

## **GROUP 1**

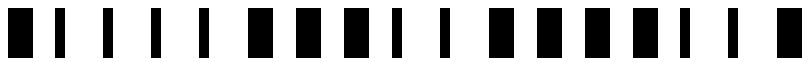
### **Visit 4a/4b Visit Code 04.0**

- Visit Summary (VS-1)
- Pelvic Exam (PE-1)
- Physical Exam (PX-1)
- STI Test Results (STI-1)
- Pharmacokinetics (PK-1)
- Study Product Accountability (SPA-1)
- Pelvic Exam Diagrams (non-DataFax)

**Site to print and add:**

- LDMS Specimen Tracking Sheet

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MTN-011 (135)

VS-1 (121)

Visit Code

1

Participant ID

-  -  - 0

Protocol PTID Chk Cohort

Visit Summary

Visit Date

dd MMM yy

1. What was the participant's last day of previous menses?	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<i>amenorrheic for past 6 months</i>
2. hCG for pregnancy:	<input type="checkbox"/> <i>not required</i> <input type="checkbox"/> <i>negative</i> <input type="checkbox"/> <i>positive</i>	<i>If positive, complete Pregnancy Report form and Product Hold/Discontinuation Log.</i>
3. Has participant's method of contraception/family planning changed since her last visit?	<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>	<i>If yes, complete Family Planning form.</i>
4. How many <b>new</b> AE Log pages were completed for the female participant at this visit?	<input type="text"/> <input type="text"/>	<i># of pages</i>
5. How many <b>new</b> Product Hold/Discontinuation Log pages were completed for this visit?	<input type="text"/> <input type="text"/>	<i># of pages</i>
6. Did the female participant complete the CASI Behavioral Questionnaire (BEH)?	<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i> <i>OR</i> <input type="checkbox"/> <i>not required</i>	
7. Time during visit of study product insertion:	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<i>24-hour clock</i> <i>OR</i> <input type="checkbox"/> <i>not required</i>
8. Did the couple complete coitus?	<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i> <input type="checkbox"/> <i>not required</i>	<i>If no or not required, go to instructions above item 9.</i>
8a. Time of completion of coitus:	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<i>24-hour clock</i>
<b>Complete item 9 for Group 1 participants only, and only at Visit Code 09.0. For all other visits, leave item 9 blank.</b>		
9. Time of post-coital study product insertion:	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<i>24-hour clock</i> <i>OR</i> <input type="checkbox"/> <i>not inserted</i>

<b>Visit Summary (VS-1)</b>	
<b>Purpose:</b>	This form is used to document completion of all Follow-up Visits (required and interim) completed by female participants once enrolled.
<b>Item-specific Instructions:</b>	
<b>Item 1:</b>	If the participant is unable to recall the complete date, obtain participant's best estimate. At a minimum, the month and year are required. Only record dates of menstrual period bleeding. Do not record dates of episodes of expected breakthrough bleeding experienced while a participant is on Depo, Mirena, or other continuous contraceptive method where a woman does not experience a monthly menstrual period.
<b>Item 4:</b>	Record in item 4 how many new AE Log pages were completed for the female participant at this visit. For example, if two new AEs were reported, record "02." Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
<b>Item 5:</b>	Record how many new Product Hold/Discontinuation Log pages were completed for this visit. For example, if two new product holds/discontinuations were reported, record "02." Note that the Visit Code recorded in item 1 of the Product Hold/Discontinuation Log pages should be the same as the Visit Code recorded on this form.
<b>Items 8 and 8a:</b>	Completion of coitus is defined as when the male partner ejaculates into the female partner's vagina.
<b>Item 9:</b>	When recording time, use a 24-hour clock (e.g., 8:12pm is recorded as 20:12).



Visit Code

1

MTN-011 (135)

PE-1 (138)

Page 1 of 1

Participant ID

-  -  - 0  
 Protocol PTID Chk Cohort

Pelvic Exam

Exam Date

dd MMM yy

1. Pelvic exam assessment:  *not done*  *abnormal findings*  *no abnormal findings* → *If no abnormal findings, go to item 2.*  
 ↘ *If not done, end of form.*

1a. Abnormal findings. Mark all that apply.

