MTN 026 Rectal Specimens   LDMS Specimen Tracking Sheet

For login of MTN 026 stored specimens into LDMS

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site Number   *Participant Number*   *Chk*

Visit Code

☐☐.☐

Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB ADD/ DER	INSTRUCTIONS FOR PROCESSING
☐	Rectal Swab – *Microflora* (REC) Collection Time:_____:_____ Hour : Min	NON	SWB	N/A	Time Frozen: _____:_____ Hour : Min Freeze at ≤-70°C within 2 hours of collection. Enter **MF** into Other Spec ID field of LDMS.
☐	Rectal Swab – *PK* (REC) **PK Time Point (circle one at Vst 3.0 and 13.0 only):** 30-60 min or 120 min Collection Time:_____:_____ Hour : Min	NON	SWB	N/A	_____.___ - _____.___ = _____.___ mg *Post-weight* *Pre-weight* *Net weight* Time Frozen: _____:_____ Hour : Min Freeze at ≤-70°C within 2 hours of collection. Enter **PK** into Other Spec ID field of LDMS.
☐	Rectal Sponge – *Mucosal Safety* (REC) Collection Time:_____:_____ Hour : Min	NON	SPG	N/A	_____.___ - _____.___ = _____.___ mg *Post-weight* *Pre-weight* *Net weight* Time Frozen: _____:_____ Hour : Min Freeze at ≤-70°C within 2 hours of collection.
☐	Rectal Enema – *PD/PK* (REC) Collection Time:_____:_____ Hour : Min	NSL	FLD	N/A	Store supernatants in aliquots of 1.0 ml. Freeze at ≤-70°C within 8 hours of collection. Enter Other Spec ID: **PD, PK, or EXT**
			PEN	NSL	Suspend in 0.5ml of normal saline and freeze at ≤-70°C within 8 hours of collection.
☐	Rectal Biopsies – *PK* (FSR) **PK Time Point (circle one at VST 3.0 and 13.0 only):** 30-60 min or 120 min Collection Time:_____:_____ Hour : Min	NON	BPS	N/A	1 _____.___ - _____.___ = _____.___ mg 2 _____.___ - _____.___ = _____.___ mg 3 _____.___ - _____.___ = _____.___ mg 4 _____.___ - _____.___ = _____.___ mg 5 _____.___ - _____.___ = _____.___ mg *Post-weight* *Pre-weight* *Net weight* Time Frozen: _____:_____ Hour : Min Freeze at ≤-70°C within 2 hours of collection. Enter **PK** into Other Spec ID field of LDMS.

Comments:_____
_____

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

Sending Staff   *Receiving Staff*   *dd*   *MMM*   *yy*   *LDMS Staff*

MTN 026 LDMS Specimen Tracking Sheet (non-DataFax)

Purpose: This non-DataFax form is used to document collection and entry of MTN 026 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.

- **NUMBER 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."

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

- **Time Frozen:** 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:

BPS: Biopsy	NON: None	REC: Rectal
FLD: Fluid	NSL: Normal Saline	SPG: Sponge
FSR: Rectal biopsy by flexible sigmoidoscopy	PEN: Non-viable cells from non-blood specimen	SWB: Swab

MTN 026 Rectal Specimens   LDMS Specimen Tracking Sheet

For login of MTN 026 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	ALIQUOT SUB ADD/ DER	INSTRUCTIONS FOR PROCESSING
☐	Rectal Biopsies – *Gene expression microarrays* **(FSR)** **Collection Time:**____:____ Hour : Min	RNL	BPS	N/A	Store at 4°C overnight then transfer to ≤-70°C. Must be stored at ≤-70°C for a minimum of 24 hours prior to shipping.
☐	Rectal Biopsy – *Histology* **(FSR)** **Collection Time:**____:____ Hour : Min	FOR	BPS	N/A	Store at room temperature and batch ship to MTN NL quarterly.
☐	Rectal Biopsies – *PD* **(FSR)** **Collection Time:**____:____ Hour : Min	BTM	BPS	N/A	**1** _____.___ - _____.___ = _____.___ **mg** **2** _____.___ - _____.___ = _____.___ **mg** **3** _____.___ - _____.___ = _____.___ **mg** **4** _____.___ - _____.___ = _____.___ **mg** *Post-weight* *Pre-weight* *Net weight* Transport biopsies to processing lab within **15-30 minutes** of collection for processing. Enter **PD** into Other Spec ID field of LDMS.
☐	Rectal Biopsies – *T Cell Phenotyping* **(FSR)** **Collection Time:**____:____ Hour : Min	BTM	BPS	N/A	Transport on ice to lab for testing. Enter **PHENO** into Other Spec ID field of LDMS.
☐	Rectal Biopsy – *Proteomics* **(FSR)** **Collection Time:**____:____ Hour : Min	NON	BPS	N/A	_____.___ - _____.___ = _____.___ **mg** *Post-weight* *Pre-weight* *Net weight* **Time Frozen:** ____:____ Hour : Min Freeze at ≤-70°C within 2 hours of collection. Enter **PRO** into Other Spec ID field of LDMS.

Comments:_____
_____
_____
_____
_____

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

LDMS Specimen Tracking Sheet

For login of MTN 026 stored specimens into LDMS

MTN 026 LDMS Specimen Tracking Sheet (non-DataFax)

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Item-specific Instructions:

- **Visit Code:** Check to make sure the Visit Code recorded on page 1 and page 2 match.

- **NUMBER 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."

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

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- **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:

BPS: Biopsy
BTM: Biopsy Transport Media
FOR: Formalin

FSR: Rectal biopsy by flexible
sigmoidoscopy
NON: None

RNL: RNAlater