|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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** | **INSTRUCTIONS FOR PROCESSING LAB** |
|  | Blood **(BLD)**  plasma archive  **Collection Time**  **\_\_ \_\_:\_\_ \_\_**  **hour : min** | **EDT**  (purple top) | **PL1**  **or**  **PL2** | **N/A** | **Single spin**: 1500xg, 10 minutes **OR**  **Double spin:** 800×g,10 minutes. Place plasma in a tube to spin again at 800×g for 10 minutes.  Into two cryovials, aliquot 1.0-mL plasma and freeze plasma ≤-70oC.  After collection, if blood tube stored:  -at room temp, freeze plasma within 4 hours.  -in refrigerator (4oC), freeze plasma within 24 hours. (Section 10.7.5) |
|  | Blood **(BLD)** *PK single time-point*  **Collection Time**  **\_\_ \_\_:\_\_ \_\_**  **hour : min** | **EDT**  (purple top) | **PL1**  **or**  **PL2** | **N/A** | **Single spin:** 1500xg, 10 minutes **OR**  **Double spin:** 800×g,10 minutes. Place plasma in a tube to spin again at 800×g for 10 minutes.  Label two cryovials and aliquot 1.0-mL or more of plasma into each cryovial.  Freeze plasma at ≤ -70oC within 8 hours of blood collection. (Section 10.7.6) |
|  | Cervicovaginal  Lavage **(CVL)**  **Collection Time**  **\_\_ \_\_:\_\_ \_\_**  **hour : min** | **NSL** | **FLD** | **N/A** | Refrigerate or keep on ice until processing.  CVL supernatant for biomarkers.  Centrifuge: 800xg, 10 minutes.  **Prepare 1.0-mL aliquots:**  **-in one cryovial marked CVL.**  **-in at least 5 additional cryovials marked “extra CVL” for future storage or backup.**  Freeze at ≤ -70oC within 8 hours of collection.  (Section 10.8.2) |
| **CEN** | **NSL** | Refrigerate or keep on ice until processing.  CVL cell pellet: After supernatant collection, re-centrifuge 800xg, 10 minutes.  Pipet remaining supernatant into a supernatant cryovial above and resuspend pellet in 0.5-mL of normal saline. Pipet into cryovial.  Freeze at ≤-70oC within 8 hours of collection. (Section 10.8.2) |

**Comments:**

LDMS Staff

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**Initials:**

Sending Staff

**LDMS Data Entry Date:**

*dd*

*MMM*

*yy*

Receiving Staff

**Purpose:** This non-DataFax 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 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 specimens were collected.

 **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.”:

 **Primary Specimen, Primary Additive, and Aliquot Derivative Codes:** See table below for a listing of the codes.

|  |  |  |
| --- | --- | --- |
| BLD: Whole Blood | IVR: Used Intravaginal Ring | PBS: Phosphate buffered saline |
| CEN: Cell Pellet | N/A: Not Applicable | PL1: Single spun plasma |
| GRS: Gram stain slide | NON: No Additive | PL 2: Double spun plasma |
| EDT: EDTA | NSL: Normal Saline | SWB: Swab |
| FLD: Fluid Supernatant | PAC: Port-a-Cul | VGL: Vagina |

 **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.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **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** | **INSTRUCTIONS FOR PROCESSING LAB** | |
|  | Vaginal Swab  **(VGL)**  *For Biomarker*  **Collection Time**  **\_\_ \_\_:\_\_ \_\_**  **hour : min** | **PBS** | **SWB** | **N/A** | Place Dacron swab in 400-uL PBS. Refrigerate or keep on ice, until frozen.  Freeze at ≤ -70oC within 8 hours.  (Section 10.9.7)  **Freezing Time**  **\_\_ \_\_:\_\_ \_\_**  **hour : min** | |
|  | Vaginal Swab  **(VGL)**  for PK  **Collection Time**  **\_\_ \_\_:\_\_ \_\_**  **hour : min** | **NON** | **SWB** | **N/A** | May be kept on ice until frozen.  Freeze at ≤ -70oC within 2 hours of collection.  (Section 10.9.8)  **Freezing Time**  **\_\_ \_\_:\_\_ \_\_**  **hour : min**   |  | | --- | | **\_\_\_\_\_\_\_\_.\_\_\_ - \_\_\_\_\_\_\_\_.\_\_\_ = \_\_\_\_\_\_\_\_.\_\_\_ mg**  **Post-weight Pre-weight Net weight** | | |
|  | Vaginal Smear  **(VGL)**  for Gram Stain | **NON** | **SLD** | **GRS** | Write the PTID and specimen collection date on the frosted end of the slide.  Roll vaginal swab across the slide.  A SCHARP-provided PTID label is to be placed on the underside of the slides. (Section 10.9.2) | |
|  | Vaginal Culture  **(VGL)** | **PAC** | **SWB** | **N/A** | Collect vaginal sample using 2 Dacron swabs and place into the agar of Port-a-Cul tube.  On the day of collection, prepare shipment on ice packs for standard overnight delivery to MTN LC. (Section 10.9.3) | |
|  | Used Vaginal Ring  **(IVR)**  for residual PK | **NON** | **IVR** | **N/A** | Rinse the ring (in sterile container), blot dry. Place ring into a labeled amber biohazard bag.  Store at room temp. (Section 10.10) | |

**Comments:**

LDMS Staff

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**Initials:**

Sending Staff

**LDMS Data Entry Date:**

*dd*

*MMM*

*yy*

Receiving Staff

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