VULVAR	VAGINAL	CERVICAL	GENERAL/OTHER
<input type="checkbox"/> vulvar edema <input type="checkbox"/> vulvar erythema <input type="checkbox"/> vulvar rash <input type="checkbox"/> vulvar tenderness <input type="checkbox"/> Bartholin's or Skene's gland abnormality <u>Vulvar lesions</u> <input type="checkbox"/> ulcer <input type="checkbox"/> blister <input type="checkbox"/> pustule <input type="checkbox"/> peeling <input type="checkbox"/> ecchymosis	<input type="checkbox"/> vaginal edema <input type="checkbox"/> vaginal erythema <input type="checkbox"/> vaginal masses (polyps, myomas, possible malignancy) <input type="checkbox"/> vaginal abrasions or lacerations <input type="checkbox"/> vaginal tenderness <u>Abnormal vaginal discharge</u> <input type="checkbox"/> slight <input type="checkbox"/> moderate <input type="checkbox"/> pooling <u>Vaginal lesions</u> <input type="checkbox"/> ulcer <input type="checkbox"/> blister <input type="checkbox"/> pustule <input type="checkbox"/> peeling <input type="checkbox"/> ecchymosis	<input type="checkbox"/> cervical edema and/or friability <input type="checkbox"/> cervical erythema <input type="checkbox"/> cervical masses (polyps, myomas, possible malignancy) <input type="checkbox"/> cervical motion tenderness <input type="checkbox"/> cervical discharge <u>Cervical lesions</u> <input type="checkbox"/> ulcer <input type="checkbox"/> blister <input type="checkbox"/> pustule <input type="checkbox"/> peeling <input type="checkbox"/> ecchymosis	<input type="checkbox"/> odor (vaginal) <input type="checkbox"/> condyloma, specify location: _____ <input type="checkbox"/> adnexal masses (based on bimanual exam; not pregnancy or infection-related) <input type="checkbox"/> uterine masses (based on bimanual exam) <input type="checkbox"/> uterine tenderness <input type="checkbox"/> adnexal tenderness <input type="checkbox"/> observed blood or bleeding; describe: _____ _____ _____ _____

1b. Other abnormal findings, specify (include anatomical location): \_\_\_\_\_

*Complete or update Pre-existing Conditions or Adverse Experience Log as applicable.*

2. Were any new pelvic finding AEs reported at this visit?

yes  no  → *If no, go to item 3.*

2a. AE Log page (#)s:

3. Cervical ectopy:  0%  1-25%  26-50%  51-75%  76-100%

<b>Pelvic Exam (PE-1)</b>	
<b>Purpose:</b>	This form is used to document the participant's required pelvic exam assessments.
<b>General Information/Instructions:</b>	Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to SCHARP DataFax.
<b>Item-specific Instructions:</b>	
<b>Item 1:</b>	Note that observation of any genital blood or bleeding is considered an abnormal finding, regardless of whether the blood is expected (menstrual blood, for example). If blood or bleeding is observed, mark the "abnormal findings" box and in item 1a, mark the "observed blood or bleeding; describe" box and describe on the lines provided.
<b>Item 1a:</b>	<p>Mark the box to the left of each abnormal finding observed. If an observed abnormal finding is not listed, mark the "other abnormal findings, specify" box and describe the abnormal finding on the line provided, including anatomical location. In general, for abnormal findings reported as adverse events on an AE Log, use text from item 1a as AE descriptive text finding (this does not apply to observations of blood or bleeding).</p> <p><b>Observed blood or bleeding; describe:</b> If blood or bleeding is observed, mark this item and in the space provided, briefly describe the color, amount, and location of the blood/bleeding. If known, specify if the blood was menstrual or non-menstrual. Assess the blood/bleeding for AE reporting purposes. Per Study-specific Procedures (SSP) manual section 10.6, all bleeding occurring during follow-up that is different from the participant's baseline bleeding pattern is an AE. This may include unusually heavy or prolonged menses, as well as non-menstrual bleeding different from baseline.</p> <p>Each instance of observed blood/bleeding should be assessed for severity grade per the applicable rows of the <i>Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Addendum 1: Female Genital Grading Table for Use in Microbicide Studies (FGGT)</i>. Refer to SSP manual section 10.6 for more information/guidance as needed.</p>



