|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **MTN-030 LDMS TRACKING SHEET** | | | | | | **PAGE 1** | | **Use for Single Timepoint PK Visits and for**  **0.0 HRS Enrollment (VIS 2, pre-ring insertion) and**  **0.0 HRS Day 14 (VIS 7, pre-ring removal)** | | | | | | |
| |  | | --- | | **Participant ID: Visit Code: Specimen Collection Date:** | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  | – |  |  |  |  |  | – |  |  |  |  | . |  |  |  |  | / |  |  |  | / |  |  |   Site Number Participant Number Chk *dd MMM yy* | | | | | | | | | | | | | | | |
| **# Primary Received** | | | **SPECIMEN** | | | **# Aliquots**  **(Lab use only)** | | **Collection Time** | **Post-**  **weight** | | **Pre-**  **weight** | **Net**  **Weight** | **Freezing**  **Time** | |
|  | | | **Blood - Plasma archive**  Primary Specimen: **BLD**  Primary Additive: **EDT**  Aliquot Derivative: **PL1 or PL2**  Aliquot Sub: **N/A**  If follow-up visit, include:  Other Spec ID: **CON** | | | 2 | | **\_\_ \_\_:\_\_ \_\_**  hour : min | **Single spin:** 1300xg, 10 minutes  **OR Double spin:** 800×g, 10 minutes. Place plasma in a tube to spin again at 800×g for 10 minutes.  For each “test”, label two cryovials and aliquot 1.5-mL or more of plasma into each cryovial. Freeze plasma at ≤ -70oC within 4 hours (archive) or 8 hours (PK) of blood collection. | | | | | |
|  | | | **Blood *PK\****  Primary Specimen: **BLD**  Primary Additive: **EDT**  Aliquot Derivative: **PL1 or PL2**  Aliquot Sub: **N/A** | | | 4  **(2 for DPV,**  **2 for LNG)** | | **\_\_ \_\_:\_\_ \_\_**  hour : min |
|  | | | **Vaginal *PK\****  Primary Specimen: **VAG**  Primary Additive: **NON**  Aliquot Derivative: **SWB**  Aliquot Sub: **N/A** | | | **Swab 1**  **□DPV □LNG** | | **\_\_ \_\_:\_\_ \_\_**  hour : min | **\_\_\_\_\_\_\_\_.\_\_\_** mg | | **\_\_\_\_\_\_\_\_.\_\_\_** mg | **\_\_\_\_\_\_\_\_.\_\_\_** mg | **\_\_ \_\_:\_\_ \_\_**  hour : min | |
| **Swab 2**  **□DPV □LNG** | | **\_\_ \_\_:\_\_ \_\_**  hour : min | **\_\_\_\_\_\_\_\_.\_\_\_** mg | | **\_\_\_\_\_\_\_\_.\_\_\_** mg | **\_\_\_\_\_\_\_\_.\_\_\_** mg | **\_\_ \_\_:\_\_ \_\_**  hour : min | |
| **Mark heavier swab for LNG.**    For LDMS, primary sample of 2 swabs, each having one aliquot. **Type LNG or DPV in OTHER SPEC ID for the aliquot.** | | | May be kept on ice until frozen.  Freeze at ≤ -70oC within 2 hours of collection. | | | | | |
|  | | | **Vaginal Gram Stain**  Primary Specimen: **VAG**  Primary Additive: **NON**  Aliquot Derivative: **SLD**  Aliquot Sub: **GRS** | | | 2 | | N/A | Write the PTID and collection date on the frosted end of the slide (Affix LDMS here). Place SCHARP-provided PTID label on the underside of the slides. Roll vaginal swab across the slide. | | | | | |
|  | | | **Used Vaginal Ring**  Primary Specimen: **IVR**  Primary Additive: **NON**  Aliquot Derivative: **IVR**  Aliquot Sub: **N/A** | | | 1 | | N/A | Place ring into a labeled amber biohazard bag. Store at -20C. | | | | **\_\_ \_\_:\_\_ \_\_**  hour : min | |
|  | | |  | | |  | |  |  | |  |  |  | |
|  | | | COMMENTS: | | |  | |  |  | |  |  |  | |
|  | | |  | | |  | |  |  | |  |  |  | |
|  | | |  | | |  | |  |  | |  |  |  | |
|  | | | **Delivered by:** | | |  | | **Date:** |  | | **Time:** |  |  | |
|  | | | **Received by:** | | |  | | **Date:** |  | | **Time:** |  |  | |
|  | | | **LDMS entry by\*:** | | |  | | **Date:** |  | |  |  |  | |
|  | | | **\***For V2 and V7, did you enter time-point for PK samples in LDMS (see Table 9-4)? | | | | | | | | |  |  | |
| **MTN-030 LDMS TRACKING SHEET** | | | | | | **PAGE 2** | | **Use for Multiple Timepoint PK visits: Enrollment (VIS 2, post-ring insertion) & Day 14 (VIS 7, 6 HR post-ring removal)** | | | | | | | |
| |  | | --- | | **Participant ID: Visit Code: Specimen Collection Date:** | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  | – |  |  |  |  |  | – |  |  |  |  | . |  |  |  |  | / |  |  |  | / |  |  | | Site | | |  | Participant Number | | | | | Chk | | |  | | | |  | dd | |  | MMM | | |  | yy | | | | S | |  | |  | |  | | | | | | | | | | | | | | | | |
