

MTN 014 Follow Up Visit LDMS Specimen Tracking Sheet

For login of 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"/>	<input type="text"/>	<input type="text"/>
Site Number	Participant Number	Chk			dd	MMM	yy
# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERV	ALIQUOT SUB ADD/ DERV	INSTRUCTIONS FOR LAB		
<input type="checkbox"/>	Blood – Plasma PK (BLD) Collection Time: ____:____ Hour : Min	EDT	PL1	N/A	Store as many 1ml aliquots as possible with a total volume of aliquots ≥ to 4ml. Freeze within 8 hours of collection. Enter PK into Other Spec ID field of LDMS.		
<input type="checkbox"/>	Blood – PBMC PK (BLD) Collection Time: ____:____ Hour : Min	CPS	CIO	MET	Keep upright at RT and process within 8 hours.		
<input type="checkbox"/>	Vaginal Gram Stain Slide (VAG)	NON	SLD	GRS	Label with LDMS label. Store duplicate slides (one for on-site storage, and one for shipping and testing at MTN Network Lab).		
<input type="checkbox"/>	Vaginal Swabs – biomarkers (VAG) Collection Time: ____:____ Hour : Min	PBS	VAG	N/A	Place swab in cryovial with PBS. Freeze within 8 hours of collection.		
<input type="checkbox"/>	Endocervical Swabs – biomarkers (CXS) Collection Time: ____:____ Hour : Min	PBS	CXS	N/A	Place swab in cryovial with PBS. Freeze within 8 hours of collection.		
<input type="checkbox"/>	Vaginal Fluid – PK (VAG) Collection Time: ____:____ Hour : Min	NON	VAG	N/A	Place swab in cryovial (no additive). Freeze within 2 hours of collection.		
<input type="checkbox"/>	Cervical Vaginal Lavage – PK, PD, and Biomarkers (CVL) Collection Time: ____:____ Hour : Min	NSL	FLD	N/A	CVL supernatant for PK, PD and Biomarkers. Freeze at ≤ -70°C within 8 hours of collection.		
			CEN	PBS	CVL cell pellet: suspended in 0.5 mL of PBS and freeze at ≤ -70°C within 8 hours of collection.		
<input type="checkbox"/>	Cervical Cytobrush – PK (CER) Collection Time: ____:____ Hour : Min	PBS	CTB	MET	Immediately store on ice or refrigerate prior to processing. Process and store at ≤ -70°C within 2 hours of collection.		

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Site Number	Participant Number	Chk			dd	MMM	yy
# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERV	ALIQUOT SUB ADD/ DERV	INSTRUCTIONS FOR LAB		
<input type="checkbox"/>	Vaginal Biopsies – PK (VGL) Collection Time: _____ : _____ Hour : Min	NON	BPS	N/A	1) _____ - _____ = _____ mg 2) _____ - _____ = _____ mg <i>Post-weight Pre-weight Net weight</i> Time Frozen: _____ : _____ Hour : Min Freeze at ≤-70°C within 2 hours of collection.		
<input type="checkbox"/>	Vaginal Biopsies – Gene Expression (VGL) Collection Time: _____ : _____ Hour : Min	RNL	BPS	N/A	Store @ 4C overnight then transfer to ≤-70°C. Must be stored at ≤-70°C for a minimum of 24 hours prior to shipping.		
<input type="checkbox"/>	Rectal Sponge – PD and biomarkers (REC) Collection Time: _____ : _____ Hour : Min	NON	SPG	N/A	1) _____ - _____ = _____ mg 2) _____ - _____ = _____ mg <i>Post-weight Pre-weight Net weight</i> Time Frozen: _____ : _____ Hour : Min Freeze at ≤-70°C within 2 hours of collection. Enter PD into Other Spec ID field of LDMS.		
<input type="checkbox"/>	Rectal Sponge – PK (REC) Collection Time: _____ : _____ Hour : Min	NON	SPG	N/A	_____ - _____ = _____ mg <i>Post-weight Pre-weight Net weight</i> Time Frozen: _____ : _____ Hour : Min Freeze at ≤-70°C within 2 hours of collection. Enter PK into Other Spec ID field of LDMS.		
<input type="checkbox"/>	Rectal Biopsies – PK (FSR) Collection Time: _____ : _____ Hour : Min	NON	BPS	N/A	1) _____ - _____ = _____ mg 2) _____ - _____ = _____ mg 3) _____ - _____ = _____ mg 4) _____ - _____ = _____ mg <i>Post-weight Pre-weight Net weight</i> Time Frozen: _____ : _____ Hour : Min Freeze at ≤-70°C within 2 hours of collection.		
<input type="checkbox"/>	Rectal Biopsies – Gene Expression (FSR) Collection Time: _____ : _____ Hour : Min	RNL	BPS	N/A	Store @ 4°C overnight then transfer to ≤-70°C. Must be stored at ≤-70°C for a minimum of 24 hours prior to shipping.		

MTN 014 Follow Up Visit LDMS Specimen Tracking Sheet

For login of stored specimens into LDMS

MTN 014 LDMS Specimen Tracking Sheet (non-DataFax)

Purpose: This non-DataFax form is used to document collection and entry of MTN 014 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 LDMS specimens were collected.
- **# of 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."
- **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

BPS: Biopsy

CEN: Fresh cells from non-blood specimen type

CER: Cervix

CIO: Cells in other solution, Non-viable

CPS: Cell Preparation Tube SCI

CTB: Cytobrush

CVL: Cervical Vaginal Lavage

CXS: Cervical Swab

EDT: EDTA (purple top)

FLD: Fluid portion from a non-blood specimen

FOR: Formalin

FSR: Rectal biopsy by flexible sigmoidoscopy

MET: Methanol

NON: None

NSL: Normal Saline

PBS: Phosphate Buffered Saline

PL1: single spun Plasma

REC: Rectal

RNL: RNALater

SPG: Sponge

URN: Urine

VAG: Vaginal Swab

VGL: Vaginal