MTN-011 (135)

PX-1 (036)

Visit Code

Participant ID

-  -  -   
 Protocol PTID Chk Cohort

Physical Exam

Visit Date

*dd MMM yy*

VITAL SIGNS				
1. Weight	<input type="text"/> <input type="text"/> <input type="text"/> kg	OR	<input type="text"/>	<i>not done</i>
2. Body Temp	<input type="text"/> <input type="text"/> . <input type="text"/> °C			
3. BP	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> mmHg			
4. Pulse	<input type="text"/> <input type="text"/> <input type="text"/>			<i>beats per minute</i>
5. Respirations	<input type="text"/> <input type="text"/>			<i>breaths per minute</i>
6. Height	<input type="text"/> <input type="text"/> <input type="text"/> cm	OR	<input type="text"/>	<i>not done</i>
FINDINGS				
	<i>not done</i>	<i>normal</i>	<i>abnormal</i>	<i>Notes:</i>
7. General appearance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
8. Genitourinary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
9. Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
10. Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
11. Heart/ Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
12. Lungs/ Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
13. Extremities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
14. Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
15. Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
16. Eyes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
17. Ears, Nose, Throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
18. Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

Record abnormal findings on Pre-existing Conditions form or Adverse Experience Log, as applicable.

<b>Physical Exam (PX-1)</b>	
<b>Purpose:</b>	This form is used to document the female participant's vital signs and physical exam findings during screening, enrollment, and follow-up.
<b>General Information/ Instructions:</b>	If abnormal findings are found in items 7–18 transcribe information onto the Pre-existing Conditions form or Adverse Experience Log form, as applicable.
<b>Item-specific Instructions:</b>	
<b>Vital Signs:</b>	Use leading zeros when needed.
<b>Items 7–17:</b>	For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings on the Notes line. If not evaluated, mark the “not done” box.
<b>Item 18:</b>	If no other abnormal findings are identified, mark the “normal” box. If abnormal, specify the body system being referenced and describe the findings on the Notes line.



MTN-011 (135)

STI-1 (190)

Visit Code

Participant ID

-  -  - 0

Protocol PTID Chk Cohort

STI Test Results

Initial Specimen Collection Date

dd MMM yy

1. Vaginal Wet Prep	Not done/Not collected	Alternate Collection Date				
	<input type="checkbox"/>	dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
	negative	positive				
<input type="checkbox"/> 1a. Homogeneous vaginal discharge	<input type="checkbox"/>	<input type="checkbox"/>				
Not done		Alternate Collection Date				
<input type="checkbox"/> 1b. pH <input type="text"/> <input type="text"/>		dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
	negative	positive				
<input type="checkbox"/> 1c. Whiff test	<input type="checkbox"/>	<input type="checkbox"/>				
Not done		Alternate Collection Date				
<input type="checkbox"/> 1d. Clue cells $\geq$ 20%		dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
	negative	positive				
Not done		Alternate Collection Date				
<input type="checkbox"/> 1e. <i>Trichomonas vaginalis</i>		dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
	negative	positive				
Not done		Alternate Collection Date				
<input type="checkbox"/> 1f. Buds and/or hyphae (yeast)		dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
	negative	positive				
2. Trichomonas Rapid Test	Not done/Not collected	Alternate Collection Date				
	<input type="checkbox"/>	dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
	negative	positive				
3. <i>N. gonorrhoeae</i>	Not done/Not collected	Alternate Collection Date				
	<input type="checkbox"/>	dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
	negative	positive				
4. <i>C. trachomatis</i>	Not done/Not collected	Alternate Collection Date				
	<input type="checkbox"/>	dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
	negative	positive				
5. Pre-coital pH:	Not done	<input type="text"/> <input type="text"/>				
6. Post-coital pH:	Not done	<input type="text"/> <input type="text"/>				

Complete or update Pre-existing Conditions or Adverse Experience Log, as applicable.

