Enrollment Visit
Visit 02.0

Required Forms

- Enrollment (ENR-1)
- Physical Exam (PX-1)
- Pelvic Exam (PE-1)
- Pharmacokinetics Specimens - Enrollment (PKS-1)
- Safety Laboratory Results (SLR-1, 2)
- Specimen Storage (SS-1)
- Pelvic Exam Diagrams (Non-DataFax)

(MTN 027) DF/Net 027 ENR (070)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number *Participant Number* *Chk*

Enrollment

1. Date the participant marked or signed the consent form for study participation: dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]

2. Did the participant consent to:

   2a. long-term specimen storage and future testing? *yes* ☐ *no* ☐

   2b. participate in Extra Samples Group (rectal fluid for PK collection)? *yes* ☐ *no* ☐

3. Plasma for archive: Collection Date dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ] *stored* ☐ *not stored* ☐ → *Reason:* _____

4. Randomization number assigned: [ ][ ][ ]

5. Randomization date and time: dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ] hr [ ][ ] : min [ ][ ] *24-hr clock*

6. Date and time vaginal ring inserted: dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ] hr [ ][ ] : min [ ][ ] *24-hr clock*

7. Was a Baseline CASI questionnaire completed at this visit? *yes* ☐ *no* ☐

8. Were there any problems or QC issues related to the administration or completion of the CASI questionnaire? *yes* ☐ *no* ☐ → *If no, end of form.*

   8a. Describe: _____

_____
Staff Initials/Date

Purpose:

This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for the randomized participant.

General Instructions:

Fax this form to DF/Net only if the participant is enrolled (that is, if she has been randomized).

Item-specific Instructions:

Item 2	Consent for long-term specimen storage or participation in the PK Subset can be changed if the participant changes her consent decision after enrollment. Update as needed if the participant changes her consent during the study.
Item 3	If the specimen for some reason is not stored, mark "not stored" and record the reason on the line provided.
Item 4	This item must match the randomization number provided within the randomization assignment confirmation email from FSTRF web-based system.
Item 5	These items must match the 'date assigned' and 'time assigned' recorded for this randomized participant within the randomization assignment confirmation email from the FSTRF web-based system.
Items 7–8	The Baseline CASI questionnaire is required at the Enrollment Visit. If it was not done, mark item 8 "yes" and provide a brief explanation in item 8a.

(MTN 027) DF/Net 027 PX (036)

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐
Site Number *Participant Number* *Chk*

Visit Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

Physical Exam

Vital Signs

Not Required ☐

1	Height: ☐☐☐ *cm*	☐	**4**	BP: ☐☐☐ / ☐☐☐	*mmHg*
2	Weight: ☐☐☐	*kg*	**5**	Pulse: ☐☐☐	*beats per minute*
3	Body Temp: ☐☐.☐	*°C*	**6**	Respirations: ☐☐	*breaths per minute*

FINDINGS:
Items 8–16 may be omitted after Enrollment.

		Not Done	Normal	Abnormal	*Notes*
7	General appearance	☐	☐	☐	
8	Abdomen/Gastrointestinal	☐	☐	☐	
9	Head, eye, ear, nose, and throat	☐	☐	☐	
10	Neck	☐	☐	☐	
11	Lymph Nodes	☐	☐	☐	
12	Heart/Cardiovascular	☐	☐	☐	
13	Lungs/Respiratory	☐	☐	☐	
14	Extremities	☐	☐	☐	
15	Neurological	☐	☐	☐	
16	Skin	☐	☐	☐	
17	Other	☐	☐	☐	

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

Comments: _____

_____
Staff Initials/Date

Purpose:

This form is used to document the participant's vital signs and physical exam findings.

General Instructions:

Complete this form at the Screening, Enrollment, and all follow-up study visits. If abnormal findings are found, for items 7–17, transcribe the information onto the Pre-existing Conditions or Adverse Experience form(s).

Item-specific Instructions:

Vital Signs	Use leading zeros as applicable.
Item 1	This item is required at Screening and Enrollment only.
Items 7–16	For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings in Notes. If not evaluated, mark "not done" and record the reason in Notes. Normal findings may also be described in Notes, but is not required.
Item 17	If no other abnormal findings are identified, mark "not done."

