# Screening Visit
# Visit 01.0

### Required Forms

- Concomitant Medications (CM-1)
- Demographics (DEM-1)
- Eligibility Criteria (ECI-1)
- Pelvic Exam (PE-1)
- Pre-Existing Conditions (PRE-1)
- Physical Exam (PX-1)
- Safety Laboratory Results (SLR-1, 2)
- Pelvic Exam Diagrams (Non-DataFax)

(MTN 027) DF/Net 027 CM (423)

*Note: Number pages sequentially (01, 02, 03) for each participant.*

Page #

Participant ID

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

☐ No medications taken at Screening/Enrollment. *Staff Initials/ Date* _____

☐ No medications taken throughout study. *Staff Initials/ Date* _____

→ *End of form. Submit to DF/Net.*

## Concomitant Medications Log

**1**

Medication Name

Staff Initials/ Log Entry Date

Indication

Taken for a reported AE?

☐ *yes* ☐ *no*

AE Log page(s) ☐☐ ☐☐ ☐☐ ☐☐

Date Started ☐☐ ☐☐☐ ☐☐ *dd MMM yy*

Date Stopped ☐☐ ☐☐☐ ☐☐ *dd MMM yy* *OR* ☐ Continuing at end of study

Dose/Units

Frequency *Mark only one.*

*prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify* ☐ _____

Route *Mark only one.*

*PO* ☐ *IM* ☐ *IV* ☐ *TOP* ☐ *IHL* ☐ *VAG* ☐ *REC* ☐ *SC* ☐ *other, specify* ☐ _____

**2**

Medication Name

Staff Initials/ Log Entry Date

Indication

Taken for a reported AE?

☐ *yes* ☐ *no*

AE Log page(s) ☐☐ ☐☐ ☐☐ ☐☐

Date Started ☐☐ ☐☐☐ ☐☐ *dd MMM yy*

Date Stopped ☐☐ ☐☐☐ ☐☐ *dd MMM yy* *OR* ☐ Continuing at end of study

Dose/Units

Frequency *Mark only one.*

*prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify* ☐ _____

Route *Mark only one.*

*PO* ☐ *IM* ☐ *IV* ☐ *TOP* ☐ *IHL* ☐ *VAG* ☐ *REC* ☐ *SC* ☐ *other, specify* ☐ _____



_____ *Staff Initials/Date*

**Purpose:**

All medication(s) that are used by the participant during the study [(including the protocol-defined screening period)], other than study product, must be documented on this form. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, and naturopathic preparations.

**General Instructions:**

When to fax this form:

- once the participant has enrolled in the study;
- when pages have been updated or additional Log pages have been completed (only fax updated or new pages);
- when the participant has completed study participation; and/or
- when instructed by SCHARP.

**Item-specific Instructions:**

| | |
|---|---|
| **Page #** | Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any **Concomitant Medications Log** pages after faxing, unless instructed by DF/Net. |
| **No medications taken at Screening/ Enrollment** | Mark this box if no medications were taken by the participant from Screening through the Enrollment visit. This box should only be marked on Page 01. |
| **No medications taken throughout study** | Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study. |
| **Medication Name** | Record generic name of medication. For combination generic medications, record the first three main active ingredients, if applicable. |
| **Indication** | For health supplements, such as multivitamins, record “general health.” For preventive medications, record “prevention of [insert condition]” (e.g., for flu shot, record “prevention of influenza”). |
| **Date Started** | If the participant is unable to recall the exact date, obtain participant’s best estimate. At a minimum, the year is required. |
| **Date Stopped** | At the participant’s Termination visit, the “Date Stopped” must be recorded for each medication OR the “Continuing at end of study” box must be marked. At a minimum, the month and year are required. |
| **Frequency** | Below is a list of common frequency abbreviations:<br>prn: as needed; qd: every day; tid: three times daily; qhs: at bedtime<br>once: one time; bid: twice daily; qid: four times daily; other specify: alternative dosing schedules |
| **Dose/Units** | If the participant does not know the dose or units, draw a single line through the blank response box and initial and date. For prescription combination medications, record the dosage of first three main active ingredients. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon). |
| **Route** | Below is a list of common route abbreviations:<br>PO: oral; IV: intravenous; IHL: inhaled; REC: rectal; other, specify:<br>IM: intramuscular; TOP: topical; VAG: vaginal; SC: subcutaneous; alternative routes |

