

PTID:	Exam Date:
Screening Attempt:	Visit Code:
Initials	Procedures
	Review relevant documentation from previous and current visits.
	Prepare and label the following per SSP Section X: <input type="checkbox"/> 2 microscope slides <input type="checkbox"/> 1 glass or plastic tube containing six drops (~100 µL) of 10% KOH solution <input type="checkbox"/> 2 cryovials each containing 0.4 mL of phosphate buffered saline (PBS)
	Explain exam procedures to the participant and answer any questions.
	Position and drape the participant comfortably.
	Palpate inguinal lymph nodes.
	Inspect external genitalia.
	Insert speculum, using warm water as lubricant if needed.
	Place pH strip against the lateral vaginal wall until moistened. Alternatively, collect vaginal fluid from the lateral vaginal wall with a swab and swab the fluid onto the pH strip. Record pH on Vaginal Test Results form.
	Swab vaginal fluid (1 swab) from the lateral vaginal wall for Gram stain assessment at the MTN NL. Roll the swab across the two labeled slides and allow to air dry.
	Swab vaginal fluid (1 swab) from the lateral vaginal wall for trichomonas rapid test.
	If clinically indicated , swab vaginal fluid (1 swab) from the lateral vaginal wall for BV rapid test.
	If clinically indicated , swab vaginal fluid (1 swab) from the lateral vaginal wall for KOH wet mount for candidiasis. Place the swab in the labeled tube (KOH).
	Swab vaginal fluid (1 swab) from the posterior fornix for biomarker analyses at the MTN NL. After the tip of the swab is saturated, place the swab in a labeled cryovial (PBS).
	Swab endocervical fluid (1 swab) for biomarker analyses at the MTN NL. After the tip of the swab is saturated, place the swab in a labeled cryovial (PBS).
	Inspect cervix and vagina.
	Collect ecto- and endocervical cells for Pap smear per site SOPs. ⇒ NOT required if documented normal Pap within 12 months prior to enrollment
	Perform bimanual exam.
	Document exam per site SOPs. <ul style="list-style-type: none"> Record all findings on Pelvic Exam Diagrams form and all abnormal findings on Screening and Enrollment Pelvic Exam form. Record all pelvic specimen test results on Vaginal Test Results form.
	Record slides and swabs collected for assessment at the MTN NL on LDMS Specimen Tracking Sheet.

Comment [JAC1]: Need input from sites. KOH wet prep is only done if clinically indicated. Would you routinely prepare and label the tube containing KOH solution in preparation for all exams, or would you only do this after initiating the exam and determining whether the wet prep is clinically indicated?

Comment [JAC2]: Need site input on preferred method. Do all sites use a swab to place fluid on the pH strip?

Comment [JAC3]: Need input from sites on where the trich and BV rapid tests are planned to be done, and who is planned to do them.

Comment [JAC4]: Need site input on whether this phrase is needed or could be deleted.