(MTN 027) DF/Net 027 PE (138)

Visit Code ☐☐.☐

Participant ID ☐☐☐-☐☐☐☐☐-☐ (*Site Number* – *Participant Number* – *Chk*)

Visit Date ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

Pelvic Exam

1 Vaginal pH: ☐ *Not done* ☐.☐ *If > 4.5, mark Positive* → ☐ *Positive*

2 Pelvic exam assessment: ☐ *Not done* → *End of form.* ☐ *Abnormal findings* ☐ *No abnormal findings* → *End of form.*

2a. Abnormal findings. *Mark all that apply.*

VULVAR	VAGINAL	CERVICAL	GENERAL/OTHER
☐ *Vulvar edema*	☐ *Vaginal edema*	☐ *Cervical edema and/or friability*	☐ *Odor (vaginal)*
☐ *Vulvar erythema*	☐ *Vaginal erythema*	☐ *Cervical erythema*	☐ *Condyloma, specify location:*
☐ *Vulvar rash*	☐ *Vaginal masses (polyps, myomas, possible malignancy)*	☐ *Cervical masses (polyps, myomas, possible malignancy)*	_____
☐ *Vulvar tenderness*	☐ *Vaginal abrasions or lacerations*	☐ *Cervical motion tenderness*	☐ *Adnexal masses (based on bimanual exam; not pregnancy or infection-related)*
☐ *Bartholin's or Skene's gland abnormality*	☐ *Vaginal tenderness*	☐ *Cervical discharge*	☐ *Uterine masses (based on bimanual exam)*
	☐ *Abnormal vaginal discharge* → *slight* ☐ *moderate* ☐ *pooling* ☐		☐ *Uterine tenderness*
			☐ *Adnexal tenderness*
Vulvar lesions	**Vaginal lesions**	**Cervical lesions**	☐ *Observed blood or bleeding, describe:*
☐ *Ulcer*	☐ *Ulcer*	☐ *Ulcer*	_____
☐ *Blister*	☐ *Blister*	☐ *Blister*	_____
☐ *Pustule*	☐ *Pustule*	☐ *Pustule*	_____
☐ *Peeling*	☐ *Peeling*	☐ *Peeling*	_____
☐ *Ecchymosis*	☐ *Ecchymosis*	☐ *Ecchymosis*	

☐ 2b. Other abnormal findings, specify (include anatomical location): _____

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

3 Are any new pelvic finding AEs reported at this visit? ☐ *Yes* ☐ *No* → *End of form.*

3a. AE Log page #(s): *Line through any unused boxes.*

☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

_____
Staff Initials/Date

Purpose:

This form is used to document the participant's pelvic exam assessment.

General Instructions:

Complete this form at Screening, Enrollment, at all follow-up study visits, and early termination visit (as applicable), and when a clinically indicated pelvic exam is performed during interim visits. Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to DataFax.

Item-specific Instructions:

Item 1	Vaginal fluid pH is required at Enrollment Visit, Day 3, Day 28, Day 29, Day 30, Day 31, and Day 35/Final Clinic Visit.
Item 2	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 "abnormal findings" and in item 2a, mark "observed blood or bleeding; describe" and describe on the lines provided.
Item 2a	• Mark the box to the left of each abnormal finding observed. In general, for abnormal findings reported as adverse events on an AE Log, use text from item 2a as AE descriptive text finding (this does not apply to observances of blood or bleeding). • **Observed blood or bleeding; describe:** 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. Please refer to Study-specific Procedures (SSP) manual section section 8 for AE reporting guidance for observed bleeding. • Each instance of observed blood/bleeding should be assessed for severity grade per the applicable rows of the *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)*. Refer to SSP manual section 8 for more information/guidance as needed.
Item 2b	If an observed abnormal finding is not listed, mark "other abnormal findings, specify" and describe the abnormal finding on the line provided, including anatomical location.

(MTN 027) DF/Net 027 PKS (162)

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐ (*Site Number* – *Participant Number* – *Chk*)

Specimen Collection Date ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

Pharmacokinetics Specimens—Enrollment

1. Last menstrual period: ☐ *None*
   Start Date ☐☐ (dd) ☐☐☐ (MMM) ☐☐ (yy)
   Stop Date ☐☐ (dd) ☐☐☐ (MMM) ☐☐ (yy)
   ongoing OR ☐

Not done/ Not collected	Specimen	*Stored*	*Not Stored*	*If not stored, specify:*	Was blood visible on swab?
	Blood				
	This row left intentionally blank.				
☐	3. 1-hour blood draw:	☐	☐		
☐	4. 2-hour blood draw:	☐	☐		
☐	5. 4-hour blood draw:	☐	☐		
☐	6. 6-hour blood draw:	☐	☐		
	Vaginal Fluid	*Stored*	*Not Stored*	*If not stored, specify:*	Was blood visible on swab?
☐	7. 0-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
☐	8. 1-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
☐	9. 2-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
☐	10. 4-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
☐	11. 6-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
	Other				
☐	12. Rectal fluid for PK:	☐	☐		

Comments:

_____
Staff Initials/Date

Purpose:

This form is used to document collection and timing of collection of pharmacokinetic (PK) laboratory specimens.

