| **Genital Exam Checklist** | | | |
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| **Procedures:** | | **Required at Visits**  (may be performed if indicated at other visits) | **Staff**  **Initials**  (NA if not female) |
|  | Prepare exam equipment, documentation, and specimen collection supplies; label as needed | All |  |
|  | Explain exam procedures to participant and answer any questions. Position and drape participant comfortably | All |  |
|  | Perform naked eye examination and evaluate for abnormalities of the external genitalia including the anus, perineum, and the perianal area.  Document applicable findings on Anorectal Exam CRF. | Screening |  |
| Enrollment |
| V 3, 7, 8, 13 |
| Per PK/PD assignment: V 4, 5 or 6 and 14, 15 or 16 |
|  | **Female participants**: Perform naked eye examination and evaluate for abnormalities of the epithelial lining of the introitus. Palpate the inguinal lymph nodes to assess for enlargement and/or tenderness.  Insert speculum, using warm water as lubricant if needed. Perform naked eye exam of the cervix and vagina  Document applicable findings on Pelvic Exam CRF and Pelvic Exam Diagrams. | Screening |  |
| Enrollment |
| V 13 |
| Per PK/PD assignment  V 4, 5 or 6 and 14, 15 or 16 |
|  | **Female participants:** Collect 1 swab for NAAT GC/CT from the lateral wall of the vagina. | Screening |  |
|  | **Female participants**: Collect 1 dacron swab of cervicovaginal fluid from the posterior fornix for PK. Document collection on the Cervical Specimen Storage CRF and on the applicable LDMS Specimen Tracking Sheet  Note: PK swab must be collected within one hour of PK blood draw. | V 13 |  |
| Per PK/PD assignment:  V 4, 5 or 6 and  V 14, 15 or 16 |
|  | **Female participants**: Perform cervicovaginal lavage (CVL) and collect saline for PD and PK. Document collection on the Cervical Specimen Storage CRF and on the applicable LDMS Specimen Tracking Sheet | Enrollment |  |
| V 13 |
| Per PK/PD assignment:  V 4, 5 or 6  V 14, 15 or 16 |
|  | **Females participants**: Collect ecto- and endocervical cells for Pap smear | Screening, if indicated |  |
|  | **Female participants**: Collect two cervical biopsies for PK, measuring approximately 3mm by 5mm. Document collection on the Cervical Specimen Storage CRF and on the applicable LDMS Specimen Tracking Sheet | V 13 |  |
| Per PK/PD assignment: V 4, 5 or 6 and 14, 15 or 16 |
|  | **Females participants**: Remove speculum and perform bimanual exam. | Screening |  |
|  | Collect 1 rectal swab for anal HSV1/2 testing, if indicated. Record results on the STI Tests CRF | If indicated at all visits |  |
|  | Perform digital rectal examination and evaluate for abnormalities. Document exam and findings on Anorectal Exam CRF. | Screening |  |
| Enrollment |
| V 3 |
| V 7 and 8 |
| V 13 |
| Per PK/PD assignment: V 4, 5 or 6 and 14, 15 or 16 |
|  | Prepare and insert anoscope for rectal fluid collection  Document anoscopy and relevant findings on Anorectal Exam CRF. | Screening |  |
| Enrollment |
| V 3, 7, 8, and 13 |
| Per PK/PD assignment: V 4, 5, or 6 and  Visit 14, 15 or 16 |
|  | Collect rectal swab for NAAT GC/CT testing. Record results on the STI Tests CRF | Screening |  |
|  | Collect 1 flocked nylon rectal swab for microflora from the lateral wall (rotating several times). Record collection on the Specimen Storage CRF (at Enrollment), the Timed Specimen Storage CRF (at Visits 3 and 13) and on the applicable LDMS Specimen Tracking Sheet | Enrollment |  |
| V 3 |
| V 13 |
|  |  |  |  |
|  | Collect 1 dacron swab for PK, holding swab in place for 2 minutes. Record collection on the Specimen Storage CRF (at Visits 4, 5 or 6, Visits 7 and 8, and Visits 14, 15, or 16) or the Timed Specimen Storage CRF (at Visits 3 and 13), and on the applicable LDMS Specimen Tracking Sheet  Note: At Visit 7, rectal fluid for PK is collected at hour 0 (prior to gel administration). At Visit 8, rectal fluid for PK is collected at approximately hour 24 (24 hours post Visit 7 dosing and prior to Visit 8 gel administration). | V 3 |  |
| V 7 and 8 |
| V 13 |
| Per PK/PD assignment:  V 4, 5 or 6 and  V 14, 15  or 16 |
|  | Collect 1 rectal sponge for mucosal safety through the anoscope; remove sponge after two minutes. Record collection on the Specimen Storage CRF (at Enrollment) or the Timed Specimen Storage CRF (Visits 3 and 13), and on the applicable LDMS Specimen Tracking Sheet. Remove anoscope after sample collection. | Enrollment |  |
| V 3 |
| V 13 |
|  | Prepare appropriate pre-packaged enema bottle for enema (rectal lavage) for PD and PK by applying a small amount of study-specified lubricant to the tip of the enema bottle. Administer the enema by gently inserting the tip into the rectum and slowly dispel the fluid. Instruct participant to hold the fluid in the rectum for approximately 3-5 minutes then expel it, including stool, into the collection ‘hat’ placed under the toilet seat designated for this purpose. Record collection of rectal enema effluent on the Specimen Storage CRF and on the applicable LDMS Specimen Tracking Sheet. | Enrollment |  |
| V 13 |
| Per PK/PD assignment:  V 4, 5 or 6 and  V 14, 15 or 16 |
|  | Prepare and insert sigmoidoscope for rectal tissue (biopsy) collection  Document sigmoidoscopy and relevant findings on Anorectal Exam CRF. | Enrollment |  |
| V 3 |
| V 13 |
| Per PK/PD assignment: V 4, 5, or 6 and  V 14, 15, or 16 |
|  | Collect rectal biopsies, measuring approximately 3mm by 5mm. Remove sigmoidoscope after sample collection.  Document on Specimen Storage CRF (at Enrollment and participant’s assigned PK/PD sampling visit) and the Timed Specimen Storage CRF (Visit 3 and 13) and record the swab and sponge weights on the LDMS Specimen Tracking Sheet |  |  |
|  | * Collect five (5) biopsies for PK | V 3 |  |
| V 13 |
| Per PK/PD assignment: V 4, 5, or 6; V 14, 15, or 16 |
|  | * Collect two (2) biopsies for Mucosal Gene Expression Array | Enrollment |  |
| V 3 |
| V 13 |
|  | * Collect one (1) biopsy for Histology | Enrollment |  |
| V 3 |
| V 13 |
|  | * Collect four (4) biopsy for PD | Enrollment |  |
| V 3 |
| V 13 |
| Per PK/PD assignment: V 4, 5, or 6; V 14, 15, or 16 |
|  | * Collect seven (7) biopsies for Mucosal T Cell Phenotyping | Enrollment |  |
| V 3 |
| V 13 |
|  | * Collect one (1) biopsies for Proteomics | Enrollment |  |
| V 3 |
| V 13 |

**Additional Notes/Comments/Referrals:**