| **PTID:** | | | **Visit Date:** | **Visit Code:** |
| --- | --- | --- | --- | --- |
|  |  | Review relevant documentation from previous and current visits. | | |
|  |  | Prepare exam equipment and specimen collection supplies; label as needed. | | |
|  |  | Explain exam procedures to participant and answer any questions. | | |
|  |  | Position and drape participant comfortably. | | |
|  |  | Palpate inguinal lymph nodes; identify all normal and abnormal findings. | | |
|  |  | Perform naked eye exam of external genitalia, including the perineum, perianal area, and the epithelial lining of the introitus. Note all findings on the Pelvic Exam Diagrams. | | |
|  |  | At **Enrollment, on D1-28, on D31, 35, or 42 (based on random assignment) and on D52 (or Early Termination)** visits collect vaginal secretions using Tear test strip at the i**ntroitus** *(see Section 12 Laboratory Considerations).*  Note: *New disposables (gloves, tweezers, tubes, etc.) should be used for each sample, as Dapivirine and Maraviroc are very sensitive to cross-contamination.*   * Weigh the glass tube containing the Tear test strip (including the lid) on an analytical balance prior to and following collection of vaginal samples. Record the pre-weight and sampling post-weight on the CRF. Place the sample tubes in the freezer at <-20˚C. | | |
|  |  | Insert speculum, using warm water as lubricant if needed.  At **post-Enrollment visits** onlyif ring is present:  If possible, leave the study VR in place during the pelvic exams. If the participant experiences discomfort when inserting the speculum with the ring in place, it is acceptable for the clinician to remove the study VR and place in a sterile container. | | |
|  |  | Perform naked eye exam of the cervix and vagina and assess for abnormal discharge. | | |
|  |  | At **D28***, study clinician/designee to remove used study VR and place in sterile container and prepare for residual drug analysis OR biofilm assessment by the Network Lab (see Section 12 Laboratory Considerations).* | | |
|  |  | At **D28*,*** perform naked eye exam of the cervix and vagina and assess for abnormal discharge following removal of the study VR.  *Note: exam should be performed before and after ring removal to assess baseline findings before ring removal and any findings after the ring is removed.* | | |
|  |  | At **Enrollment**, assess cervical ectopy. | | |
|  |  | At **Screening**, and **when clinically indicated**:  Collect vaginal fluid from the lateral vaginal wall or the posterior fornix for rapid trichomonas test. Using the rayon swab from an OSOM kit, swab fluid from lateral vaginal wall, place swab in labeled tube (plain), and cap tube. | | |
|  |  | **If clinically indicated,** collect vaginal fluid (1 swab) from lateral vaginal wall or posterior fornix for saline wet mount for clue cells (BV) and KOH wet mount for candidiasis. Place swab in labeled tube (saline) and cap tube. | | |
|  |  | At **Enrollment, D3, D31, D28 and D52 (or Early Termination)** visits and **if clinically indicated,** collect vaginal fluid (1 swab) from lateral vaginal wall for pH per local standards. | | |
|  |  | At **Enrollment, D7, D28, D52 (or Early Termination)** visits, collect vaginal fluid (2 swabs) from the lateral vaginal wall for quantitative vaginal culture assessment. | | |
|  |  | At **Enrollment, D3, D28, D31 and D52 (or Early Termination)** visits (not completed for Interim Visits): Collect vaginal fluid (1 swab) from the lateral vaginal wall for Gram stain evaluation. Roll swab across two slides and air dry. | | |
|  |  | For **Screening**, and when clinically indicated:  Collect sample (1 manufacturers recommended swab) from the vagina or cervical canal (according to the specific manufacturer’s recommendations) away from any abnormalities for NAAT for GC/CT testing. | | |
|  |  | **If clinically indicated at Screening:**  Collect ecto- and endocervical cells for Pap smear per site SOPs.  ⇒ NOT required if documented normal Pap within 12 months prior to screening | | |
|  |  | At **Enrollment, D3, D28, D31 and D52 (or Early Termination)** visits**,** collect vaginal fluid (1 Dacron swab) from the posterior fornix for vaginal biomarkers and PD assessment. | | |
|  |  | At **D3 and D28,** collect vaginal fluid from the posterior fornix for validation testing | | |
|  |  | At **Enrollment, on D1-28, on D31, 35, or 42 (based on random assignment) and on D52 (or Early Termination)** visits collect vaginal secretions using Tear test strip on the surface of the **cervix** *(see Section 12 Laboratory Considerations).*  Note: *New disposables (gloves, tweezers, tubes, etc.) should be used for each sample, as Dapivirine and Maraviroc are very sensitive to cross-contamination.*   * Weigh the glass tube containing the Tear test strip (including the lid) on an analytical balance prior to and following collection of vaginal samples. Record the pre-weight and sampling post-weight on the CRF. Place the sample tubes in the freezer at <-20˚C. | | |
|  |  | At **D28** visit, collect 3 cervical biopsy specimens for PK and PD. | | |
|  |  | At **D31, D35, or D42** (based on random assignment), collect 2 cervical biopsy specimens for PK assessment. | | |
|  |  | At **Screening** and **Enrollment** andwhen clinically indicated, remove speculum and perform bimanual exam. | | |
|  |  | At **Enrollment**, participant to insert study VR and study clinician should check placement of study VR. | | |
|  |  | Record slides and swabs collected for assessment at the MTN NL on LDMS Specimen Tracking Sheet and Specimen Storage form. | | |
|  |  | Complete all applicable DataFax and non-DataFax forms.   * Note all findings on the non-DataFax Pelvic Exam Diagrams form. * Starting at the Enrollment Visit and at all required visits, document abnormal findings only on the Pelvic Exam case report form, Pre-existing Conditions form (Enrollment visit only), the Medical History Log (all visits ), AE Log, as applicable (post-Enrollment visits only), and in chart notes as applicable. | | |