General Instructions:

Complete this form at the Enrollment visit.

Item-specific Instructions:

Item 1	If the participant has not had a period within the last 30 days, mark “none.”
Not done/ Not collected	Mark this box in the event that a specimen was not collected or not required.
Stored/ Not Stored	Mark “stored” for specimens that are collected and sent to the lab for processing. If specimens are not storedby the lab, mark “not stored” and record the reason why on the line provided.

(MTN 027) DF/Net 027 SLR-1 (144)

Visit Code ☐☐.☐

Participant ID ☐☐☐-☐☐☐☐☐-☐ (*Site Number* – *Participant Number* – *Chk*)

Initial Specimen Collection Date ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

Safety Laboratory Results

	Not done/ Not collected	Alternate Collection Date (dd MMM yy)	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
1. HEMOGRAM	☐ → *Go to item 2.*	☐☐ ☐☐☐ ☐☐			
1a. Hemoglobin	Not reported ☐	☐☐.☐ *g/dL*	☐	☐☐☐	OR ☐
1b. Hematocrit	☐	☐☐.☐ *%*			
1c. MCV	☐	☐☐☐.☐ *fL*			
1d. Platelets	☐	☐☐☐☐.☐ *x10^3/mm^3*	☐	☐☐☐	OR ☐
1e. WBC	☐	☐☐☐.☐ *x10^3/mm^3*	☐	☐☐☐	OR ☐

	Not done	Absolute Count *cells/mm3*	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
DIFFERENTIAL	☐ → *Go to item 2.*				
1f. Neutrophils	Not reported ☐	☐☐☐☐☐	☐	☐☐☐	OR ☐
1g. Lymphocytes	☐	☐☐☐☐	☐	☐☐☐	OR ☐
1h. Monocytes	☐	☐☐☐☐			
1i. Eosinophils	☐	☐☐☐☐			
1j. Basophils	☐	☐☐☐☐			

Staff Initials/Date _____

Purpose:

This form is used to provide data on the participant's baseline and follow-up laboratory test results.

General Instructions:

Use this form to report the hematology, differential, and liver and renal function test results as they become available. Do not fax the form to DF/Net until all results are available and the participant has enrolled in the study.

Item-specific Instructions:

Initial Specimen Collection Date	Record the date that the first specimen was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date	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.
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. Record the reason why the result is not available in Comments on page 2.
Visit Code	Record the visit code assigned to this visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
Repeat Testing	If any or all of the lab tests listed on this form are repeated (re-drawn) between the Screening and Enrollment Visit, document the repeated results on the same SLR form assigned Visit Code 1.0. Line through the original result(s), record the new result(s) and the Alternate Collection Date for each repeat test result.
Results Reporting	• Results should be documented on the form using the units present on the source laboratory results document. If the units present on the form do not match your source results report, contact the MTN-027 Management Team. Note that the following units are equivalent: IU/L = U/L, I/I x 100 = %, 10^9/L = 10^3/mm^3 = 10^3/μL For creatinine, only record the result in the units listed on the source document. • If the site lab does not report results to the same level of precision allowed on the form, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the form. For example, a lab-reported hemoglobin value of 11.05 g/dL would be recorded as 11.1 g/dL. A lab-reported hemoglobin value of 11.04 g/dL would be recorded as 11.0 g/dL. • If the site lab does not produce test results in the units used on this form, first perform the conversion, then round the converted result if necessary.

Severity Grade	• If any values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the result. If value is below Grade 1, leave the severity grade box blank.
	• Always compare the severity grade range to the value that was recorded on the form (not thelab-reported value).
	• When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.
	  • Treat all missing digits in the lab value as zeros.
	  • If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
	  • At Screening/Enrollment, record any Grade 1 or higher lab values on the Pre-existing Conditions form.

