff initials next to procedures completed. Do not initial for other staff members. If other staff members are not available to initial checklist items themselves, initial and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by nurse.” If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why (if not self-explanatory); initial and date this entry. If any procedures are not conducted on the date recorded above, ensure the date procedure conducted is included in the comments section.

| **Procedure** | **Visits Required**  | **Staff Initials** |
| --- | --- | --- |
|  | Prepare for exam: * Exam equipment, documentation, and specimen collection supplies; label as needed.
* Explain exam procedures to participant and answer any questions.
* Position and drape participant comfortably.
 | * V1-10
 |  |
|  | Collect rectal fluid for **DPV levels testing** (for MTN LC) * Prepare and insert anoscope.
* 1 swab held against rectal mucosa for 2 minutes
* Remove anoscope.

Document on **Specimen Collection CRF** and **LDMS Tracking Sheet;** record pre- and post-collection weights.*Note: Collect blood, rectal fluid, CVF samples for DPV level testing in as close time proximity as possible (within 30 minutes).* | * V 5, 6, 7, 8 and 10
* *Note: V2 - post-VR insertion collection point is documented on the Enrollment Visit Checklist*
 |  |
|  | Collect cervicovaginal fluid (CVF) for **DPV level testing** (for MTN LC). * Using 1 vaginal swab near the site of the VR

Document storage on the **Specimen Storage CRF** and **LDMS Specimen Tracking Sheet;** record pre- and post-collection weights.*Note: Collect blood, rectal fluid, CVF samples for DPV level testing in as close time proximity as possible (within 30 minutes).* | * V3-9
* V10 *immediately prior to VR removal (note: also collected at 1, 2, and 4 hours post ring removal* *and documented on PUEV Checklist)*

*Note: Post-VR insertion collection points at V2 and collection at V11 are documented on the respective visit checklists.* |  |
|  | Palpate the inguinal lymph nodes to assess for enlargement and/or tenderness. Document applicable findings on **Pelvic Exam CRF** and **Pelvic Exam Diagrams**. | * V1-10
 |  |
|  | Perform naked eye examination of the external genitalia including the perineum, perianal area, and the epithelial lining of the introitus. Document applicable findings on **Pelvic Exam CRF** and **Pelvic Exam Diagrams**. | * V1-10
 |  |
|  | Insert speculum, using warm water as lubricant if needed. Perform naked eye exam of the vagina and cervix, if applicable. Document applicable findings on **Pelvic Exam CRF** and **Pelvic Exam Diagram**. Document abnormal findings on the **Baseline Medical History Log** or **AE Log** | * V1-10
 |  |
|  | Perform visual confirmation of VR in place and document on **Pelvic Exam CRF.** | * V3-10
 |  |
|  | Collect vaginal fluid for **Trichomonas** **NAAT test** at local lab.* 1 swab from lateral vaginal wall.

Document collection on **STI Tests Results CRF**. | * V1
* If indicated at V2-10
 |  |
|  | Collect vaginal fluid for **GC/CT NAAT test** at local lab.* 1 swab from lateral vaginal wall.

Document collection on **STI Tests Results CRF**. | * V1
* If indicated at V2-10
 |  |
|  | Collect vaginal fluid for **microbiota analyses** (for MTN LC). * 2 flocked swabs from lateral vaginal wall (for q-PCR)
* 2 swab from lateral vaginal wall (for culture)

Document storage on the **Specimen Storage CRF** and **LDMS Specimen Tracking Sheet**. | * V2
* V8-10
 |  |
|  | *If clinically indicated (symptomatic),* collect vaginal fluid for **pH testing** for evaluation of BV at local lab/clinic.* 1 swab from lateral vaginal wall; swab onto pH strip

Document collection and results on **STI Tests Results CRF**. | * If indicated at all visits
 |  |
|  | *If clinically indicated (symptomatic),* collect vaginal fluid for **wet prep/KOH wet mounts** for evaluation of candidiasis and/or BV at local lab/clinic.* 1 swab from lateral vaginal wall.

Document collection and results on **STI Tests Results CRF**. | * If indicated at all visits
 |  |
|  | Collect vaginal fluid for **Gram stain analysis** (for MTN LC)**.**  * 1 swab from lateral vaginal wall; turn swab 3x. Roll swab across two labeled slides and air dry.

Document storage on [site-specific source document, **Specimen Storage CRF** and **LDMS Specimen Tracking Sheet**]. | * V2
* V8-10
 |  |
|  | If participant (over age 21) is unable to provide documentation of a satisfactory Pap test within 3 yrs prior to enrollment, collect and perform **Pap Test** at local lab.* Ecto- and endocervical cells per site SOP.

Document collection on **STI Test Results** **CRF** | * V1
 |  |
|  | Collect cervicovaginal lavage (CVL) for **PK, PD and** **biomarker analyses** (for MTN LC). * From cervix/ upper-end of vagina using syringe technique.

Document storage on the **Cervical Specimen Storage CRF** and **LDMS Specimen Tracking Sheet**. | * V2 *prior to VR insertion*
* V8-9

*Note: V10 post-VR removal collection point is documented on PUEV checklist* |  |
|  | Collect cervical tissue biopsy for **PK testing** (for MTN LC)* 2 biopsies, 3x5 mm in size, of cervical tissue taken from two different locations.

Document collection on the **Cervical Specimen Storage CRF** and **LDMS Specimen Tracking Sheet;** record pre- and post-collection weights. | * V8
* V10 *prior to VR removal*
 |  |
|  | Remove speculum; and perform bimanual exam, if indicated. | * V1-10
 |  |
|  | Document all findings on [site-specific pelvic exam source document(s), e.g., **Pelvic Exam Diagrams** and **Pelvic Exam CRF**].  | * V1-10
 |  |

|  |
| --- |
| **Comments** |
|  |