

Participant ID:		Visit Code:		Specimen Collection Date:		
[] [] []	-	[] [] [] [] [] []	-	[]	[] []	[]
Site Number		Participant Number		Chk	dd	MMM
[]	Blood (BLD) <i>plasma archive</i>	EDT <small>(purple top)</small>	PL1/2	N/A	<ul style="list-style-type: none"> Prepare as many 1.5 mL aliquots as possible with a total volume of aliquots ≥ to 3ml. If sample is collected and held at room temp, freeze within 4 hours. If refrigerated after collection, freeze within 24 hours. 	
[]	Blood (BLD) <i>PK single time-point</i>	EDT <small>(purple top)</small>	PL1/2	N/A	Complete for Visit days: 1,2, 3, 7, 14, 21, 29, 30, 31 & 35 <ul style="list-style-type: none"> Centrifuge, split, and label two or more cryovials with a minimum of 1.5 mL of plasma in each cryovial. Freeze within 8 hours of blood collection. 	
[]	Cervical tissue biopsy (CVB) <i>for PK</i>	NON	BPS	N/A	<ul style="list-style-type: none"> Collect 1 biopsy and place in a 2 mL cryovial, immediately freeze, and store at ≤ -70°C. Deliver to lab on dry ice. 	
[]	Cervical tissue biopsy (CVB) <i>For PD Pitt Only</i>	BTM	BPS	N/A	<ul style="list-style-type: none"> Place biopsy into a 2 mL cryovial tube containing 1 mL of chilled transport medium. Transport to Dezzutti lab immediately! Do NOT freeze! 	

Comments: _____

Initials: _____ **LDMS Data Entry Date:** [] [] / [] [] [] [] [] [] / _____
Sending Staff Receiving Staff dd MMM yy LDMS Staff

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<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Site Number Participant Number Chk		dd MMM yy

# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB	INSTRUCTIONS FOR PROCESSING LAB												
<input style="width: 30px; height: 30px;" type="checkbox"/>	Cervical cytobrush (CER) <i>Flow Cytometry</i> Collection Time ___:___ hour : min	RPM	CTB	N/A	Pitt: <ul style="list-style-type: none"> Keep on ice and deliver to Laboratory ASAP to process within 2 hours from collection. UAB: <ul style="list-style-type: none"> Ship stained on ice overnight to LC 												
<input style="width: 30px; height: 30px;" type="checkbox"/>	Rectal Sponge for PK (REC) Collection Time ___:___ hour : min	NON	SPG	N/A	<ul style="list-style-type: none"> Perform pre & post weights. Put on ice immediately and freeze at ≤-70°C within 4 hours of collection. Enter net weight in LDMS <div style="text-align: right; margin-top: 10px;"> <table style="border: none;"> <tr> <td style="border: none;">_____</td> <td style="border: none;">-</td> <td style="border: none;">_____</td> <td style="border: none;">=</td> <td style="border: none;">_____</td> <td style="border: none;">mg</td> </tr> <tr> <td style="border: none;"><i>Post-weight</i></td> <td style="border: none;"></td> <td style="border: none;"><i>Pre-weight</i></td> <td style="border: none;"></td> <td style="border: none;"><i>Net weight</i></td> <td style="border: none;"></td> </tr> </table> </div>	_____	-	_____	=	_____	mg	<i>Post-weight</i>		<i>Pre-weight</i>		<i>Net weight</i>	
_____	-	_____	=	_____	mg												
<i>Post-weight</i>		<i>Pre-weight</i>		<i>Net weight</i>													
<input style="width: 30px; height: 30px;" type="checkbox"/>	Vaginal Swab (VAG) <i>For Biomarker</i> Collection Time ___:___ hour : min	PBS	SWB	N/A	<ul style="list-style-type: none"> Place Dacron swab in a 1.5 mL cryovial with 400 uL PBS, Freeze within 8 hours, and store at ≤ -70°C. 												
<input style="width: 30px; height: 30px;" type="checkbox"/>	Vaginal Smear (VAG) for Gram Stain	NON	SLD	GRS	<ul style="list-style-type: none"> Make 2 slides. Re-label with LDMS label. Ship one slide to MTN LC and store other slide on-site. 												
<input style="width: 30px; height: 30px;" type="checkbox"/>	Vaginal Culture (VAG)	PAC	SWB	N/A	<ul style="list-style-type: none"> Ship overnight on ice packs to MTN LC on the day of collection. 												

