

Participant ID:	Visit Code:	Specimen Collection Date:																				
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Site Number	Participant Number	Chk																				
		dd / MMM / yy																				

# Primary Received	SPECIMEN	# Aliquots (Lab use only)	Collection Time (hour: min)	Post-weight (mg)	Pre-Weight (mg)	Net Weight (mg)	Freezing Time (hour: min)
	Blood - Plasma archive Primary Specimen: BLD Primary Additive: EDT Aliquot Derivative: PL1 or PL2 Aliquot Sub: N/A If follow-up visit, include: Other Spec ID: CON	2	__:__ hour : min				Single spin: 1300xg, 10 minutes OR Double spin: 800xg, 10 minutes. Place plasma in a tube to spin again at 800xg for 10 minutes. Aliquot 1.5-mL or more of plasma into each cryovial. Freeze plasma at ≤ -70°C within 4 hours (archive) or 8 hours (PK) of blood collection.
	0.0 HRS Cervico-vaginal Lavage (CVL)	CVL Supernatant Primary Specimen: CVL Primary Additive: NSL Aliquot Derivative: FLD Aliquot Sub: N/A	At least 6	__:__			__:__
		CVL Cell Pellet Primary Specimen: CVL Primary Additive: NSL Aliquot Derivative: CEN Aliquot Sub: NSL	1			1 st spin: 800xg, 10 minutes Aliquot supernatant into at least 6 cryovials, 1-mL each. 2 nd spin: Discard remaining supernatant, resuspend pellet in 0.5-mL normal saline. Freeze at ≤ -70°C within 2 hours of collection.	
	Vaginal Gram Stain Primary Specimen: VAG Primary Additive: NON Aliquot Derivative: SLD Aliquot Sub: GRS	2	N/A				Write the PTID and collection date on the frosted end of the slide (Affix LDMS here). Place SCHARP-provided PTID label on the underside of the slides. Roll vaginal swab across the slide.
	Vaginal Swab for q-PCR Primary Specimen: VAG Primary Additive: NON Aliquot Derivative: FLS Aliquot Sub: N/A	2	N/A				Freeze at ≤ -70°C.
	Vaginal Swab for Culture Primary Specimen: VAG Primary Additive: CTK Aliquot Derivative: SWB Aliquot Sub: N/A	1	N/A				Starplex Starswab (2-swab) transport kit. On the day of collection ship overnight on ice packs to MTN LC with one vaginal Gram stain slide in a slide holder.

COMMENTS: _____

Delivered by: _____ Date: _____ Time: _____
 Received by: _____ Date: _____ Time: _____
 LDMS entry by*: _____ Date: _____

*Did you enter Time Point for PK sample in LDMS?

Participant ID:	Visit Code:	Specimen Collection Date:
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Site Number	Participant Number	Chk
		dd / MMM yy

Delivered By Received By Date/Time	# Primary Received	SPECIMEN	# Aliquots (Lab use only)	Collection Time (hour: min)	Post- weight (mg)	Pre- Weight (mg)	Net Weight (mg)	Freezing Time (hour: min)
		1.0 HRS Blood PK Primary Specimen: BLD Primary Additive: EDT Aliquot Derivative: PL1/PL2 Aliquot Sub: N/A	2	--:--	1 st spin: 1300xg, 10 minutes. Aliquot supernatant into at least 2 cryovials, 1-mL each. Freeze at < -70°C within 8 hours of collection.			--:--
		1.0 HRS Vaginal PK Primary Specimen: VAG Primary Additive: NON Aliquot Derivative: SWB Aliquot Sub: N/A	1	--:--	--	--	--	--:--
		2.0 HRS Blood PK Primary Specimen: BLD Primary Additive: EDT Aliquot Derivative: PL1/PL2 Aliquot Sub: N/A	2	--:--	1 st spin: 1300xg, 10 minutes. Aliquot supernatant into at least 2 cryovials, 1-mL each. Freeze at < -70°C within 8 hours of collection.			--:--
		2.0 HRS Vaginal PK Primary Specimen: VAG Primary Additive: NON Aliquot Derivative: SWB Aliquot Sub: N/A	1	--:--	--	--	--	--:--
		4.0 HRS Blood PK Primary Specimen: BLD Primary Additive: EDT Aliquot Derivative: PL1/PL2 Aliquot Sub: N/A	2	--:--	1 st spin: 1300xg, 10 minutes. Aliquot supernatant into at least 2 cryovials, 1-mL each. Freeze at < -70°C within 8 hours of collection.			--:--
		4.0 HRS Rectal Swab PK Primary Specimen: REC Primary Additive: NON Aliquot Derivative: SWB Aliquot Sub: N/A	1	--:--	--	--	--	--:--
		4.0 HRS Vaginal PK Primary Specimen: VAG Primary Additive: NON Aliquot Derivative: SWB Aliquot Sub: N/A	1	--:--	--	--	--	--:--

