Instructions: Use the table below to document a participant's eligibility status for MTN-014 study participation. Initial and date below each set of "yes/no" checkboxes upon assessment of each eligibility criterion. For each item, the reference/source document is listed. Once ineligibility status is determined, the form may be stopped and the remaining questions may be left blank. Complete the Eligibility Criteria CRF for all screened participants once the participant's eligibility/enrollment status is determined.

Inclusion Criteria	**Screening Visit**	**Enrollment Visit**
	Yes No	**Yes No**
1. Age 21 through 45 years (inclusive) at Screening, verified per site SOPs *Source: copy of identification card or other documents as specified in SOP*	☐ ☐ _____	*not required*
2. Able and willing to provide written informed consent *Source: signed/marked Screening/Enrollment consent form*	☐ ☐ _____	*not required*
3. Able and willing to comply with all study procedure requirements, including, clinical and laboratory assessments, vaginal and rectal examinations, urine and blood testing, as well as attendance at all scheduled study visits *Source: signed/marked Screening/Enrollment consent form, Screening/Enrollment Behavioral Eligibility Worksheet*	☐ ☐ _____	☐ ☐ _____
4. In general good health at Screening and Enrollment as determined by the Investigator of Record (IoR)/ or designee *Source: Screening/Abbreviated Physical Exam CRF*	☐ ☐ _____	☐ ☐ _____
5. Negative pregnancy test at Screening and Enrollment *Source: pregnancy testing logs*	☐ ☐ _____	☐ ☐ _____
6. HIV-negative at Screening and Enrollment, per applicable protocol algorithm in Appendix II *Source: rapid HIV testing logs*	☐ ☐ _____	☐ ☐ _____
7. Able and willing to provide adequate locator information, as defined in the site SOP *Source: signed/marked Screening/Enrollment consent form*	*review and proceed accordingly*	☐ ☐ _____
8. Willingness to use study-provided male condoms for the duration of the study participation for penetrative intercourse *Source: Screening/Enrollment Behavioral Eligibility Worksheet*	☐ ☐ _____	☐ ☐ _____

Note: In order for the participant to be eligible , all of the responses to items 1-8 above must be 'yes'.

Inclusion Criteria	Screening Visit	Enrollment Visit
	Yes No	Yes No
9. Per participant report at Screening, regular menstrual cycles with at least 21 days between menses (does not apply to participants who report using a progestin-only method of contraception at screening e.g., Depo-Provera, progesterone-containing IUDs or extended use of oral contraceptives *Source: Screening Menstrual History non-DataFax form*	☐ ☐ _____	*not required*
10. Per participant report at Enrollment, using an effective method of contraception and intending to use an effective method of contraception for the duration of study participation; effective methods include hormonal methods, excluding vaginal rings, Intrauterine device (IUD) inserted at least 42 days prior to Enrollment, sterilization of participant or partner at least 42 days prior to Enrollment, self-identifies as a woman who has sex with women exclusively, sexually abstinent for at least 90 days prior to enrollment and the intention to remain sexually abstinent for the duration of study participation *Source: Screening/Enrollment Behavioral Eligibility Worksheet*	*review and proceed accordingly*	☐ ☐ _____
11. Per participant report at Screening, states a willingness to refrain from inserting any non-study vaginal or rectal products or objects into the vagina or rectum, including but not limited to, spermicides, female condoms, diaphragms, contraceptive vaginal rings, vaginal medications, menstrual cups, cervical caps (or any other vaginal barrier method), vaginal/rectal douches, enemas, non-study approved lubricants, sex toys (vibrators, dildos, etc.), and tampons for the duration of the study product use periods and for 24 hours prior to Period Initiation and Period End Visits. *Source: Screening Behavioral Eligibility Worksheet*	☐ ☐ _____	*not required*
12. Pap result consistent with Grade 0 according to FGGT* or satisfactory evaluation of non-Grade 0 Pap result with no treatment required per clinical judgment of IoR/designee in the 12 months prior to Enrollment *Source: STI and RTI laboratory results, baseline medical history questions*	*review and proceed accordingly*	☐ ☐ _____
13. At Screening, participant agrees not to take part in other research studies involving drugs, medical devices, or vaginal/rectal products for the duration of study participation (including between Screening and Enrollment) *Source: Screening Behavioral Eligibility Worksheet*	☐ ☐ _____	*not required*
14. At Screening, willing to abstain from inserting any non-study products into the vagina or rectum for 72 hours prior to and following the collection of biopsies. *Source: Screening Behavioral Eligibility Worksheet*	☐ ☐ _____	*not required*
15. At Screening, willing to abstain from vaginal and rectal intercourse for 72 hours prior to and following the collection of biopsies. *Source: Screening Behavioral Eligibility Worksheet*	☐ ☐ _____	*not required*
16. At Screening, willing to abstain from the use of non-steroidal anti-inflammatory drugs (NSAIDs), aspirin and/or other drugs that are associated with the increased likelihood of bleeding following mucosal biopsy collection for 72 hours prior to and following the collection of biopsies. *Source: Screening Behavioral Eligibility Worksheet*	☐ ☐ _____	*not required*