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# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB	INSTRUCTIONS FOR PROCESSING LAB
<input type="text"/>	Single Self-collected Vaginal Swab (VAG) for PK Collection Time ____:____ hour : min	NON	SWB	N/A	<ul style="list-style-type: none"> Freeze at $\leq -70^{\circ}\text{C}$ within 2 hours of collection. If frozen in clinic, transport to lab on dry ice. $\underline{\hspace{1cm}} - \underline{\hspace{1cm}} = \underline{\hspace{1cm}} \text{ mg}$ <p style="text-align: center;"><i>Post-weight Pre-weight Net weight</i></p>
<input type="text"/>	Triple Self-collected Vaginal Swab (VAG) for PK Pitt only Collection Time ____:____ hour : min	NON	SWB	N/A	First 8 Pitt participants on Visit days 1 & 7: <ul style="list-style-type: none"> Label (1, 2 & 3), pre & post weigh each tube + swab including shaft. Freeze at $\leq -70^{\circ}\text{C}$ within 2 hours of collection. If frozen in clinic, transport to lab on dry ice. 1: $\underline{\hspace{1cm}} - \underline{\hspace{1cm}} = \underline{\hspace{1cm}} \text{ mg}$ <i>Post-weight Pre-weight Net weight</i> 2: $\underline{\hspace{1cm}} - \underline{\hspace{1cm}} = \underline{\hspace{1cm}} \text{ mg}$ <i>Post-weight Pre-weight Net weight</i> 3: $\underline{\hspace{1cm}} - \underline{\hspace{1cm}} = \underline{\hspace{1cm}} \text{ mg}$ <i>Post-weight Pre-weight Net weight</i>
<input type="text"/>	Used Vaginal Ring (IVR) for residual PK	NON	IVR	N/A	<ul style="list-style-type: none"> Rinse (in a cup) and blot dry used ring. Place into a labeled amber biohazard bag. Store at room temperature.

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Fill out this form for multiple time-point Visits: ENR and Day 28. BLD & VAG PK swabs are collected within 5 minutes of each other.

Participant ID:			Visit Code:		Specimen Collection Date:		
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number			Participant Number		Chk		
					dd		MMM
							yy

# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB	INSTRUCTIONS FOR PROCESSING LAB
<input type="checkbox"/>	Blood PK – 0 Hour (BLD) Collection Time ____: ____ Hour Min	EDT (purple top)	PL1/2	N/A	<ul style="list-style-type: none"> Transport to lab ASAP. Spin, split, and label 2 or more cryovials with a minimum of 1.5 mL of plasma/each. Freeze within 8 hrs.
<input type="checkbox"/>	Self-collected swab for PK 0 Hour (VAG) Collection Time ____: ____	NON	SWB	N/A	<ul style="list-style-type: none"> Freeze at ≤ -70°C within 2 hours. <p style="text-align: right;">____.____ - _____.____ = _____.____ mg <i>Post-weight Pre-weight Net weight</i></p>
<input type="checkbox"/>	Blood PK – 1 Hour (BLD) Collection Time ____: ____	EDT (purple top)	PL1/2	N/A	<ul style="list-style-type: none"> Transport to lab ASAP. Spin, split, and label 2 or more cryovials with a minimum of 1.5 mL of plasma/each. Freeze within 8 hrs.
<input type="checkbox"/>	Self-collected swab for PK 1 Hour (VAG) Collection Time ____: ____	NON	SWB	N/A	<ul style="list-style-type: none"> Freeze at ≤ -70°C within 2 hours. <p style="text-align: right;">____.____ - _____.____ = _____.____ mg <i>Post-weight Pre-weight Net weight</i></p>
<input type="checkbox"/>	Blood PK – 2 Hour (BLD) Collection Time ____: ____	EDT (purple top)	PL1/2	N/A	<ul style="list-style-type: none"> Transport to lab ASAP. Spin, split, and label 2 or more cryovials with a minimum of 1.5 mL of plasma/each. Freeze within 8 hrs.
<input type="checkbox"/>	Self-collected swab for PK 2 Hour (VAG) Collection Time ____: ____	NON	SWB	N/A	<ul style="list-style-type: none"> Freeze at ≤ -70°C within 2 hours. <p style="text-align: right;">____.____ - _____.____ = _____.____ mg <i>Post-weight Pre-weight Net weight</i></p>
<input type="checkbox"/>	Blood PK – 4 Hour (BLD) Collection Time ____: ____	EDT (purple top)	PL1/2	N/A	<ul style="list-style-type: none"> Transport to lab ASAP. Spin, split, and label 2 or more cryovials with a minimum of 1.5 mL of plasma/each. Freeze within 8 hrs.
<input type="checkbox"/>	Self-collected swab for PK 4 Hour (VAG) Collection Time ____: ____	NON	SWB	N/A	<ul style="list-style-type: none"> Freeze at ≤ -70°C within 2 hours. <p style="text-align: right;">____.____ - _____.____ = _____.____ mg <i>Post-weight Pre-weight Net weight</i></p>
<input type="checkbox"/>	Blood PK – 6 Hour (BLD) Collection Time ____: ____	EDT (purple top)	PL1/2	N/A	<ul style="list-style-type: none"> Transport to lab ASAP. Spin, split, and label 2 or more cryovials with a minimum of 1.5 mL of plasma/each. Freeze within 8 hrs.
<input type="checkbox"/>	Self-collected swab for PK 6 Hour (VAG) Collection Time ____: ____	NON	SWB	N/A	<ul style="list-style-type: none"> Freeze at ≤ -70°C within 2 hours. <p style="text-align: right;">____.____ - _____.____ = _____.____ mg <i>Post-weight Pre-weight Net weight</i></p>

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Purpose: This non-DataFax form is used to document collection and entry of study specimens into the Laboratory Data Management System (LDMS).

General Information/Instructions: A copy of this form accompanies specimens for storage (in their original specimen collection containers) to the LDMS entry laboratory. Once the specimens have been entered into LDMS, this form is kept on file at the LDMS entry laboratory. If the site chooses, a copy of this completed form may be made once the specimens have been entered into LDMS and the copy kept in the participant’s study notebook. This is not required, however. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Item-specific Instructions:

- **Visit Code:** Record the visit code of the visit at which the specimens were collected.
- **TUBES or SPECIMENS COLLECTED:** In the box provided, record the total number of tubes or specimens collected for that primary specimen type. If no LDMS specimens of the primary specimen type were collected, record “0.”.
- **Primary Specimen, Primary Additive, and Aliquot Derivative Codes:** See table below for a listing of the codes.

BLD: Whole Blood	GRS: Gram Stain	PL1/2: Single or double spun plasma
BPS: Biopsy	IVR: Used Intravaginal Ring	SWB: Swab
BTM: Biopsy Transport Medium	N/A: Not Applicable	SLD: Slide
CVB Cervical Biopsy	NON: No Additive	SPG: Sponge
CER: Cervix	PAC: Port-a-Cul or BD Max V (culture transport medium)	REC: Rectal
CTB: Cytobrush		RPM: RPMI Transport Media
EDT: EDTA	PBS: Phosphate buffered saline	VAG: Vaginal Swab

- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials – Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
- **LDMS Data Entry Date – LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.