(MTN 027) DF/Net 027 DEM (001)

Participant ID ___ – ___ – ___
*Site Number* *Participant Number* *Chk*

Form Completion Date ___ ___ ___
*dd* *MMM* *yy*

## Demographics

1. What is your date of birth? dd ___ MMM ___ yy ___

2. What was your sex at birth? ☐ *male* ☒ *female*

3. Are you currently married? ☐ *yes* ☐ *no*

4. Do you currently live with your partner? ☐ *yes* ☐ *no*

5. What is your highest level of education?
   - ☐ no schooling
   - ☐ primary school, not complete
   - ☐ primary school, complete
   - ☐ secondary school, not complete
   - ☐ secondary school, complete
   - ☐ attended college or university

6. Do you consider yourself to be Latino/a or of Hispanic origin? ☐ *yes* ☐ *no*

7. What is your race? *Mark all that apply.*
   - ☐ 7a. American Indian or Alaska Native
   - ☐ 7b. Asian
   - ☐ 7c. Black or African American
   - ☐ 7d. Native Hawaiian or other Pacific Islander
   - ☐ 7e. White
   - ☐ 7f. Other, specify: _____

8. Do you earn an income of your own? *yes* ☐ *no* ☐ → *If no, go to item 9.*

   8a. How do you earn income? *Mark all that apply.*
   ☐ *formal employment* ☐ *self-employment* ☐ *other*

9. How do you identify your gender? *Mark all that apply.*
   - ☐ 9a. male
   - ☐ 9b. female
   - ☐ 9c. transgender male (female to male)
   - ☐ 9d. additional category, specify: _____
   - ☐ 9e. decline to state



_____
*Staff Initials/Date*

**Purpose:**

This form is interviewer-administered and is used to collect participant's demographic and socioeconomic information.

**General Instructions:**

This form is faxed to DataFax only if the participant enrolls in the study. This form is completed at the Screening Visit. Read each item aloud, except item 2, and record the participant's response.

**Item-specific Instructions:**

| | |
|---|---|
| **Item 3** | Mark "yes" if the participant is in a legally-binding marriage and has obtained a marriage certificate. |
| **Item 5** | If the participant attended or completed a post-secondary diploma or certificate program mark "attended college or university." |
| **Item 6** | This item is based on self-definition. Per NIH policy, Latina or Hispanic includes a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. |
| **Item 7** | Record the participant's race based on self-definition. In the case of mixed race, mark all that apply and/or "other" and indicate the mixed race background. Per NIH policy, Latino/a is considered an ethnic group and not a race and should not be entered in item 7f. |
| **Item 9** | This item must be self-reported by the participant. Site staff is encouraged to document in chart notes if the participant during study participation prefers to be referred to by a specific pronoun or gender. |

(MTN 027) DF/Net 027 ECI (023)

Participant ID ☐☐☐ – ☐☐☐☐☐ – ☐
*Site Number* *Participant Number* *Chk*

Form Completion Date ☐☐ ☐☐☐ ☐☐
*dd* *MMM* *yy*

## Eligibility Criteria

1. Does this participant meet all eligibility criteria? *yes* ☐ *no* ☐ → *If no, go to item 2*

1a. Obtain signature _____
*Signature of Principal Investigator (or designee)* *Date*

1b. Obtain signature _____
*Signature of second staff member verifying eligibility* *Date*

2. Was the participant enrolled? *yes* ☐ *no* ☐ → *If yes, end of form.*

3. Why was the participant not enrolled?

- ☐ participant did not complete all screening procedures → *End of form.*
- ☐ eligible but declined enrollment → *End of form.*
- ☐ not eligible

4. Reason(s) for ineligibility *Mark all that apply.*

- ☐ 4a. participant < 18 or > 45 years old
- ☐ 4b. plans for relocation/travel
- ☐ 4c. participant is pregnant or planning to become pregnant within the next 3 months
- ☐ 4d. participant is breastfeeding
- ☐ 4e. participant unwilling to refrain from receptive sexual activity
- ☐ 4f. participant has enrolled in another research study in the last 60 days
- ☐ 4g. diagnosed with PID, RTI, or STI, which has not resolved
- ☐ 4h. PEP or PrEP exposure in the last 6 months
- ☐ 4i. participant is HIV-positive
- ☐ 4j. participant declines effective method of contraception
- ☐ 4k. participant has a grade 1 or higher pelvic exam finding
- ☐ 4l. participant does not meet laboratory eligibility criteria. Specify or provide test results: _____
- ☐ 4m. participant does not meet other clinical eligibility criteria
- ☐ 4n. other reason, including investigator decision. Specify: _____

Comments: _____



_____
*Staff Initials/Date*

**Purpose:**

This form is used to document participant eligibility for enrollment in this study or reasons for participant ineligibility.