Note: In order for the participant to be <u>eligible</u> , all of the responses to items 9-16 above <u>must be 'yes'.</u>

Exclusion Criteria	**Screening Visit**	**Enrollment Visit**
	Yes No	**Yes No**
1. Participant report of any of the following: a) Known adverse reaction to the study product (ever) *Source: Screening Behavioral Eligibility Worksheet*	☐ ☐	not required
b) Known adverse reaction to latex (ever) *Source: Screening Behavioral Eligibility Worksheet*	☐ ☐	not required
c) Current male sex partner with known history of adverse reaction to latex (ever) *Source: Screening Behavioral Eligibility Worksheet*	☐ ☐	not required
d) History of serum HBsAg positivity (ever) *Source: Screening Behavioral Eligibility Worksheet*	☐ ☐	not required
e) Non-therapeutic injection drug use in the 12 calendar months prior to Enrollment *Source: Screening/Enrollment Behavioral Eligibility Worksheet*	*review and proceed accordingly*	☐ ☐
f) STI requiring treatment in the 6 calendar months prior to Enrollment *Source: Screening/Enrollment Behavioral Eligibility Worksheet*	*review and proceed accordingly*	☐ ☐
g) Post-exposure prophylaxis (PEP) or Pre-exposure prophylaxis (PrEP) within 6 months prior to Enrollment *Source: Screening/Enrollment Behavioral Eligibility Worksheet*	*review and proceed accordingly*	☐ ☐
h) Last pregnancy outcome within 90 days or less prior to Enrollment *Source: Screening/Enrollment Behavioral Eligibility Worksheet*	*review and proceed accordingly*	☐ ☐
i) Gynecologic or genital procedure (e.g. tubal ligation, dilation, curettage) within the 42 days prior to Enrollment *Source: Screening/Enrollment Behavioral Eligibility Worksheet*	*review and proceed accordingly*	☐ ☐
Note: *This does not include biopsy for the evaluation of an abnormal pap result or endometrial biopsy that occurred more than 7 days prior to Enrollment, provided that all that all other inclusion/exclusion criteria are met.*		
j) Participation in any other research study involving drugs, medical devices, or vaginal products 42 days or less prior to Enrollment *Source: Screening/Enrollment Behavioral Eligibility Worksheet*	*review and proceed accordingly*	☐ ☐

Note: In order for the participant to be <u>eligible</u> , all of the responses to items 1a-1j above <u>must be 'no'.</u>

