

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"/> - <input type="text"/> 0	<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	Cohort	dd	MMM	yy

# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB	INSTRUCTIONS FOR PROCESSING LAB
<input type="checkbox"/>	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 \geq to 4ml. If sample is collected and held at room temp, freeze within 4 hours. If refrigerated after collection, freeze within 24 hours.
<input type="checkbox"/>	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 type="checkbox"/>	Cervicovaginal Lavage (CVL) Collection Time ____:____ hour : min	NSL	FLD	N/A	CVL supernatant for PD. Freeze at $\leq -70^{\circ}\text{C}$ within 8 hours of collection.
					CVL supernatant for PK. Freeze at $\leq -70^{\circ}\text{C}$ within 8 hours of collection.
					CVL supernatant for semen biomarker. Freeze at $\leq -70^{\circ}\text{C}$ within 8 hours of collection.
					CVL supernatant: 3 or more additional aliquots (used for backup or future testing marked "extra CVL") and frozen at $\leq -70^{\circ}\text{C}$ within 8 hours of collection.
			CEN	PBS	CVL cell pellet: suspended in 0.5 mL of PBS & frozen at $\leq -70^{\circ}\text{C}$ within 8 hours of collection.

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	NON: No Additive	SWB: Swab
CVB: Cervical Biopsy	MET: Methanol lysate	REC: Rectal
CEN: Cell Pelet	NSL: Normal Saline	RPM: RPMI Transport Media
CER: Cervix	PBS: Phosphate buffered saline	TIS: Tissue
CTB: Cytobrush	PL1/2: Single or double spun plasma	VGL: Vagina
EDT: EDTA	SEM: Semen	
FLU: Fluid Supernatant	SPG: Sponge	

- **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.

Participant ID: <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"/> 0		Visit Code: <input type="text"/> <input type="text"/> . <input type="text"/>		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	Cohort	dd	MMM	yy
# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB	INSTRUCTIONS FOR PROCESSING LAB	
<input type="checkbox"/>	Cervical cytobrush (CER) <i>Flow Cytometry</i> Pitt only Collection Time ____ : ____ hour : min	RPM	CTB	NON	Keep on ice and deliver to Flow Cytometry ASAP to process within 2 hours from collection.	
<input type="checkbox"/>	Cervical cytobrush (CER) <i>for PK</i> Case only Collection Time ____ : ____ hour : min	RPM	CTB	MET	Transfer at least 1mL of lysate into a cryovial. If more than 0.5mL of extra lysate is available, place in another cryovial and mark 'extra cytobrush lysate'. Freeze Immediately at $\leq -70^{\circ}\text{C}$.	
<input type="checkbox"/>	Cervical tissue biopsy (CVB) <i>for PK</i> Collection Time ____ : ____ hour : min	NON	TIS	N/A	Place each tissue in a cryovial, immediately freeze, and store at $\leq -70^{\circ}\text{C}$. Freezing Time ____ : ____ hour : min $\underline{\hspace{1cm}} - \underline{\hspace{1cm}} = \underline{\hspace{1cm}} \text{ mg}$ <i>Post-weight Pre-weight Net weight</i>	
<input type="checkbox"/>	Vaginal tissue biopsy (VGL) <i>for PK</i> Collection Time ____ : ____ hour : min	NON	TIS	N/A	Place each tissue in a cryovial, immediately freeze, and store at $\leq -70^{\circ}\text{C}$. Freezing Time ____ : ____ hour : min $\underline{\hspace{1cm}} - \underline{\hspace{1cm}} = \underline{\hspace{1cm}} \text{ mg}$ <i>Post-weight Pre-weight Net weight</i>	

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	NON: No Additive	SWB: Swab
CVB Cervical Biopsy	MET: Methanol lysate	REC: Rectal
CEN: Cell Pelet	NSL: Normal Saline	RPM: RPMI Transport Media
CER: Cervix	PBS: Phosphate buffered saline	TIS: Tissue
CTB: Cytobrush	PL1/2: Single or double spun plasma	VGL: Vagina
EDT: EDTA	SEM: Semen	
FLU: Fluid Supernatant	SPG: Sponge	

- **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.

Participant ID: - - - **Visit Code:** **Specimen Collection Date:**

Site Number Participant Number Chk Cohort dd MMM yy

# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB	INSTRUCTIONS FOR PROCESSING LAB
<input type="checkbox"/>	Rectal sponge (REC) for PK Collection Time ____:____ hour : min	NON	SPG	N/A	Put on ice immediately and freeze at ≤ -70°C within 4 hours of collection. Freezing Time ____:____ hour : min $\underline{\hspace{1cm}} - \underline{\hspace{1cm}} = \underline{\hspace{1cm}} \text{ mg}$ <i>Post-weight Pre-weight Net weight</i>

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	NON: No Additive	SWB: Swab
CVB Cervical Biopsy	MET: Methanol lysate	REC: Rectal
CEN: Cell Pelet	NSL: Normal Saline	RPM: RPMI Transport Media
CER: Cervix	PBS: Phosphate buffered saline	TIS: Tissue
CTB: Cytobrush	PL1/2: Single or double spun plasma	VGL: Vagina
EDT: EDTA	SEM: Semen	
FLU: Fluid Supernatant	SPG: Sponge	

- **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.