**General Instructions:**

Complete this form for each participant screened for this study. Complete and fax this form once it is determined whether the participant will enroll in the study. If not enrolled, this is the only form that is faxed for the participant.

If the participant has a second screening attempt, update this form with data from the second screening attempt and refax. Do not complete a new form for the second attempt.

**Item-specific Instructions:**

| | |
|---|---|
| **Items 1a and 1b** | Local site Standard Operating Procedures (SOPs) must specify staff members designated to affirm eligibility. |
| **Item 3** | Mark “participant did not complete all screening procedures” when a participant begins the screening process and is eligible, but does not return to the clinic to complete screening procedures within the 45-day screening window. |
| **Item 4** | Mark all reasons for participant ineligibility. Refer to the Eligibility Checklist for the Screening and Enrollment Visit. If the reason for ineligibility is not listed, mark the “other reason, including investigator decision” box and specify ineligibility reason on the line provided. |

(MTN 027) DF/Net 027 PE (138)

Visit Code ☐☐.☐

Participant ID ☐☐☐-☐☐☐☐☐-☐ (*Site Number* – *Participant Number* – *Chk*)

Visit Date ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

## Pelvic Exam

**1** Vaginal pH: ☐ *Not done* ☐.☐ *If > 4.5, mark Positive* → ☐ *Positive*

**2** Pelvic exam assessment: ☐ *Not done* → *End of form.* ☐ *Abnormal findings* ☐ *No abnormal findings* → *End of form.*

2a. Abnormal findings. *Mark all that apply.*

| VULVAR | VAGINAL | CERVICAL | GENERAL/OTHER |
|---|---|---|---|
| ☐ *Vulvar edema* | ☐ *Vaginal edema* | ☐ *Cervical edema and/or friability* | ☐ *Odor (vaginal)* |
| ☐ *Vulvar erythema* | ☐ *Vaginal erythema* | ☐ *Cervical erythema* | ☐ *Condyloma, specify location:* |
| ☐ *Vulvar rash* | ☐ *Vaginal masses (polyps, myomas, possible malignancy)* | ☐ *Cervical masses (polyps, myomas, possible malignancy)* | _____ |
| ☐ *Vulvar tenderness* | ☐ *Vaginal abrasions or lacerations* | ☐ *Cervical motion tenderness* | ☐ *Adnexal masses (based on bimanual exam; not pregnancy or infection-related)* |
| ☐ *Bartholin's or Skene's gland abnormality* | ☐ *Vaginal tenderness* | ☐ *Cervical discharge* | ☐ *Uterine masses (based on bimanual exam)* |
| | ☐ *Abnormal vaginal discharge* → *slight* ☐ *moderate* ☐ *pooling* ☐ | | ☐ *Uterine tenderness* |
| | | | ☐ *Adnexal tenderness* |
| **Vulvar lesions** | **Vaginal lesions** | **Cervical lesions** | ☐ *Observed blood or bleeding, describe:* |
| ☐ *Ulcer* | ☐ *Ulcer* | ☐ *Ulcer* | _____ |
| ☐ *Blister* | ☐ *Blister* | ☐ *Blister* | _____ |
| ☐ *Pustule* | ☐ *Pustule* | ☐ *Pustule* | _____ |
| ☐ *Peeling* | ☐ *Peeling* | ☐ *Peeling* | _____ |
| ☐ *Ecchymosis* | ☐ *Ecchymosis* | ☐ *Ecchymosis* | |

☐ 2b. Other abnormal findings, specify (include anatomical location): _____

*Complete or update Pre-existing Conditions or Adverse Experience Log, as applicable.*

**3** Are any new pelvic finding AEs reported at this visit? ☐ *Yes* ☐ *No* → *End of form.*

3a. AE Log page #(s): *Line through any unused boxes.*

☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐



_____
*Staff Initials/Date*

**Purpose:**

This form is used to document the participant's pelvic exam assessment.