COMMENTS: _____

LDMS entry by*: _____ Date: _____

*Did you enter Time Point for PK samples in LDMS?

MTN-036 LDMS Tracking Sheet Instructions

Three sets of LDMS Tracking Sheets are available:

- Enrollment V2 2-page form
- Day 91, V10/PUEV 2-page form
- Single Time Point PK: 2-page form, but you may print only Page 1, if only PK samples are collected at that visit. Please fill in “0” if a sample is NOT received.

Purpose: This 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 laboratory. Once the specimens have been entered in LDMS, this form is kept on file at the LDMS laboratory. Although not required, a copy of this completed form may be made once the specimens have been entered in LDMS and the copy kept in the participant’s study notebook.

Item-specific Instructions:

- **# Primary Received:** Record the total number of tubes or specimens collected for that primary specimen type. If none, record “0”.
- **Primary Specimen, Primary Additive, and Aliquot Derivative Codes:** See table below for a listing of the codes.

*List of Codes and their definitions:

BLD: Whole Blood	IVR: Used Intravaginal Ring	PL1/2: Single or double spun plasma	BPS: Biopsy
VAG: Vaginal Swab	EDT: EDTA	SLD: Slide	GRS: Gram stain slide
CVB: Cervical Biopsy	NON: No Additive	SWB: Swab	N/A: Not Applicable
FLD: Fluid	CTK: Culture transporter	CEN: Centrifuge	NSL: Normal saline
FLS: Flocked Swab	REC: rectal		

- **Collection Time** is required for all PK specimens. Use 24-hour (military) time clock; for LDMS entry.
 - **Freezing Time** is required for all PK specimens. Use 24-hour (military) time clock; for LDMS entry.
 - **Post-** and **Pre-weight** are recorded on the LDMS tracking sheet; however, only **NET WEIGHT** is entered into LDMS. Important: Check calculation.
 - **Delivered by** and **Received by** are completed by **Transferring/Delivering Staff** and **Receiving Staff** who will record their initials, date, and time (in 24-hour time clock).
 - **LDMS Data Entry and Date:** The LDMS laboratory member, who ensured that all specimens were entered in LDMS, records his/her initials and dates the form.
 - **For Blood Plasma Archive:** If blood is collected at a follow-up visit for the MTN LC Virology Core to perform confirmatory testing (i.e. HIV-resistance and viral load), in LDMS, enter “CON” for Other Specimen ID to distinguish it from PK plasma aliquots.
- For Multiple PK Time-point visits (V2 and V10), page 2:** After each sample transaction, a copy of the tracking sheet may be issued to the LDMS laboratory for LDMS entry and sample processing. To ensure all original recordings are on it, the original LDMS tracking sheet will remain in the possession of the clinical staff until the last set of samples is collected.
- **Delivered by, Received by, and Date/Time** are completed by the persons involved in the sample exchange, one person from the clinic and the other from the LDMS laboratory.
 - **Multiple Time-point visits, page 2, LDMS entries completed:** The LDMS laboratory representative attesting to all samples being logged into LDMS, including the Time Points, will mark “Yes” and record his/her initials and date.