Comments: \_\_\_\_\_

01-AUG-12

<b>STI Test Results (STI-1)</b>	
<b>Purpose:</b>	This form is used to document Vaginal Wet Prep and STI Test Results during screening, enrollment, and follow-up for female participants.
<b>General Information/ Instructions:</b>	<ul style="list-style-type: none"> <li>• <b>Initial Specimen Collection Date:</b> Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form). A complete date is required.</li> <li>• <b>Alternate Collection Date:</b> This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. A complete date is required.</li> <li>• <b>Not done/Not collected:</b> Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available on the Comments lines.</li> </ul>
<b>Item-specific Instructions:</b>	
<b>Items 1–4:</b>	If a test result(s) recorded on this form indicates that the participant has a new (or increased severity) laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as an adverse experience on an Adverse Experience (AE) Log.
<b>Item 1:</b>	If a vaginal wet prep was performed but not all assays were completed, mark the “Not done/Not collected” box for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason on the Comments lines.
<b>Item 1a:</b>	Mark the “positive” box if homogeneous vaginal discharge was observed.
<b>Item 1d:</b>	Mark the “positive” box if 20% or more of the cells were clue cells.
<b>Item 1e:</b>	Mark the “positive” box if trichomonads were observed.
<b>Item 1f:</b>	Mark the “positive” box if yeast buds and/or hyphae were observed.
<b>Item 5:</b>	Record the result of the pre-coital vaginal fluid pH.
<b>Item 6:</b>	Record the result of the post-coital vaginal fluid pH.



Visit Code

1

MTN-011 (135)

PK-1 (061)

Participant ID  
 -  -  - 0  
Protocol PTID Chk Cohort

Pharmacokinetics

Specimen Collection Date  
    
dd MMM yy

Not done/ Not collected  
 1. Participant height  cm  
 2. Participant weight  kg

SPECIMEN COLLECTION TIMES

Not done/ Not collected  
 3. Cervicovaginal lavage  hr :  min 24-hour clock  
↓  
Go to item 4.  
3a. Supernatant  stored  not stored Reason not stored: \_\_\_\_\_  
3b. Cell pellet  stored  not stored Reason not stored: \_\_\_\_\_

4. Vaginal tissue biopsy  hr :  min 24-hour clock

5. Cervical tissue biopsy  hr :  min 24-hour clock

6. Cervical cytobrush  hr :  min 24-hour clock

7. Blood draw  hr :  min 24-hour clock

8. Rectal sponge  hr :  min 24-hour clock  
NO LONGER RECORDED ON THIS CRF. .  weight (grams)  
NO LONGER RECORDED ON THIS CRF. .  weight (grams)  
NO LONGER RECORDED ON THIS CRF. .  weight (grams)

BIOPSY WEIGHTS

PRE-COLLECTION Note: Weight includes empty cryovial and screw lid

Not done/ Not collected  
 9. Vaginal biopsy for PK: Pre-collection .  weight (mg)  
 10. Cervical biopsy for PK: Pre-collection .  weight (mg)  
**NO LONGER RECORDED ON THIS CRF.**

POST-COLLECTION Note: Weight includes cryovial, tissue biopsy, and screw lid

Not done/ Not collected  
 11. Vaginal biopsy for PK: Post-collection .  weight (mg)  
 12. Cervical biopsy for PK: Post-collection .  weight (mg)  
**NO LONGER RECORDED ON THIS CRF.**

Comments: \_\_\_\_\_

## Pharmacokinetics (PK-1)

**Purpose:** This form is used to document pharmacokinetics, stored specimen collection, as well as pre- and post-collection weights of vaginal tissue (biopsy) pharmacokinetic (PK) specimens for female participants.

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Specimen Collection Date:** Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form). A complete date is required.
- **Not done/Not collected:** Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage.

**Items 3a and 3b:** • These items must be completed after the lab has processed the primary specimen. If these specimens are not stored, mark the "not stored" box and record the reason why on the line provided.

