**Instructions:** Use of this checklist is intended at study visits for both MTN-015 and MTN-020 on the same day. When an item is performed, complete “Staff Initials” cell. If not done but required, write “ND” and staff initials in “Staff Initials” cell, and provide more details in the chart notes as needed. Do not initial for other staff members. If other staff members are not available to initial items themselves, write and initial/ date a note documenting who completed the procedure, e.g., “done by {name}” or “done by nurse.” If visit procedures are split across more than one date, ensure the date is captured in the comments cell for procedures conducted on a date different than that provided above.

| **MTN-020 PTID: Visit Code:**  |
| --- |
|  **Visit:** | **Monthly**  | **Quarterly**  | **Semi-Annual**  | **PUEV/ Early Term** |
| **MTN-015 PTID: Visit Code:** |
| **Non-ART Visit:** | **Month 1** | **Month 3** | **Semi-Annual**  | **Annual** |
| **ART Visit:** | **Week 2** | **Month 1** | **Month 3** | **Semi-Annual** | **Annual** |
| **Seroconverter Visit Procedure**  | **Required at Visits:** | **Staff Initials** |
| 1 | Prepare exam equipment, documentation, and specimen collection supplies; label as needed. | All |  |
| 2 | Explain exam procedures to participant and answer any questions. Position and drape participant comfortably. | All |  |
| 3 | Palpate the **inguinal lymph nodes** to assess for enlargement and/or tenderness | All |  |
| 4 | Perform naked eye examination of the **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 | Assess for **cervical ectopy.** Document on MTN-020 Pelvic Exam CRF. | All |  |
| 7 | Collect 1 swab for **rapid Trichomonas** from the lateral vaginal wall with the rapid test kit. If required for both studies, use a tube labeled for MTN-020. Prepare a certified copy of results for MTN-015. | MTN-020:Semi-ann, AnnualMTN-015:Annual, if indicated  |  |
| 8 | If indicated (symptomatic), collect swab for **vaginal saline and/or KOH wet mounts** for evaluation of vaginitis (yeast, trichomonas or BV) from the lateral vaginal wall. | If indicated (at any visit) |  |
| 9 | Collect 1 swab from lateral vaginal wall for **Gram stain** (turn swab 3x)**.**  Roll swab across two labeled slides and air dry.  | MTN-020: All |  |
| 10 | Collect 1 swab from lateral vaginal wall for **pH assessment**. Swab fluid onto pH strip. If required for both studies, record on MTN-020 STI test result CRF. Prepare certified copy for MTN-015 study binder and transcribe results onto MTN-015 Sexually Transmitted Diseases Results form. | MTN-020: AllMTN-015: Annual, if indicated |  |
| 11 | Collect **endocervical fluid** for biomarker analyses at MTN NL (turn swab 2x). | MTN-020: All |  |
| 12 | Collect two (2) vaginal fluid swabs from the posterior fornix for archive | MTN-015: All (except at ART Week 2) |  |
| 13 | Collect **CVL** for archive | MTN-015: All (except at ART Week 2) |  |
| 14 | If indicated and per local standard of care, send fluid from a suspicious genital lesion for genital herpes testing. | MTN-020: If indicated |  |
| 15 | Collect ecto- and endocervical cells for **Pap smear**  | MTN-020: PUEV/Early TermMTN-015: 6 month intervals in the first year post-seroconversion, and then annually thereafter; if indicated at all other visits |  |
| 16 | If indicated, lavage to remove visual obstruction (e.g., mucus, cellular debris) and complete the naked eye exam.  | MTN-020: If indicated |  |
| 17 | Remove speculum and perform bimanual exam. | All |  |
| 18 | Document all findings on MTN-020 Pelvic Exam Diagrams (non DataFax) CRF. Make certified copies of all MTN-020 forms to file in MTN-015 study binder. Transcribe results onto MTN-015 Sexually Transmitted Diseases form as needed. If pelvic exam, or components of pelvic exam, are not conducted for MTN-020, make certified copies of MTN-015 forms to file in MTN-020 study notebook. Record AEs for MTN-020 as needed. | All |  |
| 19 | Record vaginal/cervical swabs and CVL collection on LDMS Specimen Tracking Sheet and Specimen Storage form for both studies | All |  |