### MTN 026 Rectal Specimens

**LDMS Specimen Tracking Sheet**

For login of MTN 026 stored specimens into LDMS

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Visit Code</th>
<th>Specimen Collection Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

**Site Number**  
**Participant Number**  
**Chk**  

clickable link to MTN 026 Rectal Specimens

<table>
<thead>
<tr>
<th># of TUBES or SPECIMENS</th>
<th>PRIMARY SPECIMEN</th>
<th>PRIMARY ADDITIVE</th>
<th>ALIQUOT DERIVATIVE</th>
<th>ALIQUOT SUB ADD/DER</th>
<th>INSTRUCTIONS FOR PROCESSING</th>
</tr>
</thead>
</table>
|                          | Rectal Swab – *Microflora* (REC) | 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) | NON | SWB | N/A | Post-weight Pre-weight Net weight
|                          | PK Time Point (circle one at Vst 3.0 and 13.0 only): 30-60 min or 120 min |       |     |                 | 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) | NON | SPG | N/A | Post-weight Pre-weight Net weight
|                          |                  |                 |                    |                     | Time Frozen: ___:_____
|                          |                  |                 |                    |                     | Hour : Min                  |
|                          |                  |                 |                    |                     | Freeze at ≤-70°C within 2 hours of collection. |
|                          | Rectal Enema – *PD/PK* (REC) | 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) | NON | BPS | N/A | 1 Post-weight Pre-weight Net weight
|                          | PK Time Point (circle one at VST 3.0 and 13.0 only): 30-60 min or 120 min |       |     |                 | 2 Post-weight Pre-weight Net weight
|                          |                  |                 |                    |                     | Hour : Min                  |
|                          |                  |                 |                    |                     | Freeze at ≤-70°C within 2 hours of collection. Enter PK into Other Spec ID field of LDMS. |

**Comments:**

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**Initials:**  

**Sending Staff**  
**Receiving Staff**  

**LDMS Data Entry Date:**  

clickable link to MTN 026 Rectal Specimens

**Version 2.0 02-Jan-18**  
**Page 1 of 4**
MTN 026 Rectal Specimens  LDMS Specimen Tracking Sheet  
For login of MTN 026 stored specimens into LDMS

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  PEN: Non-viable cells from non-
sigmoidoscopy  blood specimen  SWB: Swab
<table>
<thead>
<tr>
<th># of TUBES or SPECIMENS</th>
<th>PRIMARY SPECIMEN</th>
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<th>ALIQUOT DERIVATIVE</th>
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<th>INSTRUCTIONS FOR PROCESSING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rectal Biopsies – Gene expression microarrays (FSR)</td>
<td>RNL</td>
<td>BPS</td>
<td>N/A</td>
<td>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.</td>
</tr>
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<td></td>
<td>Collection Time:</td>
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<tr>
<td></td>
<td>Rectal Biopsy – Histology (FSR)</td>
<td>FOR</td>
<td>BPS</td>
<td>N/A</td>
<td>Store at room temperature and batch ship to MTN NL quarterly.</td>
</tr>
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<td>Collection Time:</td>
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</tr>
<tr>
<td></td>
<td>Rectal Biopsies – PD (FSR)</td>
<td>BTM</td>
<td>BPS</td>
<td>N/A</td>
<td>1 ____<em><strong>.</strong></em> - ____<em><strong>.</strong></em> = ____<em><strong>.</strong></em> mg</td>
</tr>
<tr>
<td></td>
<td>Collection Time:</td>
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<td></td>
<td>2 ____<em><strong>.</strong></em> - ____<em><strong>.</strong></em> = ____<em><strong>.</strong></em> mg</td>
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<td>3 ____<em><strong>.</strong></em> - ____<em><strong>.</strong></em> = ____<em><strong>.</strong></em> mg</td>
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<td>4 ____<em><strong>.</strong></em> - ____<em><strong>.</strong></em> = ____<em><strong>.</strong></em> mg</td>
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<td>Post-weight - Pre-weight = Net weight</td>
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<td>Transport biopsies to processing lab within 15-30 minutes of collection for processing. Enter PD into Other Spec ID field of LDMS.</td>
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<td></td>
<td>Rectal Biopsies – T Cell Phenotyping (FSR)</td>
<td>BTM</td>
<td>BPS</td>
<td>N/A</td>
<td>Transport on ice to lab for testing. Enter PHENO into Other Spec ID field of LDMS.</td>
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<td>Collection Time:</td>
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<tr>
<td></td>
<td>Rectal Biopsy – Proteomics (FSR)</td>
<td>NON</td>
<td>BPS</td>
<td>N/A</td>
<td>Post-weight - Pre-weight = Net weight</td>
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<td>Collection Time:</td>
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<td>Time Frozen:</td>
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**Rectal Biopsies – Gene expression microarrays (FSR)**
- 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.
- Transport biopsies to processing lab within 15-30 minutes of collection for processing. Enter PD into Other Spec ID field of LDMS.

**Rectal Biopsy – Histology (FSR)**
- Store at room temperature and batch ship to MTN NL quarterly.

**Rectal Biopsies – PD (FSR)**
- 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)**
- Transport on ice to lab for testing. Enter PHENO into Other Spec ID field of LDMS.

**Rectal Biopsy – Proteomics (FSR)**
- Post-weight - Pre-weight = Net weight
- Time Frozen:                   
- Freeze at ≤-70°C within 2 hours of collection. Enter PRO into Other Spec ID field of LDMS.

**Comments:**

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________________________________________________________________________________

**Initials:**
- Sending Staff
- Receiving Staff

**LDMS Data Entry Date:**
- Sending Staff
- Receiving Staff

**Version 2.0 02-Jan-18**
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**LDMS CODES:**

- BPS: Biopsy
- BTM: Biopsy Transport Media
- FOR: Formalin
- FSR: Rectal biopsy by flexible sigmoidoscopy
- NON: None
- RNL: RNAlater