Exclusion Criteria	**Screening Visit**	**Enrollment Visit**
	Yes No	**Yes No**
k) Anticipated IUD replacement within the next 3 months or an IUD inserted 42 days or less prior to Enrollment *Source: Screening/Enrollment Behavioral Eligibility Worksheet*	*review and proceed accordingly*	☐ ☐ _____
l) Participant self-report at Screening and/or Enrollment intention of becoming pregnant in the next 3 months *Source: Screening/Enrollment Behavioral Eligibility Worksheet*	*review and proceed accordingly*	☐ ☐ _____
m) Currently breastfeeding at the time of Screening and/or Enrollment *Source: Screening/Enrollment Behavioral Eligibility Worksheet*	☐ ☐ _____	☐ ☐ _____
n) History of bleeding problems *Source: Screening Behavioral Eligibility Worksheet*	☐ ☐ _____	not required
o) Other reproductive tract infection (RTI) (e.g., candida and BV) requiring treatment in the 2 calendar months prior to Enrollment *Source: Screening/Enrollment Behavioral Eligibility Worksheet*	review and proceed accordingly	☐ ☐ _____
2. Laboratory abnormalities at Screening greater than or equal to a Grade 2 (unless otherwise stated):** *Source for 2a-2e: laboratory test results reports* a) Aspartate aminotransferase (AST) or alanine transminase (ALT)	☐ ☐ _____	*review and proceed accordingly*
b) Hemoglobin	☐ ☐ _____	*review and proceed accordingly*
c) Platelet count	☐ ☐ _____	*review and proceed accordingly*
d) Serum creatinine	☐ ☐ _____	*review and proceed accordingly*
e) Prothrombin time (PT) > 1.25 X site laboratory ULN/ International normalized ratio (INR) > 1.5 X site laboratory ULN	☐ ☐ _____	*review and proceed accordingly*
Otherwise eligible participants with an exclusionary test result(s) listed above may be re-tested during the Screening process. If a participant is re-tested and a non-exclusionary result is documented within the 42 days of providing informed consent, the participant may be enrolled.		

Note: In order for the participant to be <u>eligible</u> , all of the responses to items 1k-2e above <u>must be 'no'.</u>

Exclusion Criteria	**Screening Visit**	**Enrollment Visit**
	Yes No	**Yes No**
3. Urinary Tract Infection (UTI) at Screening and/or Enrollment ***Note:*** *Otherwise eligible participants diagnosed with UTI during Screening will be offered treatment and may be enrolled after completing treatment and all symptoms have resolved. If treatment is completed and symptoms have resolved within 42 days of obtaining informed consent, the participant may be enrolled.* *Source: urine culture, Baseline Medical History Questions, Pre-exisiting Conditions CRF*	*review and proceed accordingly*	☐ ☐ _____
4. Pelvic inflammatory disease or an STI or RTI requiring treatment per current WHO guidelines at Screening and/or Enrollment *Source: Baseline Medical History Questions, Pre-existing Conditions, Pelvic Exam Diagram, STI and RTI lab results*	☐ ☐ _____	☐ ☐ _____
5. Clinically apparent Grade 2 or higher pelvic* and/or rectal*** examination finding (observed by study staff) at Screening and/or Enrollment *Source: Pelvic Exam Diagram, Pre-exisiting Conditions CRF*	*review and proceed accordingly*	☐ ☐ _____
Note: *Cervical bleeding associated with speculum insertion and/or speculum collection judged to be within the range of normal according to the clinical judgment of the IOR/designee is considered expected non-menstrual bleeding and is not exclusionary.* ***Note:*** *Otherwise eligible participants with exclusionary pelvic and/or rectal examination findings may be enrolled/randomized after the findings have improved to a non-exclusionary severity grading or resolved. If improvement to a non-exclusionary grade or resolution is documented within 42 days of providing informed consent, the participant may be enrolled.*		
6. Any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives	*review and proceed accordingly*	☐ ☐ _____

Note: In order for the participant to be <u>eligible</u> , all of the responses to items 3-6 above <u>must be 'no'.</u>

* per the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 1.0, December, 2004 (Clarification dated August 2009), Addendum 1 Female Genital Grading Table for Use in Microbicide Studies

** per the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 1.0, December, 2004 (Clarification dated August 2009)

*** per the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 1.0, December, 2004 (Clarification dated August 2009), Addendum 3 Rectal Grading Table for Use in Microbicide Studies (Clarification dated May 2012).

At enrollment visit, participant is found to meet all eligibility criteria:

_____	_____	_____	_____
Signature of staff member	*Date*	*Signature of Investigator of Record (or designee)*	*Date*