

MTN 037 Specimens

LDMS Specimen Tracking Sheet

For login of MTN 037 stored specimens into LDMS

Participant ID <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> - <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> - <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> </div> <div style="display: flex; justify-content: space-around; font-size: 10px; margin-top: 5px;"> Site Number Participant Number Chk </div>	Visit Code <div style="display: flex; justify-content: center; align-items: center; margin-top: 5px;"> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> . <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> </div>	Specimen Collection Date <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 5px;"> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> </div> <div style="display: flex; justify-content: space-around; font-size: 10px; margin-top: 5px;"> dd MMM yy </div>
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Visit 3/5/7 Randomization PK Time Point (circle one): **0.5-1.0 hr** **1.5-3.0 hr** **3.5-5.0 hr** **24 hr**
 Note: When logging PK/PD samples into LDMS use latest timepoint identified in the range.
 For example, for 0.5-1.0hr time point range, log into LDMS as 1.0 hr

# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB ADD/DER	INSTRUCTIONS FOR PROCESSING
<input type="checkbox"/>	Vaginal Swab – PK (VAG) (WHITE cryovial) Collection Time: _____ : _____ Hour : Min	NON	SWB	N/A	$\frac{\text{Post-weight}}{\text{Pre-weight}} = \frac{\text{Net weight}}{\text{mg}}$ Time Frozen: _____ : _____ Hour : Min Freeze at ≤-70°C within 2 hours of collection.
<input type="checkbox"/>	Anal Swab – HPV (ANL) (Digene kit) Collection Time: _____ : _____ Hour : Min	VTM	SWB	N/A	Time Frozen: _____ : _____ Hour : Min Freeze at ≤-70°C within 2 hours of collection. Enter HPV into Other Spec ID field of LDMS.
<input type="checkbox"/>	Rectal Sponge – PK (REC) (5ml plain vial) Collection Time: _____ : _____ Hour : Min	NON	SPG	N/A	$\frac{\text{Post-weight}}{\text{Pre-weight}} = \frac{\text{Net weight}}{\text{mg}}$ 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 Sponge – PD and Biomarkers (REC) (5ml ORANGE vial) Collection Time: _____ : _____ Hour : Min	NON	SPG	N/A	$\frac{\text{Post-weight}}{\text{Pre-weight}} = \frac{\text{Net weight}}{\text{mg}}$ 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 Enema – PD/PK (REC) (50mL conical) 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.

Comments: _____

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

MTN 037 Specimens

LDMS Specimen Tracking Sheet

For login of MTN 037 stored specimens into LDMS

MTN 037 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:

ANL: Anal
BPS: Biopsy
FLD: Fluid
FSR: Rectal biopsy by flexible sigmoidoscopy

NON: None
NSL: Normal Saline
PEN: Non-viable cells from non-blood specimen
REC: Rectal

SPG: Sponge
SWB: Swab
VAG: Vaginal Swab
VTM: Viral Transport Media

MTN 037 Specimens

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For login of MTN 037 stored specimens into LDMS

MTN 037 LDMS Specimen Tracking Sheet (non-DataFax)

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.
- **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.
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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