| **MTN-033 Rectal Exam Checklist** | | | | |
| --- | --- | --- | --- | --- |
| **Procedures** | | **Visit Required** | **Staff**  **Initials** |
|  | Prepare exam equipment, documentation, and specimen collection supplies; label as needed. | * All |  |
|  | Explain exam procedures to participant and answer any questions. | * All |  |
|  | Have the participant stand in front of you and raise their gown to the level of the navel, exposing the entire genital region. Perform general inspection via naked eye examination (including using a hand-held magnifying glass) and evaluate for abnormalities (areas to be examined noted below):   * Internal and external foreskin (if present) * Entire penile surface * Shaft of the penis * Glans * Urethral meatus * Scrotum * Inguinal lymph nodes (right and left)   *Document all findings on the Genital Exam CRF. Abnormal findings should be added to the Baseline Medical History Log (at Screening and Enrollment) or on the AE Log CRF (during follow up).* | * Screening (Visit 1) * Enrollment (Visit 2) * *If indicated* |  |
|  | Perform visual exam, including perianal exam, of the external genitalia including the anus, perineum, perianal area.  *Document all findings on the Anorectal Exam CRF. Abnormal findings should be added to the Baseline Medical History Log (at Screening and Enrollment) or on the AE Log CRF (during follow up) as applicable.* | * Screening (Visit 1) * Enrollment (Visit 2) * Visit 3 * Visit 4 * Visit 5 * Visit 6/Early Termination |  |
|  | *If indicated, collect 1 rectal swab for anal HSV1/2 testing and record results on the STI Tests CRF.* | * *If indicated* |  |
|  | Perform digital examination and evaluate for abnormalities. *Document findings on the Anorectal Exam CRF. Abnormal findings should be added to the Baseline Medical History Log (at Screening and Enrollment) or on the AE Log CRF (during follow up) as applicable.* | * Screening (Visit 1) * Enrollment (Visit 2) * Visit 3 * Visit 4 * Visit 5 * Visit 6/Early Termination |  |
|  | Prepare and insert anoscope for rectal fluid collection. | * Screening * Enrollment (Visit 2) * Visit 3 * Visit 4 * Visit 5 * Visit 6/Early Termination |  |
|  | Collect rectal swab for NAAT GC/CT testing. *Document results on the STI Test Results CRF.* | * Screening (Visit 1) * *If indicated at all other visits* |  |
|  | Collect 1 flocked nylon rectal swab for microbiome from the lateral wall (rotating several times). *Document collection on the LDMS Tracking Sheet and Anorectal Specimen Storage CRF.* | * Enrollment (Visit 2) * Visit 4 * Visit 6/Early Termination |  |
|  | Collect 1 dacron swab for PK, swabbing against the mucosa for 2 minutes.  **Visit 3 and 5: □ 1-hour post dose □ 4-hours post dose**  *Document collection on the LDMS Tracking Sheet and the Timed Anorectal Specimen Storage (Visits 3 and 5) and Anorectal Specimen Storage (Enrollment, Visit 4 and 6) CRFs.* | * Visit 3 (1 or 4 hrs post dose) * Visit 4 * Visit 5 (1 or 4 hrs post dose) * Visit 6/Early Termination |  |
|  | Remove anoscope following sample collection. Evaluate for abnormalities. Document findings on the Anorectal Exam CRF. Abnormal findings should be added to the Baseline Medical History Log (at Screening and Enrollment) or on the AE Log CRF (during follow up) as applicable. |  |  |
|  | Prepare and administer pre-packaged enema and collect enema effluent for PK and/or PD.  **Visit 3 and 5: □ 1-hour post dose □ 4-hours post dose**  *Prepare appropriate pre-packaged enema bottle for enema (rectal lavage) for PK and/or /PD 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.*  *Document collection on the LDMS Tracking Sheet and the Timed Anorectal Specimen Storage (Visits 3 and 5) and Anorectal Specimen Storage (Enrollment, Visits 4 and 6) CRFs.* | * Enrollment (Visit 2) (PD only) * Visit 3 (1 or 4 hrs post dose) * Visit 4 * Visit 5 (1 or 4 hrs post dose) * Visit 6/Early Termination |  |
|  | Prepare and insert sigmoidoscope for rectal tissue (biopsy) collection. Collect rectal biopsies, measuring approximately 3mm by 5mm. | * Enrollment (Visit 2) * Visit 3 * Visit 4 * Visit 5 * Visit 6/Early Termination |  |
|  | Via inserted sigmoidoscope, collect six (6) biopsies for PK.  **Visit 3 and 5: □ 1-hour post dose □ 4-hours post dose**  *Document collection on the LDMS Tracking Sheet and the Timed Anorectal Specimen Storage (Visits 3 and 5) and Anorectal Specimen Storage (Visits 4 and 6) CRFs.* | * Visit 3 (1 or 4 hrs post dose) * Visit 4 * Visit 5 (1 or 4 hrs post dose) * Visit 6/Early Termination |  |
|  | Via inserted sigmoidoscope, collect two (2) biopsies for mucosal gene expression array/transcriptomics.  *Document collection on the LDMS Tracking Sheet and the Anorectal Specimen Storage.* | * Enrollment (Visit 2) * Visit 4 * Visit 6/Early Termination |  |
|  | Via inserted sigmoidoscope, collect one (1) biopsies for histology.  *Document collection on the LDMS Tracking Sheet and the Anorectal Specimen Storage CRF.* | * Enrollment (Visit 2) * Visit 4 * Visit 6/Early Termination |  |
|  | Via inserted sigmoidoscope, collect three (3) biopsies for PD/Ex-Vivo challenge.  **Visit 3 and 5: □ 1-hour post dose □ 4-hours post dose**  *Document collection on the LDMS Tracking Sheet and the Timed Anorectal Specimen Storage CRF.* | * Enrollment (Visit 2) * Visit 3 (1 or 4 hrs post dose) * Visit 5 (1 or 4 hrs post dose) |  |
|  | Via inserted sigmoidoscope, collect one (1) biopsies for proteomics.  *Document collection on the LDMS Tracking Sheet and the Anorectal Specimen Storage CRF.* | * Enrollment (Visit 2) * Visit 4 * Visit 6/Early Termination |  |
|  | Remove sigmoidoscope slowly. Evaluate for abnormalities.  *Document findings on the Anorectal Exam CRF. Abnormal findings should be added to the Baseline Medical History Log (at Screening and Enrollment) or on the AE Log CRF (during follow up) as applicable.* |  |  |