(MTN 027) DF/Net 027 SLR-2 (145)

Visit Code ____ . ____

Participant ID

___ – _____ – ___

Site Number *Participant Number* *Chk*

Safety Laboratory Results

Alternate Collection Date

2. SERUM CHEMISTRIES — Not done/ Not collected ☐ → *Go to item 3.* — dd ___ MMM ___ yy ___

	Not reported		Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
2a. AST (SGOT)	☐	____ *U/L*	☐	____	OR ☐
2b. ALT (SGPT)	☐	____ *U/L*	☐	____	OR ☐
2c. Creatinine	☐	___ . ___ *mg/dL*	☐	____	OR ☐
2c1. Calculated creatinine clearance		____ *mL/min*			

Alternate Collection Date

3. DIPSTICK URINALYSIS TESTS — Not done/ Not collected ☐ → *End of form.* — dd ___ MMM ___ yy ___

	Not done	*negative*	*positive*
3a. Leukocyte esterase (LE)	☐	☐	☐
3b. Nitrites	☐	☐	☐

	negative	*trace*	*1+*	*2+*	*3+*	*4+*	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
3c. Protein	☐	☐	☐	☐	☐	☐	☐	____	OR ☐
3d. Glucose	☐	☐	☐	☐	☐	☐	☐	____	OR ☐

Comments: _____

_____

_____

Version 2.0, 01-MAY-15

_____
Staff Initials/Date

Purpose:

This form is used to provide data on the participant's baseline and follow-up laboratory test results.

General Instructions:

Use this form to report the hematology, differential, and liver and renal function test results as they become available.

Do not fax the form to DF/Net until all results are available and the participant has enrolled in the study.

Item-specific Instructions:

Alternate Collection Date	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.
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. Record the reason why the result is not available in Comments on page 2.
Visit Code	Record the visit code assigned to this visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
Repeat Testing	If any or all of the lab tests listed on this form are repeated (re-drawn) between the Screening and Enrollment Visit, document the repeated results on the same SLR form assigned Visit Code 1.0. Line through the original result(s), record the new result(s) and the Alternate Collection Date for each repeat test result.
Item 2c1	When calculating the participant's creatinine clearance use the age and weight of the participant at the time the blood specimen is drawn. If the participant was not weighed at the visit when the blood specimen was drawn, but was weighed at a previous visit (within the allowable window for creatinine clearance per the SSP Manual), record the weight from the previous visit. Also, record in the "Alternative Collection Date" boxes the date of the previous visit when the participant was weighed. If the participant has a creatinine value but cannot have her creatinine clearance calculated (due to missing weight data), line through the response boxes and initial and date.
Item 3	If a dipstick urinalysis was done, but a given result was not reported, mark the "not done" box.
Items 3a-3b	If the result is negative or trace, mark the 'negative' box. If the result is 1+ or greater, mark the 'positive' box.
Item 3d	Grade the severity of the urine glucose value according to the "Proteinuria, random collection" row of the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events.*

(MTN 027) DF/Net 027 SS (149)

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐
Site Number *Participant Number* *Chk*

Initial Specimen Collection Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

Specimen Storage

Not done/ Not collected ☐ 1. Vaginal smear for gram stain

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐ *stored* ☐ *not stored* ☐

Reason not stored _____

Not done/ Not collected ☐ 2. Quantitative vaginal culture

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐ *stored* ☐ *not stored* ☐

Reason not stored _____

Not done/ Not collected ☐ 3. Vaginal swab for biomarkers:

3a. Was blood visible on the swab? *yes* ☐ *no* ☐

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐ *stored* ☐ *not stored* ☐

Reason not stored _____

Not done/ Not collected ☐ 4. Cervical cytobrush

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐ *stored* ☐ *not stored* ☐

Reason not stored _____

Not done/ Not collected ☐ 5. Used vaginal ring

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐

Collection Time *(24-hour clock)* *hh* ☐☐ : *mm* ☐☐ *stored* ☐ *not stored* ☐

Reason not stored _____

Comments: _____

_____

_____

_____
Staff Initials/Date

Purpose:

This form is used to document collection and storage of vaginal and cervical specimens by the local site laboratory.

General Instructions:

Complete this form at Enrollment, Day 3, Day 28 and Day 35/Final Clinic Visit, as applicable.

Item-specific Instructions:

Visit Code	Record the visit code assigned to this visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
Initial Specimen Collection Date	Record the date that the first specimen was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date	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.
Not done/ Not collected	Mark this box in the event that a specimen was not collected.
Stored/ Not Stored	Mark “stored” for specimens that are collected and sent to the lab for processing. If specimens are not stored by the lab, mark “not stored” and record the reason why on the line provided.