| **Processing Instructions** | | | | **Vaginal PK processing** | | May be kept on ice until frozen. Freeze at ≤ -70oC within 2 hours of collection. | | | | | | | | | |
| **Blood PK processing** | | **Single spin:** 1300xg, 10 minutes **OR Double spin:** 800×g, 10 minutes. Aliquot plasma into a tube to spin again at 800×g for 10 minutes. For each “test”, label two cryovials and aliquot 1.5-mL or more of plasma into each cryovial. Freeze plasma at ≤ -70oC within 8 hours (PK) of blood collection. | | | | | | | | | |
|  |  | | | | | | | | | | | | | | |
| **Delivered by, Time** | **Received by, Time, Date** | | **# Primary Received** | | **SPECIMEN\***  **(with Time and Time Unit values for LDMS)** | **Aliquot #**  **(with Other Spec ID for LDMS; Lab use only)** | | **Collection Time**  **(hr : min)** | | **Post-**  **Weight**  **(mg)** | **Pre-**  **Weight**  **(mg)** | **Net**  **Weight**  **(mg)** | **Freezing**  **Time**  **(hr: min)** | | |
|  |  | |  | | **1.0 HRS Vaginal *PK***  Primary Specimen: **VAG**  Primary Additive: **NON**  Aliquot Derivative: **SWB**  Aliquot Sub: **N/A** | **Swab 1**  **□DPV □LNG** | | \_\_ \_\_:\_\_ \_\_ | | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_ \_\_:\_\_ \_\_ | | |
|  |  | |  | | **Swab 2**  **□DPV □LNG** | | \_\_ \_\_:\_\_ \_\_ | | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_ \_\_:\_\_ \_\_ | | |
|  |  | |  | | **1.0 HRS Blood *PK***  Primary Specimen: **BLD**  Primary Additive: **EDT**  Aliquot Derivative: **PL1/PL2**  Aliquot Sub: **N/A** | 4 aliquots  **(2 for DPV,**  **2 for LNG)** | | \_\_ \_\_:\_\_ \_\_ | | Comments, 1-HR samples: | | | | | |
|  |  | |  | | **2.0 HRS Vaginal *PK***  Primary Specimen: **VAG**  Primary Additive: **NON**  Aliquot Derivative: **SWB**  Aliquot Sub: **N/A** | **Swab 1**  **□DPV □LNG** | | \_\_ \_\_:\_\_ \_\_ | | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_ \_\_:\_\_ \_\_ | | |
|  |  | |  | | **Swab 2**  **□DPV □LNG** | | \_\_ \_\_:\_\_ \_\_ | | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_ \_\_:\_\_ \_\_ | | |
|  |  | |  | | **2.0 HRS Blood *PK***  Primary Specimen: **BLD**  Primary Additive: **EDT**  Aliquot Derivative: **PL1/PL2**  Aliquot Sub: **N/A** | 4 aliquots  **(2 for DPV,**  **2 for LNG)** | | \_\_ \_\_:\_\_ \_\_ | | Comments, 2-HR samples: | | | | | |
|  |  | |  | | **4.0 HRS Vaginal *PK***  Primary Specimen: **VAG**  Primary Additive: **NON**  Aliquot Derivative: **SWB**  Aliquot Sub: **N/A** | **Swab 1**  **□DPV □LNG** | | \_\_ \_\_:\_\_ \_\_ | | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_ \_\_:\_\_ \_\_ | | |
|  |  | |  | | **Swab 2**  **□DPV □LNG** | | \_\_ \_\_:\_\_ \_\_ | | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_ \_\_:\_\_ \_\_ | | |
|  |  | |  | | **4.0 HRS Blood *PK***  Primary Specimen: **BLD**  Primary Additive: **EDT**  Aliquot Derivative: **PL1/PL2**  Aliquot Sub: **N/A** | 4 aliquots  (**2 for DPV,**  **2 for LNG**) | | \_\_ \_\_:\_\_ \_\_ | | Comments, 4-HR samples: | | | | | |
|  |  | |  | | **6.0 HRS Vaginal *PK***  Primary Specimen: **VAG**  Primary Additive: **NON**  Aliquot Derivative: **SWB**  Aliquot Sub: **N/A** | **Swab 1**  **□DPV □LNG** | | \_\_ \_\_:\_\_ \_\_ | | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_ \_\_:\_\_ \_\_ | | |
|  |  | |  | | **Swab 2**  **□DPV □LNG** | | \_\_ \_\_:\_\_ \_\_ | | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_\_\_\_\_\_\_.\_\_\_ | \_\_ \_\_:\_\_ \_\_ | | |
|  |  | |  | | **6.0 HRS Blood *PK***  Primary Specimen: **BLD**  Primary Additive: **EDT**  Aliquot Derivative: **PL1/PL2**  Aliquot Sub: **N/A** | 4 aliquots  **(2 for DPV,**  **2 for LNG)** | | **\_\_ \_\_:\_\_ \_\_** | | Comments, 6-HR samples: | | | | | |
|  |  |  | | |  | |  |  | |  |  |  |  |  | | |
|  | **Is all information, including TIME and**  **TIME UNIT, entered into LDMS?** | | | | | | | Yes□ | | No□ | **Initial/Date:** |  |  |  | | |

