| **Pelvic Exam Checklist** | | | | |
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| **Procedures** | | **Required at visits:** | **Staff Initials** | **Comments** |
| 1 | Prepare exam equipment, documentation, and specimen collection supplies; label as needed. Explain exam procedures to participant and answer any questions. Position and drape participant comfortably. | All |  |  |
| 2 | Have the clinician/designee remove used vaginal ring. Document on Ring Collection and Insertion CRF. Store for residual drug level testing and document storage on the Specimen Storage CRF. | 4-Week; 8-Week; 12-Week |  |  |
| 3 | Palpate the **inguinal lymph nodes** to assess for enlargement and/or tenderness. Document applicable findings on Pelvic Exam and Pelvic Exam Diagram CRFs. | All |  |  |
| 4 | 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 and Pelvic Exam Diagram CRFs. | All |  |  |
| 5 | 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 and Pelvic Exam Diagram CRFs. | All |  |  |
| 6 | **PK and Intensive PK Subsets ONLY**: Collect vaginal fluid near the site of the vaginal ring for **PK** using one vaginal swab. Document storage on the Pharmacokinetics CRF.  **Note: Must be collected within one hour of PK blood draw**  ***Important note for clinicians****: Subsequent specimens must be collected away from the previously contacted mucosal surface where the PK swab was collected. Swabbed areas should also have sufficient vaginal discharge to adequately collect the sample.* | 4-Week; 8-Week; 12-Week |  |  |
| 7 | Collect 1 swab for **rapid Trichomonas** from the lateral vaginal wall with the rapid test kit. Document results on STI Results CRF. | Screening; if clinically indicated all other visits |  |  |
| 8 | If clinically indicated (symptomatic), collect swab for **vaginal saline and/or KOH wet mounts** for evaluation of vaginitis (yeast and BV) from the lateral vaginal wall. Document results on STI Results CRF. | All |  |  |
| 9 | Collect 1 swab from lateral vaginal wall for **pH assessment**. Swab fluid onto pH strip. Document findings on Pelvic Exam CRF. | Enrollment  4-Week; 8-Week; 12-Week |  |  |
| 10 | Collect vaginal fluid (2 swabs) from the lateral vaginal wall for **quantitative vaginal culture assessment**. Document storage on the Specimen Storage CRF. | Enrollment  4-Week; 8-Week; 12-Week |  |  |
| 11 | Collect 1 swab from lateral vaginal wall for **Gram stain** (turn swab 3x)**.**  Roll swab across two labeled slides and air dry. Document storage on the Specimen Storage CRF. | Enrollment;  4-Week; 8-Week; 12-Week |  |  |
| 12 | Collect vaginal fluid (1 swab) for **biomarker analyses** at MTN NL. Document storage on the Specimen Storage CRF. | Enrollment,  4-Week; 12-Week |  |  |
| 13 | If clinically indicated and per local standard of care, swab suspicious genital lesion for **genital herpes testing**. | All |  |  |
| 14 | Collect ecto- and endocervical or vaginal cells for **Pap smear** (if indicated at screening to confirm eligibility). | Only if indicated |  |  |
| 15 | Collect 1 manufacturers recommended swab from the vaginal canal (according to the specific manufacturer’s recommendations) away from any abnormalities for **NAAT for GC/CT testing**. | Screening; if clinically indicated at Enrollment |  |  |
| 16 | Collect **CVL** for **biomarker analyses** at the MTN NL**.** Document storage on the Specimen Storage CRF. | Enrollment;  4-Week; 12-Week |  |  |
| 17 | **PITTSBURGH and CASE sites ONLY**: Place **cytobrush** for flow cytometry in the cervical os and collect sample. Document storage on the Specimen Storage CRF. | Enrollment; 12-Week |  |  |
| 18 | **Intensive PK SUBSET ONLY**: Collect two (2) **cervical biopsies for PK**. Document storage on the Pharmacokinetics CRF. | 12-Week |  |  |
| 19 | Remove speculum and perform bimanual exam. | All |  |  |
| 20 | Document all findings on Pelvic Exam Diagrams (non-DataFax) and Pelvic Exam CRF. Document specimen collection on the LDMS Tracking Sheet. | All |  |  |

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