**General Instructions:**

Complete this form at Screening, Enrollment, at all follow-up study visits, and early termination visit (as applicable), and when a clinically indicated pelvic exam is performed during interim visits. Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to DataFax.

**Item-specific Instructions:**

| | |
|---|---|
| **Item 1** | Vaginal fluid pH is required at Enrollment Visit, Day 3, Day 28, Day 29, Day 30, Day 31, and Day 35/Final Clinic Visit. |
| **Item 2** | Note that observation of any genital blood or bleeding is considered an abnormal finding, regardless of whether the blood is expected (menstrual blood, for example). If blood or bleeding is observed, mark "abnormal findings" and in item 2a, mark "observed blood or bleeding; describe" and describe on the lines provided. |
| **Item 2a** | • Mark the box to the left of each abnormal finding observed. In general, for abnormal findings reported as adverse events on an AE Log, use text from item 2a as AE descriptive text finding (this does not apply to observances of blood or bleeding).<br>• **Observed blood or bleeding; describe:** If blood or bleeding is observed, mark this item and in the space provided, briefly describe the color, amount, and location of the blood/bleeding. If known, specify if the blood was menstrual or non-menstrual. Assess the blood/bleeding for AE reporting purposes. Please refer to Study-specific Procedures (SSP) manual section section 8 for AE reporting guidance for observed bleeding.<br>• Each instance of observed blood/bleeding should be assessed for severity grade per the applicable rows of the *Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Addendum 1: Female Genital Grading Table for Use in Microbicide Studies (FGGT)*. Refer to SSP manual section 8 for more information/guidance as needed. |
| **Item 2b** | If an observed abnormal finding is not listed, mark "other abnormal findings, specify" and describe the abnormal finding on the line provided, including anatomical location. |

(MTN 027) DF/Net 027 PRE (012)

*Note: Number pages sequentially (01, 02, 03) for each participant.* Page #

Participant ID

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

☐ No pre-existing conditions reported or observed.

*Staff Initials/Date*

→ *End of form. Submit to DF/Net.*

## Pre-existing Conditions

| | | | |
|---|---|---|---|
| **1** | Condition | Onset Date MMM yy | Staff Initials/Date |
| | Comments | Ongoing at Enrolment? *yes* ☐ *no* ☐ | Severity Grade ☐ *or* ☐ *not gradable* |
| **2** | Condition | Onset Date MMM yy | Staff Initials/Date |
| | Comments | Ongoing at Enrolment? *yes* ☐ *no* ☐ | Severity Grade ☐ *or* ☐ *not gradable* |
| **3** | Condition | Onset Date MMM yy | Staff Initials/Date |
| | Comments | Ongoing at Enrolment? *yes* ☐ *no* ☐ | Severity Grade ☐ *or* ☐ *not gradable* |
| **4** | Condition | Onset Date MMM yy | Staff Initials/Date |
| | Comments | Ongoing at Enrolment? *yes* ☐ *no* ☐ | Severity Grade ☐ *or* ☐ *not gradable* |



*Staff Initials/Date*

**Purpose:**

The Pre-existing Conditions form serves as the "starting point" or baseline from which study clinicians must determine whether conditions identified during follow-up are adverse events (AEs).

**General Instructions:**

- At the Screening Visit, record relevant baseline medical history. This includes conditions and symptoms reported by the participant during the baseline medical/menstrual history as well as any conditions identified via pelvic exam, physical exam, or laboratory testing. This includes, but is not limited to, history of hospitalizations, surgeries, allergies, any condition that required prescription or chronic medication (that is, more than 2 weeks in duration), and acute conditions ongoing at screening and/or that occur between screening and enrollment.
- At the Enrollment Visit, review and update as needed.
- Do record pre-existing conditions if identified during follow-up. Add a chart note to explain why the PRE entry was added after Enrollment.

