| **Pelvic Exam Checklist**  PTID: \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ - \_\_\_ Date: \_\_\_ \_\_\_ -\_\_\_ \_\_\_ \_\_\_-\_\_\_ \_\_\_  Visit Type: Visit Code: \_\_\_ \_\_\_ . \_\_\_\_ | | | |
| --- | --- | --- | --- |
| **Procedures** | | **Required at:** | **Staff Initials** |
| 1 | Prepare exam equipment and specimen collection supplies; label as needed. | **All** |  |
| 2 | If Day 28, have participant (or study clinician/designee, if needed) remove vaginal ring. Place in sterile container until end of examination or prepare for residual drug analysis (see Section 9 Laboratory Considerations). Note ring remains inserted for all exams between enrollment and day 28. | **Day 28** |  |
| 3 | Palpate inguinal lymph nodes; identify all normal and abnormal findings. | **All** |  |
| 4 | Perform naked eye exam of external genitalia, including the perineum, perianal area, and the epithelial lining of the introitus. | **All** |  |
| 5 | Insert speculum, using warm water as lubricant if needed. Perform naked eye exam of the cervix and vagina. | **All** |  |
| 6 | Collect vaginal fluid from the lateral vaginal wall or the posterior fornix for **rapid trichomonas** test. Using the manufacturer-provided swab from an OSOM kit, swab fluid from lateral vaginal wall, place swab in labeled tube (plain), and cap tube. | **Screening** |  |
| 7 | If 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. Document results on STI Test Results CRF during follow-up. | **If indicated at any visit** |  |
| 8 | Collect vaginal fluid (1 swab) from lateral vaginal wall for **pH**. Document results on the Pelvic Exam CRF. | **Enrollment, Days 3, 28, 29, 30, 31 and 35** |  |
| 9 | Collect vaginal fluid (2 swabs) from the lateral vaginal wall for **quantitative vaginal culture** using Dacron or kit-provided swabs (turn swabs 3-4x). | **Enrollment, Days 3, 28 and 35** |  |
| 10 | Collect vaginal fluid (1 swab) from the lateral vaginal wall for **Gram stain** evaluation (turn swab 3x). Roll swab across two slides and air dry. | **Enrollment, Days 3, 28 and 35** |  |
| 11 | Collect 1 manufacturer’s recommended vaginal swab for **NAAT for GC/CT testing**. | **Screening** |  |
| 12 | If indicated, collect ecto- and endocervical cells for **Pap smear** per site SOPs. | **If indicated at Screening** |  |
| 13 | Collect vaginal fluid (1 Dacron swab) from the posterior fornix for **vaginal biomarkers**. | **Enrollment, Days 3, 28 and 35** |  |
| 14 | Collect cervical fluid for **cytobrush**. Insert cytobrush into cervical os and turn 2x. | **Enrollment and Day 28** |  |
| 15 | Collect 1 **cervical biopsies for PK**. Note: If silver nitrate/monsels solution is used to stop bleeding note this in comments section of Pharmacokinetics Specimens—Day 28 CRF. | **Day 28** |  |
| 16 | Collect 1 **cervical biopsy for PD** (Pittsburgh only). | **Day 28** |  |
| 17 | Remove speculum and perform bimanual exam. | **All** |  |
| 18 | If participant has consented to optional rectal fluid collection: Prepare anoscope, collect 1 **rectal sponge for PK,** and remove anoscope. | **Enrollment and Day 28, if participant has consented to rectal fluid collection** |  |
| 19 | Record specimen collection on **LDMS Specimen Tracking Sheet** and **Specimen Storage CRF**. | **As Applicable** |  |
| 20 | Complete all applicable DataFax and non-DataFax forms.   * Note all findings on the **Pelvic Exam Diagrams CRF**. * Document abnormal findings only on the **Pelvic Exam CRF, Pre-existing Conditions** form (Enrollment visit only), **AE Log CRF** as applicable (post-Enrollment visits only), and in chart notes as applicable. | **All** |  |