MTN 029 Enrollment PK/PD

LDMS Specimen Tracking Sheet

For login of MTN 029 stored specimens into LDMS

Participant ID			Visit Code	Specimen Collection Date		
☐☐☐	-☐☐☐☐☐-	☐	☐☐.☐	☐☐	☐☐☐	☐☐
Site Number	*Participant Number*	*Chk*		*dd*	*MMM*	*yy*

# of TUBES or SPECIMENS		PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	INSTRUCTIONS FOR PROCESSING
Pre-dose (Pre-insertion)	☐	Blood – *Plasma* (**BLD**) **Collection Time:**_____:_____ Hour : Min	**EDT** (purple top)	**PL1**	Store in aliquots of 1.0 ml and freeze within 8 hours of collection. Enter **PK** into Other Spec ID field of LDMS.
	☐	Breast Milk (**BMK**) **Collection Time:**_____:_____ Hour : Min	**NON**	**BMK**	Store in aliquots of 2.0 ml and freeze immediately. Assign 2 aliquots to PD and 2 aliquots to PK. Enter **PD** or **PK** into the Other Spec ID fields respectively.
	☐	Cervicovaginal Fluid (**CVF**) **Collection Time:**_____:_____ Hour : Min	**NON**	**SWB**	_____.___ - _____.___ = _____.___ **mg** *Post-weight* *Pre-weight* *Net weight* **Time Frozen:** _____:_____ Freeze at ≤-70°C within 2 Hour : Min hours of collection.
3 Hour	☐	Blood – *Plasma* (**BLD**) **Collection Time:**_____:_____ Hour : Min	**EDT** (purple top)	**PL1**	Store in aliquots of 1.0 ml and freeze within 8 hours of collection. Enter **PK** into Other Spec ID field of LDMS.
	☐	Breast Milk (**BMK**) **Collection Time:**_____:_____ Hour : Min	**NON**	**BMK**	Store in aliquots of 2.0 ml and freeze immediately. Assign 2 aliquots to PD and 2 aliquots to PK. Enter **PD** or **PK** into the Other Spec ID fields respectively.
	☐	Cervicovaginal Fluid (**CVF**) **Collection Time:**_____:_____ Hour : Min	**NON**	**SWB**	_____.___ - _____.___ = _____.___ **mg** *Post-weight* *Pre-weight* *Net weight* **Time Frozen:** _____:_____ Freeze at ≤-70°C within 2 Hour : Min hours of collection.
6 Hour	☐	Blood – *Plasma* (**BLD**) **Collection Time:**_____:_____ Hour : Min	**EDT** (purple top)	**PL1**	Store in aliquots of 1.0 ml and freeze within 8 hours of collection. Enter **PK** into Other Spec ID field of LDMS.
	☐	Breast Milk (**BMK**) **Collection Time:**_____:_____ Hour : Min	**NON**	**BMK**	Store in aliquots of 2.0 ml and freeze immediately. Assign 2 aliquots to PD and 2 aliquots to PK. Enter **PD** or **PK** into the Other Spec ID fields respectively.
	☐	Cervicovaginal Fluid (**CVF**) **Collection Time:**_____:_____ Hour : Min	**NON**	**SWB**	_____.___ - _____.___ = _____.___ **mg** *Post-weight* *Pre-weight* *Net weight* **Time Frozen:** _____:_____ Freeze at ≤-70°C within 2 Hour : Min hours of collection.

Comments:_____

_____

_____

_____

Initials: _____ _____   **LDMS Data Entry Date:** ☐☐ ☐☐☐ ☐☐ / _____
Sending Staff   Receiving Staff   *dd*   *MMM*   *yy*   LDMS Staff

MTN 029 LDMS Specimen Tracking Sheet (non-DataFax)

Purpose: This non-DataFax form is used to document collection and entry of MTN 029 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 LMDS specimens were collected.

• **# of TUBES or SPECIMENS**: 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."

• **Collection Time:** Record the time that the specimen collection was completed, using the 24-hour clock format.

• **Frozen Time:** Record the time the specimen was frozen using the 24-hour clock format.

• **Post-weight:** Record the weight of the collection device after the sample has been collected.

• **Pre-weight:** Record of the weight of the collection device prior to the sample being collected.

• **Net-weight:** Subtract the pre-weight from the post-weight and record the difference.

• **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.

LDMS CODES:

BLD: Whole Blood	EDT: EDTA	PL1: Single spun Plasma
BMK: Breast milk	NON: None	SWB: Swab
CVF: Cervicovaginal Fluid		