

MTN-008 Maternal PK- LDMS Specimen Tracking Sheet

For login of **maternal** MTN-008 stored specimens into LDMS

Participant ID	Visit Code	Specimen Collection Date																																									
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MATERNAL PK BLOOD COLLECTION (PREGNANCY AND LACTATION COHORTS)

PK SPECIMEN TIME	PRIMARY SPECIMEN TYPE	TIME COLLECTED hh:mm <i>24-hr clock</i>	NUMBER OF TUBES COLLECTED	INSTRUCTIONS FOR PROCESSING LAB
Pre-gel	Maternal Blood (BLD) Tenofovir Level		<input type="checkbox"/> Non (red top)	Process within eight hours of collection. Freeze immediately after centrifugation. Store with derivative SER
	Maternal Blood (BLD) PBMC		<input type="checkbox"/> CPS (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.
1 Hour	Maternal Blood (BLD) Tenofovir Level		<input type="checkbox"/> Non (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Maternal Blood (BLD) PBMC		<input type="checkbox"/> CPS (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.
2 Hour	Maternal Blood (BLD) Tenofovir Level		<input type="checkbox"/> Non (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Maternal Blood (BLD) PBMC		<input type="checkbox"/> CPS (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.
4 Hour	Maternal Blood (BLD) Tenofovir Level		<input type="checkbox"/> Non (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Maternal Blood (BLD) PBMC		<input type="checkbox"/> CPS (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.

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Site Number	Participant Number	Chk	Who	<i>dd</i>	<i>MMM</i>	<i>yy</i>

6 Hour	Maternal Blood (BLD) Tenofovir Level		<input type="checkbox"/>	Non (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Maternal Blood (BLD) PBMC		<input type="checkbox"/>	CPS (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.
8 Hour	Maternal Blood (BLD) Tenofovir Level		<input type="checkbox"/>	Non (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Maternal Blood (BLD) PBMC		<input type="checkbox"/>	CPS (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.
Delivery visit	Maternal Blood (BLD) Tenofovir Level		<input type="checkbox"/>	Non (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Maternal Blood (BLD) PBMC		<input type="checkbox"/>	CPS (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.

MATERNAL PK BREAST MILK COLLECTION (LACTATION COHORT)

PK SPECIMEN TIME POINT	PRIMARY SPECIMEN TYPE	TIME COLLECTED hh:mm <i>24-hr clock</i>	NUMBER OF TUBES COLLECTED	INSTRUCTIONS FOR PROCESSING LAB
Pre-gel	Breast milk (BMK)		<input type="checkbox"/> Non (cryovial)	Freeze immediately. Store with derivative BMK.
2 Hour	Breast milk (BMK)		<input type="checkbox"/> Non (cryovial)	Freeze immediately. Store with derivative BMK.
4 Hour	Breast milk (BMK)		<input type="checkbox"/> Non (cryovial)	Freeze immediately. Store with derivative BMK.
6 Hour	Breast milk (BMK)		<input type="checkbox"/> Non (cryovial)	Freeze immediately. Store with derivative BMK.

MTN-008 Maternal PK- LDMS Specimen Tracking Sheet

For login of **maternal** MTN-008 stored specimens into LDMS

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"/> 0 <small>Site Number Participant Number Chk Who</small>	<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"/> <small>dd MMM yy</small>

ALL OTHER MATERNAL SPECIMENS

# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQOT DERIVATIVE	ALIQOT SUB ADDITIVE/ DERIVATIVE	NOTES FOR LAB
<input type="checkbox"/>	Blood (BLD) <i>Plasma</i> Collection Time: ____:____ <i>hour : min</i>	EDT (purple top)	PLA	N/A	Store in aliquots of 1-2 ml. If held at room temperature, plasma must be frozen within 4 hours of collection. If refrigerated or on ice, plasma must be frozen within 8 hours of collection.
<input type="checkbox"/>	Endo-cervical Swab (CXS) Collection Time: ____:____ <i>hour : min</i>	PBS (Phosphate buffered saline)	CXS	N/A	Place swab in crovial with PBS. Freeze within 8 hours of collection.
<input type="checkbox"/>	Vaginal Swab (VAG) Collection Time: ____:____ <i>hour : min</i>	PBS (Phosphate buffered saline)	VAG	N/A	Place swab in crovial with PBS. Freeze within 8 hours of collection.
<input type="checkbox"/>	Vaginal Gram Stain Slide (VAG)	NON (no additive)	SLD	GRS	Re-label with LDMS label. Store duplicate slides (one for on-site storage, and one for shipping and testing at MTN Network Lab).

Comments: _____

Initials: _____ **LDMS Data Entry Date:** / / / _____

Sending Staff
Receiving Staff
dd
MMM
yy
LDMS Staff

MTN-008 Maternal PK- LDMS Specimen Tracking Sheet

*For login of **maternal** MTN-008 stored specimens into LDMS*

Maternal PK - LDMS Specimen Tracking Sheet (nonDataFax)

Purpose: This non-DataFax form is used to document collection and entry of MTN-008 maternal PK blood and breast milk specimens into the Laboratory Data Management System (LDMS).

General Information/Instructions: A copy of this form accompanies maternal PK blood and breast milk specimens (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 LDMS specimens were collected.
- **NUMBER OF TUBES COLLECTED:** In the box to the left of each additive type, record the total number of tubes collected. If no LDMS specimens of the primary specimen type were collected, record "0."
- **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.