**Items 3-8:** • When recording time, use a 24-hour clock (e.g., 8:12pm is recorded as 20:12).



MTN-011 (135)

SPA-1 (415)

Visit Code

Participant ID

-  -  -   
 Protocol PTID Chk Cohort

### Study Product Accountability

Form Completion Date

dd MMM yy

1. Was study product given to the participant for clinic and/or home use? *yes*  *no*  → *If no, go to item 2.*

1a. Date dispensed:     
 dd MMM yy

1b. Number of study product applicators dispensed at this visit: *1*  *2*  *7*  *8*  *other, specify:* \_\_\_\_\_

---

2. Was study product returned by the participant? *yes*  *no, specify:* \_\_\_\_\_ → *If no, end of form.*

2a. Date study product was returned by participant:     
 dd MMM yy

2b. Number of **used** applicators returned:  *used applicators returned*

2c. Number of **unused** applicators returned:  *unused applicators returned*

Comments: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

<b>Study Product Accountability (SPA-1)</b>	
<b>Purpose:</b>	This form is used to document all study product dispensation, and used and unused product returns.
<b>General Information/ Instructions:</b>	This form should be completed at each visit when product is dispensed.
<b>Item-specific Instructions:</b>	
<b>Item 1b:</b>	Mark the box corresponding to the total number of applicators dispensed at this visit. For example, for Group 2 female participants at Visit 6 (26.0), the "8" box should be marked (1 applicator for clinic use, 6 applicators for home use, 1 applicator extra).
<b>Item 2:</b>	This item must be completed when participant returns product from the previous dispensation. For some visits, dispensation and returns will occur on the same day (e.g., Group 1, Visits 3a and 3b; Group 2, Visits 3a and 3b). For other visits, product returns will be several days after dispensation (e.g., Group 1, Visits 6a and 6b; Group 2, Visits 2 and 3a). Always record product returns on the SPA-1 form which documents that dispensation. If study product was not returned, record the reason on the line provided.
<b>Item 2a:</b>	Record the exact day, month, and year study product was returned by the participant.

Not a DataFax form. Do not fax to DataFax.

MTN-011 (135)

Page 1 of 1

Participant ID

-  -

Protocol      PTID      Chk      Cohort

Exam Date

/    /

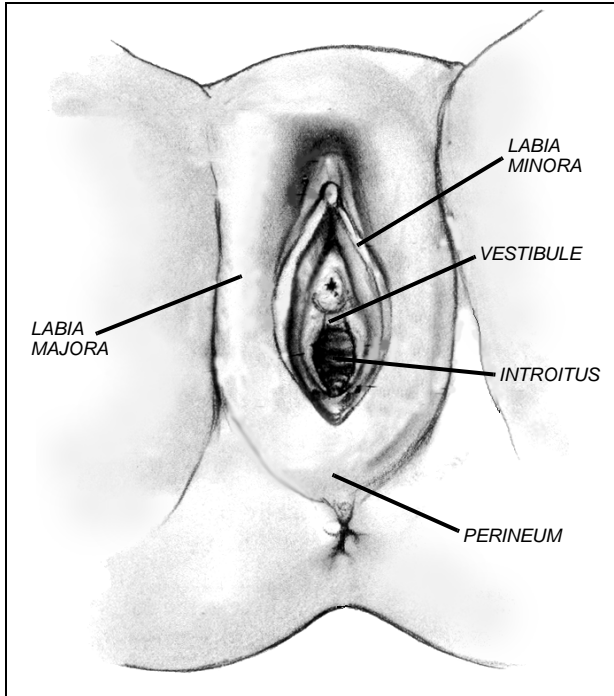
dd      MMM      yy

Pelvic Exam Diagrams

no normal variants or abnormal findings observed

Speculum Type (screening only)			Speculum Size (screening only)		
Pederson	Graves	Cusco	small	medium	large
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

