

**MTN-024 /IPM 031**

# LDMS Specimen Tracking Sheet

*For login of stored specimens into LDMS*

Participant ID:	Visit Code:	Specimen Collection Date:
<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">-</div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">-</div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> </div> <div style="display: flex; justify-content: space-between; font-size: 0.8em;"> <span>Site Number</span> <span>Participant Number</span> <span>Chk</span> </div>	<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">-</div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> </div> <div style="display: flex; justify-content: space-between; font-size: 0.8em;"> <span></span> <span></span> </div>	<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">-</div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">-</div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> </div> <div style="display: flex; justify-content: space-between; font-size: 0.8em;"> <span>dd</span> <span>MMM</span> <span>yy</span> </div>

  

# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQOT DERIVATIVE	ALIQOT SUB	INSTRUCTIONS FOR PROCESSING LAB
<div style="border: 1px solid black; width: 40px; height: 40px; margin: 0 auto;"></div>	<p style="text-align: center;">Blood (BLD) <i>plasma archive</i></p> <p style="text-align: center;"><b>Collection Time</b> __ : __ : __ hour : min</p>	<p><b>EDT</b> (purple top)</p>	<p><b>PL1/2</b></p>	<p><b>N/A</b></p>	<p>Prepare as many 1.5 mL aliquots as possible with a total volume of aliquots ≥ to 4ml. If sample is collected and held at room temp, freeze within 4 hours. If refrigerated after collection, freeze within 24 hours.</p>
<div style="border: 1px solid black; width: 40px; height: 40px; margin: 0 auto;"></div>	<p style="text-align: center;">Blood (BLD) <i>PK single time-point</i></p> <p style="text-align: center;"><b>Collection Time</b> __ : __ : __ hour : min</p>	<p><b>EDT</b> (purple top)</p>	<p><b>PL1/2</b></p>	<p><b>N/A</b></p>	<p>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.</p>
<div style="border: 1px solid black; width: 40px; height: 40px; margin: 0 auto;"></div>	<p style="text-align: center;">Cervicovaginal Lavage (CVL)</p> <p style="text-align: center;"><b>Collection Time</b> __ : __ : __ hour : min</p>	<p><b>NSL</b></p>	<p><b>FLD</b></p>	<p><b>N/A</b></p>	<p>CVL supernatant for biomarkers. Freeze at ≤ -70°C within 8 hours of collection.</p>
			<p><b>CEN</b></p>	<p><b>NSL</b></p>	<p>CVL cell pellet: suspended in 0.5 mL of normal saline &amp; frozen at ≤ -70°C within 8 hours of collection.</p>

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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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="text"/>	Cervical cytobrush <b>(CER)</b> <i>Flow Cytometry</i> <b>CASE &amp; Pitt only</b>  <b>Collection Time</b> ____:____ hour : min	<b>RPM</b>	<b>CTB</b>	<b>N/A</b>	Keep on ice and deliver to Flow Cytometry ASAP to process within 2 hours from collection.
<input type="text"/>	Cervical tissue biopsy <b>(CVB)</b> <i>for PK</i>  <b>1:Collection Time</b> ____:____ hour : min  <b>2:Collection Time</b> ____:____ hour : min	<b>NON</b>	<b>TIS</b>	<b>N/A</b>	Collect 2 biopsies and place each tissue in a cryovial, immediately freeze, and store at $\leq -70^{\circ}\text{C}$  Freezing Time for both Biopsies ____:____ hour : min  1: ____:____ - ____:____ = ____:____ mg Post-weight    Pre-weight    Net weight  2: ____:____ - ____:____ = ____:____ mg Post-weight    Pre-weight    Net weight
<input type="text"/>	Vaginal Swab <b>(VGL)</b> <i>For Biomarker</i>  <b>Collection Time</b> ____:____ hour : min	<b>PBS</b>	<b>SWB</b>	<b>N/A</b>	Place Dacron swab in 400 uL PBS, freeze within 8 hours, and store at $\leq -70^{\circ}\text{C}$ .  Freezing Time ____:____ hour : min

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

\_\_\_\_\_

\_\_\_\_\_

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<div style="border: 1px solid black; width: 40px; height: 40px; margin: 0 auto;"></div>	Vaginal Swab <b>(VGL)</b> <i>for PK</i>  <b>Collection Time</b> <div style="display: flex; align-items: center; justify-content: center; gap: 5px;"> <div style="border-bottom: 1px solid black; width: 30px;"></div> <span>:</span> <div style="border-bottom: 1px solid black; width: 30px;"></div> <span>hour : min</span> </div>	<b>NON</b>	<b>SWB</b>	<b>N/A</b>	Put on ice immediately and freeze at $\leq -70^{\circ}\text{C}$ within 2 hours of collection. Freezing Time <div style="display: flex; align-items: center; justify-content: center; gap: 5px;"> <div style="border-bottom: 1px solid black; width: 30px;"></div> <span>:</span> <div style="border-bottom: 1px solid black; width: 30px;"></div> <span>hour : min</span> </div>  <div style="display: flex; align-items: center; justify-content: center; gap: 10px;"> <div style="border-bottom: 1px solid black; width: 100px;"></div> <span>–</span> <div style="border-bottom: 1px solid black; width: 100px;"></div> <span>=</span> <div style="border-bottom: 1px solid black; width: 100px;"></div> <span>mg</span> </div> <div style="display: flex; justify-content: space-around; font-weight: bold; margin-top: 5px;"> <span><i>Post-weight</i></span> <span><i>Pre-weight</i></span> <span><i>Net weight</i></span> </div>			
<div style="border: 1px solid black; width: 40px; height: 40px; margin: 0 auto;"></div>	Vaginal Smear <b>(VAG)</b> <i>for Gram Stain</i>	<b>NON</b>	<b>SLD</b>	<b>GRS</b>	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			
<div style="border: 1px solid black; width: 40px; height: 40px; margin: 0 auto;"></div>	Vaginal Culture <b>(VGL)</b>	<b>PAC</b>	<b>SWB</b>	<b>N/A</b>	Insert 2 Dacron swabs into PAC, and ship overnight on ice packs to MTN NL on the day of collection.			
<div style="border: 1px solid black; width: 40px; height: 40px; margin: 0 auto;"></div>	Used Vaginal Ring <b>(IVR)</b> <i>for residual PK</i>	<b>NON</b>	<b>IVR</b>	<b>N/A</b>	Rinse (in a cup) and blot dry used ring and place into a labeled biohazard bag. Store at room temperature.			

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

**Initials:** \_\_\_\_\_  
                     Sending Staff      Receiving Staff

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 /                       
*dd* *MMM* *yy* LDMS Staff

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