**MTN-030 LDMS Tracking Sheet Instructions**

**Purpose:** This form is used to document collection and entry of study 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 laboratory. Once the specimens have been entered into LDMS, this form is kept on file at the LDMS laboratory. Although not required, 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.

**Item-specific Instructions:**

* **SCHARP** **Visit Code:** Record the visit code using Section 11 DATA COLLECTION SSP, Table 11-2:Visit Code Assignments
* **# Primary Received:** Record the total number of tubes or specimens collected for that primary specimen type. If none, record “0”.
* **Primary Specimen, Primary Additive, and Aliquot Derivative Codes:** See table below for a listing of the codes.

|  |  |
| --- | --- |
| **BLD**: Whole Blood | **EDT**: EDTA |
| **VAG**: Vaginal Swab | **NON**: No Additive |
| **IVR**: Used Intravaginal Ring | **SLD**: Slide |
| **PL1/2**: Single or double spun plasma | **SWB**: Swab |
| **N**/**A**: Not Applicable | **GRS**: Gram stain slide |

* **Collection Time** is required for all blood and vaginal PK specimens. Use 24 hour (military) time clock; for LDMS entry.
* **Freezing Time** is required for all vaginal PK swabs. Use 24 hour (military) time clock; for LDMS entry.
* **Post-** and **Pre-weight** is recorded on the LDMS tracking sheet; however, only **NET WEIGHT** is entered into LDMS. Important: Check calculation.
* **Initials, Date, and Time** – **Transferring Staff**: The clinical staff representative, who transferred the LDMS form and specimens to a representative of the LDMS laboratory, records his/her initials here, date, and time (in 24 hour time clock).
* **Initials, Date, and Time – Receiving Staff:** The LDMS laboratory representative, who received this form and samples, records his/her initials, date, and time (in 24 hour clock).
* **Vaginal PK, DPV or LNG check box** (for LDMS laboratory personnel only). For the swab with the larger value for net weight, check the LNG box and ensure that it is stored virtually and in the freezer box for LNG PK testing. The remaining swab is marked for DPV and stored virtually and in the freezer box for DPV PK testing.
* **LDMS Data Entry and Date:** The LDMS laboratory member, who ensured that all specimens were entered into LDMS, records his/her initials and dates the form.
* **For Blood Plasma Archive:** If blood is collected at a follow-up visit for the MTN LC Virology Core to perform confirmatory testing (i.e. HIV-resistance and viral load), in LDMS, enter “CON” for Other Specimen ID to distinguish it from PK plasma aliquots.

**For Multiple PK Time-point visits, page 2:** A copy may be issued to the LDMS laboratory for the purpose of LDMS entry and sample processing after each sample transaction. To ensure all original recordings are on it, the original LDMS tracking sheet will remain in the possession of the clinical staff until the last set of samples is collected.

* **Delivered by and Time** are recorded by the person from the clinic transferring the samples to the LDMS laboratory representative. If the samples being transferred are adjacent on the list, a single recording for that transaction time is acceptable, and appropriate samples are marked with a line drawn from the representative’s recording.
* **Received by, Time, AND Date** are recorded by the representative of the LDMS laboratory receiving samples. If the samples being transferred are adjacent on the list, a single recording for that transaction time is acceptable, and appropriate samples are marked with a line drawn from the representative’s recording.
* **Multiple Time-point visits, page 2, LDMS entries completed:** The LDMS laboratory representative attesting to all samples being logged into LDMS will mark “Yes” and record his/her initials and date.