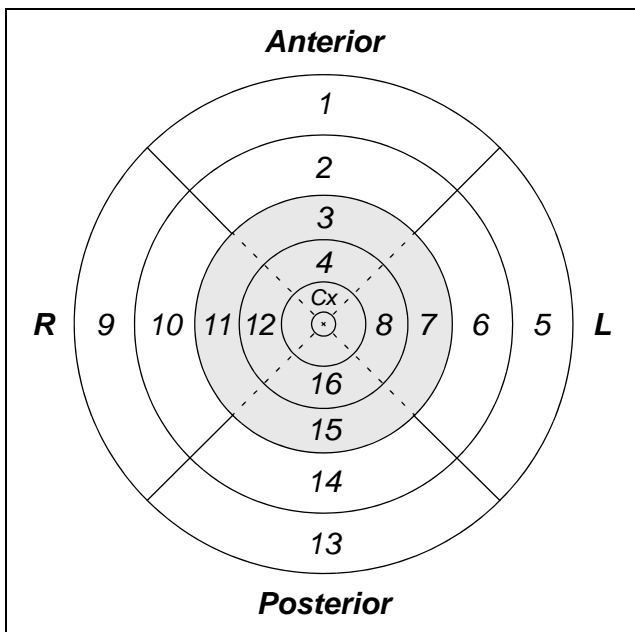
External Genitalia



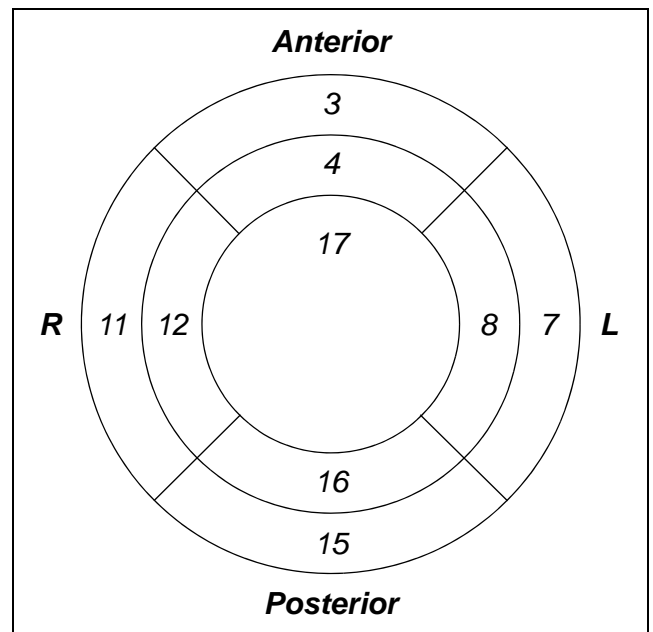
Legend for Vagina/Cervix

1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina, proximal half
11. Right lateral fornix
12. Cervical trunk, right lateral
13. Posterior vagina, distal half
14. Posterior vagina, proximal half
15. Posterior fornix
16. Cervical trunk, post
17. Cervical face

Vagina



Cervix



01-AUG-12

English

Staff Initials / Date

<b>Pelvic Exam Diagrams (non-DataFax)</b>	
<b>Purpose:</b>	This form is used to document all variants of normal and all abnormal findings observed during study pelvic exams (screening through termination/study exit).
<b>General Information/ Instructions:</b>	This form is completed with each required pelvic exam, and whenever a pelvic exam is clinically indicated during the study. This is a non-DataFax form and should not be faxed to SCHARP DataFax. Transcribe information onto the appropriate Pelvic Exam DataFax form for submission to DataFax and store this form in the participant's chart notes.
<b>Item-specific Instructions:</b>	
<b>Findings:</b>	<p>All variants of normal (normal findings) and all abnormal findings must be documented on this form. Variants of normal need only be recorded on this form, and not on any of the Pelvic Exam DataFax forms. The following findings are considered normal variants:</p> <ul style="list-style-type: none"> <li>• anatomic variants</li> <li>• gland openings</li> <li>• Nabothian cysts</li> <li>• mucus retention cysts</li> <li>• Gartner's duct cysts</li> <li>• blood vessel changes other than disruption</li> <li>• skin tags</li> <li>• scars</li> </ul> <p>If there are no variants of normal or abnormal findings observed mark the "no normal variants or abnormal findings observed" box.</p>
<b>Documenting findings on the cervix:</b>	If helpful, draw the os in the center of the diagram labeled "Cervix" (lower right corner).