INSTRUCTIONS: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why (if not self-explanatory); initial and date this entry. Use a new Genital Exam Checklist for each study visit in which either a rectal, male genital, and/or pelvic exam is performed. Samples must be collected in the order listed on the checklist.

* Rectal exams are required for all participants at all study visits except for the final contact/Early Termination visit (V11), which is to be performed if indicated.
* Pelvic exams and male genital exams are only performed if indicated at study visits. Pelvic exams are performed if applicable (i.e., for participants assigned female sex at birth and if anatomy allows). Note that sample collection may be required, even if other elements of the exam are not indicated.

| Procedure | Required at Visit(s) | Staff Initials |
| --- | --- | --- |
|  | Prepare for exam: * Exam equipment, documentation, and specimen collection supplies; label as needed.
* Explain exam procedures to participant and answer any questions.
* Position and drape participant comfortably.
 | Visits 1-10Visit 11/Early Term, *if indicated*  |  |
| 2. | Palpate the inguinal lymph nodes to assess for enlargement and/or tenderness.  | *If indicated all visits* |  |
| 3. | Perform naked eye examination and evaluate for abnormalities of the external genitalia per applicable exam performed:* Rectal (ALL participants): perineum and perianal area
* *If indicated,* Pelvic: epithelial lining of the introitus
* *If indicated,* Male Genital: entire penile surface (glans, urethral meatus, internal/external foreskin (if present), shaft; scrotum. (Use hand-held magnifying glass)
 | Visits 1-10Visit 11/Early Term, *if indicated*  |  |
| 4. | FOR PELVIC EXAM* Insert speculum, using warm water as lubricant if needed.
* Perform naked eye exam of the vagina and cervix, if applicable.
* Remove speculum and perform bimanual exam.
 | *If indicated, all visits* |  |
| 5. | Participants assigned female sex at birth and if anatomy allows: Collect vaginal fluid for GC/CT/TV NAAT test at local lab.* 2 swabs from lateral vaginal wall. Blind collection.
 | Screening (V1)*If indicated at all other visits* |  |
| 6. | Participants assigned female sex at birth and if anatomy allows: Collect vaginal fluid for PK analysis. * 2 swabs from posterior fornix. Blind collection.
 | * V 3 and 7 - 4 Hours Post Dose
* V4 and 8 - 24 hours Post Dose
* V6 and 10 - 72 hours Post Dose
 |  |
| 7. | Participants assigned female sex at birth and if anatomy allows: Collect vaginal fluid for PD analysis. * 1 swab from posterior fornix. Blind collection.

*.* | * Enrollment (V2)
* V4 and 8 - 24 hours Post Dose
* V6 and 10 - 72 hours Post Dose
 |  |
| 8. | Participants assigned female sex at birth and if anatomy allows: Collect vaginal fluid for microflora/gram stain analysis. * 2 swabs from lateral vaginal wall. Blind collection.
 | * Enrollment (V2)
* V4 and 8 - 24 hours Post Dose
 |  |
| 9. | Perform digital rectal examination and evaluate for abnormalities. * Lubricate gloved index finger with study-specified lubricant
* Gently and slowly insert finger (palmar surface down) into the anus.
* Sweep finger circumferentially around the entire anal/distal rectal surface.
 | Visits 1-10Visit 11/Early Term, *if indicated*  |  |
| 10. | Prepare and insert anoscope for rectal fluid collection. Perform anoscopy.*Note: Anoscopy is only done during rectal fluid collection. Anoscopy is not required prior to insert administration at Dosing Visits unless clinically indicated.* | As needed during subsequent specimen collection.  |  |
| 11. | Collect rectal fluid for GC/CT NAAT test at local lab.* 1 swab inserted through the anoscope to proximal rectal lumen.
 | Screening *If indicated at all other visits* |  |
| 12. | Collect rectal fluid for PK testing.* 2 swabs from proximal rectal lumen holding in place for 2 minutes

  | * V3 and 7 - 4 Hours Post Dose
* V4 and 8 - 24 hours Post Dose
* V6 and 10 - 72 hours Post Dose
 |  |
| 13. | Collect rectal fluid for PD analysis. * 1 swab inserted through the anoscope to proximal rectal lumen; remove after 2 minutes.
 | * Enrollment (V2)
* V4 and 8 - 24 hours Post Dose
* V6 and 10 - 72 hours Post Dose
 |  |
| 14. | Collect rectal fluid for microbiome analysis. * 1 swab inserted through the anoscope and rotate several times over the lateral wall

Remove anoscope after sample collection. | * Enrollment (V2)
* V4 and 8 - 24 hours Post Dose
 |  |
| 15. | Prepare participant for rectal enema (rectal lavage). Apply a small amount of study-specified lubricant to the tip of the pre-packaged enema bottle. Instruct participant to self-administer the enema by gently inserting the tip into the rectum and slowly dispelling the fluid, holding the fluid in the rectum for approximately 3-5 minutes then expelling it, including stool, into the toilet. | * Enrollment
* V6 and 10 - 72 hours Post Dose
 |  |
| 16. | Prepare and insert sigmoidoscope for rectal tissue (biopsy) collection. Perform sigmoidoscopy. | As needed during subsequent specimen collection.  |  |
| 17. | Collect rectal tissue for PK analysis.* Eleven (11) for PK
 | * V4 and 8 - 24 hours Post Dose
* V6 and 10 - 72 hours Post Dose
 |  |
| 18. | Collect rectal tissue for PD analysis.* Four (4) for PD
 | * Enrollment (V2)
* V4 and 8 - 24 hours Post Dose
* V6 and 10 - 72 hours Post Dose
 |  |
| 19. | Collect rectal tissue for biomarkers analysis.* One (1) for histology
* Four (4) for flow cytometry/T cell Phenotyping
* One (1) for metabolomics
* One (1) for proteomics

Remove sigmoidoscope after sample collection.  | * Enrollment (V2)
* V4 and 8 - 24 hours Post Dose
 |  |
| 20. | Document all findings on Anorectal Exam CRF, Pelvic Exam Diagram and Pelvic Exam CRF (if applicable), and STI Test Results CRF, as applicable. Document storage of all specimens collected on the following, as applicable: Specimen Collection and Storage-Group 2 CRF; LDMS Specimen Tracking Sheet | All visits |  |

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| Comments: |
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