

Participant ID:			Visit Code:			Specimen Collection Date:		
<input style="width:20px; height:20px;" type="text"/> <input style="width:20px; height:20px;" type="text"/> <input style="width:20px; height:20px;" type="text"/>	-	<input style="width:20px; height:20px;" type="text"/> <input style="width:20px; height:20px;" type="text"/> <input style="width:20px; height:20px;" type="text"/> <input style="width:20px; height:20px;" type="text"/> <input style="width:20px; height:20px;" type="text"/>	-	<input style="width:20px; height:20px;" type="text"/>	<input style="width:20px; height:20px;" type="text"/> <input style="width:20px; height:20px;" type="text"/>	<input style="width:20px; height:20px;" type="text"/>	<input style="width:20px; height:20px;" type="text"/> <input style="width:20px; height:20px;" type="text"/>	<input style="width:20px; height:20px;" type="text"/> <input style="width:20px; height:20px;" 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:40px; height:40px;" type="text"/>	Blood (BLD) <i>plasma archive</i> Collection Time ___:___ hour : min	EDT (purple top)	PL1/2	N/A	Prepare as many 1.5 mL aliquots as possible with a total volume of aliquots ≥ 4ml. If sample is collected and held at room temp, freeze within 4 hours. If refrigerated after collection, freeze within 24 hours.
<input style="width:40px; height:40px;" type="text"/>	Blood (BLD) <i>PK single time-point</i> Collection Time ___:___ hour : min	EDT (purple top)	PL1/2	N/A	Centrifuge, split, and label two or more cryovials with a minimum of 1.5mL of plasma in each cryovial. Freeze within 8 hours of blood collection.
<input style="width:40px; height:40px;" type="text"/>	Cervicovaginal Lavage (CVL) Collection Time ___:___ hour : min	NSL	FLD	N/A	CVL supernatant for biomarkers. Freeze at ≤ -70°C within 8 hours of collection.
			CEN	NSL	CVL supernatant: 3 or more additional aliquots (used for backup or future testing marked "extra CVL") and frozen at ≤ -70°C within 8 hours of collection.
					CVL cell pellet: suspended in 0.5 mL of normal saline & frozen at ≤ -70°C within 8 hours of collection.

Comments: _____

Initials: _____
Sending Staff Receiving Staff

LDMS Data Entry Date: / _____
dd MMM yy LDMS Staff

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	IVR: Used Intravaginal Ring	SWB: Swab
CVB Cervical Biopsy	N/A: Not Applicable	RPM: RPMI Transport Media
CEN: Cell Pellet	NON: No Additive	TIS: Tissue
CER: Cervix	NSL: Normal Saline	VAG: Vaginal Swab
CTB: Cytobrush	PAC: Port-a-Cul	VGL: Vagina
EDT: EDTA	PBS: Phosphate buffered saline	
FLD: Fluid Supernatant	PL1/2: Single or double spun plasma	

- **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.
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Site Number	Participant Number	Chk			<i>dd</i>	<i>MMM</i>	<i>yy</i>
# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB	INSTRUCTIONS FOR PROCESSING LAB		
□	Cervical cytobrush (CER) <i>Flow Cytometry CASE & Pitt only</i> Collection Time ____:____ hour : min	RPM	CTB	N/A	Keep on ice and deliver to Flow Cytometry ASAP to process within 2 hours from collection.		
□	Cervical tissue biopsy (CVB) <i>for PK</i> 1:Collection Time ____:____ hour : min 2:Collection Time ____:____ hour : min	NON	TIS	N/A	Collect 2 biopsies and place each tissue in a cryovial, immediately freeze, and store at ≤ -70°C Freezing Time for both Biopsies ____:____ hour : min 1: ____:____ - ____:____ = ____:____ mg <i>Post-weight Pre-weight Net weight</i> 2: ____:____ - ____:____ = ____:____ mg <i>Post-weight Pre-weight Net weight</i>		
□	Vaginal Swab (VGL) <i>For Biomarker</i> Collection Time ____:____ hour : min	PBS	SWB	N/A	Place Dacron swab in 400 uL PBS, freeze within 8 hours, and store at ≤ -70°C. Freezing Time ____:____ hour : min		

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dd MMM yy LDMS Staff

For login of stored specimens into LDMS

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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="text"/>	Vaginal Swab (VGL) for PK Collection Time __:__:__ hour : min	NON	SWB	N/A	Put on ice immediately and freeze at ≤ -70°C within 2 hours of collection. Freezing Time __:__:__ hour : min ____:____ - ____:____ = ____:____ mg <i>Post-weight Pre-weight Net weight</i>
<input type="text"/>	Vaginal Smear (VAG) for Gram Stain	NON	SLD	GRS	Write the PTID and specimen collection date on one the frosted end of the slide. A SCHARP-provided PTID label is to be placed on the underside of the slides
<input type="text"/>	Vaginal Culture (VGL)	PAC	SWB	N/A	Insert 2 Dacron swabs into PAC, and ship overnight on ice packs to MTN NL on the day of collection.
<input type="text"/>	Used Vaginal Ring (IVR) for residual PK	NON	IVR	N/A	Rinse (in a cup) and blot dry used ring and place into a labeled biohazard bag. Store at room temperature.

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