(MTN 027) DF/Net 027

Participant ID

			–					–	

Site Number *Participant Number* *Chk*

Exam Date

dd *MMM* *yy*

☐ no normal variants or abnormal findings observed

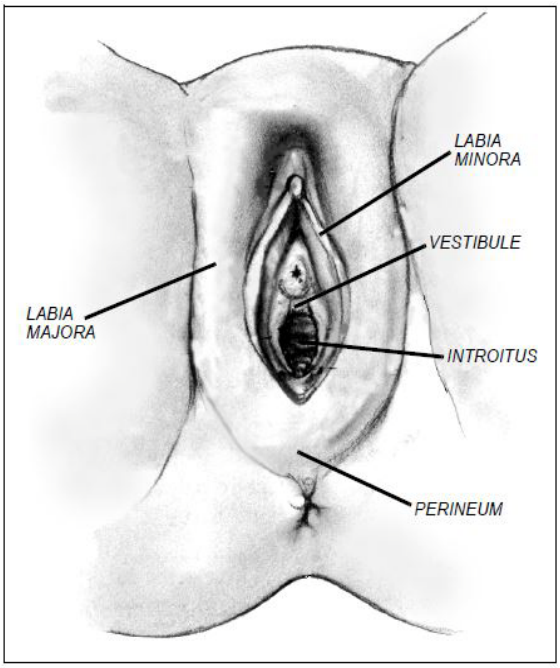
Speculum Type (screening only)

Pederson ☐ *Graves* ☐ *Cusco* ☐

Speculum Size (screening only)

small ☐ *medium* ☐ *large* ☐

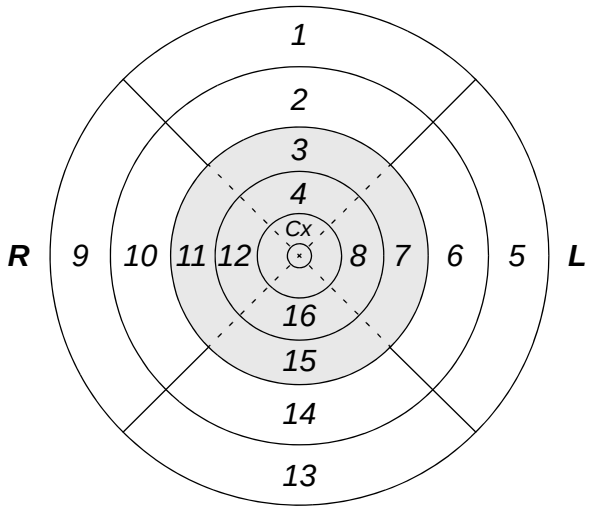
External Genitalia



Legend for Vagina/Cervix

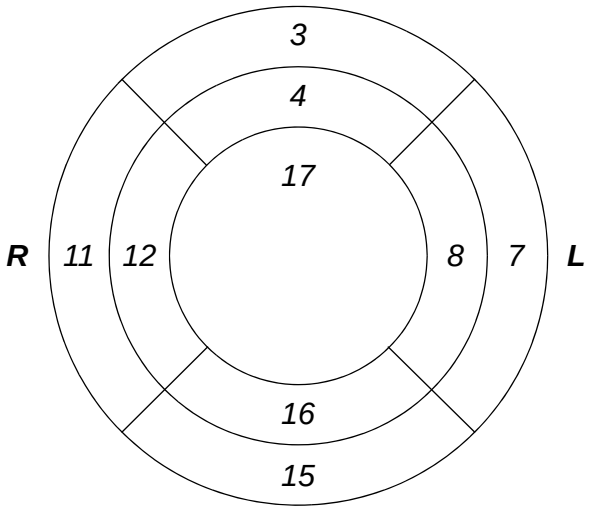
1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina, 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: Anterior



Posterior

Cervix: Anterior



Posterior

Version 1.0, 01-APR-15

Staff Initials/Date

Purpose:

This form is used to document all variants of normal and all abnormal findings observed during study pelvic exams (screening through termination/study exit).

General Instructions:

This form is completed at the Screening Visit, the Enrollment Visit, at all scheduled study visits, and whenever a pelvic exam is clinically indicated during the study. This is a non-DataFax form and should not be faxed to DF/Net DataFax. Transcribe information onto the appropriate Pelvic Exam DataFax form for submission to DataFax and store this form in the participant's chart notes..

Item-specific Instructions:

Findings	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: • anatomic variants • gland openings • Nabothian cysts • mucus retention cysts • Gartner's duct cysts • blood vessel changes other than disruption • skin tags • scars • cervical ectopy If there are no variants of normal or abnormal findings observed mark the "no normal variants or abnormal findings observed" box.
Documenting findings on the cervix:	If helpful, draw the os in the center of the diagram labeled "Cervix" (lower right corner).