**Item-specific Instructions:**

| | |
|---|---|
| **Page** | Number pages sequentially throughout the study, starting with "01." Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by DF/Net. |
| **Condition** | Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Pre-existing Conditions form. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT." |
| **Onset Date** | If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required. |
| **Comments** | This field is optional. Use it to record any additional relevant information about the condition, including any associated signs/symptoms. |
| **Ongoing at Enrollment?** | Mark "yes" for chronic conditions, as well as any other conditions, ongoing at the Enrollment Visit. If a condition resolves or increases in severity or frequency after the Enrollment Visit, document this in chart notes and/or another document other than this form. |
| **Severity Grade** | For each condition, grade the severity according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* and the *DAIDS Female Genital Grading Table for Use in Microbicide Studies* (as appropriate). If a condition is not gradable, mark "not gradable". Review and update as needed for conditions ongoing at the Enrollment Visit. |

(MTN 027) DF/Net 027 PX (036)

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐
*Site Number* *Participant Number* *Chk*

Visit Date ☐☐ ☐☐☐ ☐☐
*dd* *MMM* *yy*

## Physical Exam

### Vital Signs

Not Required ☐

| | | | | | |
|---|---|---|---|---|---|
| **1** | Height: ☐☐☐ *cm* | ☐ | **4** | BP: ☐☐☐ / ☐☐☐ | *mmHg* |
| **2** | Weight: ☐☐☐ | *kg* | **5** | Pulse: ☐☐☐ | *beats per minute* |
| **3** | Body Temp: ☐☐.☐ | *°C* | **6** | Respirations: ☐☐ | *breaths per minute* |

FINDINGS:
*Items 8–16 may be omitted after Enrollment.*

| | | Not Done | Normal | Abnormal | *Notes* |
|---|---|---|---|---|---|
| **7** | General appearance | ☐ | ☐ | ☐ | |
| **8** | Abdomen/Gastrointestinal | ☐ | ☐ | ☐ | |
| **9** | Head, eye, ear, nose, and throat | ☐ | ☐ | ☐ | |
| **10** | Neck | ☐ | ☐ | ☐ | |
| **11** | Lymph Nodes | ☐ | ☐ | ☐ | |
| **12** | Heart/Cardiovascular | ☐ | ☐ | ☐ | |
| **13** | Lungs/Respiratory | ☐ | ☐ | ☐ | |
| **14** | Extremities | ☐ | ☐ | ☐ | |
| **15** | Neurological | ☐ | ☐ | ☐ | |
| **16** | Skin | ☐ | ☐ | ☐ | |
| **17** | Other | ☐ | ☐ | ☐ | |

*Record abnormal findings on Pre-existing Conditions or Adverse Experience Log form as applicable.*

Comments: _____



_____
*Staff Initials/Date*

**Purpose:**

This form is used to document the participant's vital signs and physical exam findings.

**General Instructions:**

Complete this form at the Screening, Enrollment, and all follow-up study visits. If abnormal findings are found, for items 7–17, transcribe the information onto the Pre-existing Conditions or Adverse Experience form(s).

**Item-specific Instructions:**

| | |
|---|---|
| **Vital Signs** | Use leading zeros as applicable. |
| **Item 1** | This item is required at Screening and Enrollment only. |
| **Items 7–16** | For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings in Notes. If not evaluated, mark "not done" and record the reason in Notes. Normal findings may also be described in Notes, but is not required. |
| **Item 17** | If no other abnormal findings are identified, mark "not done." |

(MTN 027) DF/Net 027 SLR-1 (144)

Visit Code ☐☐.☐

Participant ID ☐☐☐-☐☐☐☐☐-☐ (*Site Number* – *Participant Number* – *Chk*)

Initial Specimen Collection Date ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

## Safety Laboratory Results



| | Not done/ Not collected | Alternate Collection Date (dd MMM yy) | Severity Grade *If applicable* | AE Log Page # | Not reportable as an AE |
|---|---|---|---|---|---|
| 1. HEMOGRAM | ☐ → *Go to item 2.* | ☐☐ ☐☐☐ ☐☐ | | | |
| 1a. Hemoglobin | Not reported ☐ | ☐☐.☐ *g/dL* | ☐ | ☐☐☐ | OR ☐ |
| 1b. Hematocrit | ☐ | ☐☐.☐ *%* | | | |
| 1c. MCV | ☐ | ☐☐☐.☐ *fL* | | | |
| 1d. Platelets | ☐ | ☐☐☐☐.☐ *x10$^3$/mm$^3$* | ☐ | ☐☐☐ | OR ☐ |
| 1e. WBC | ☐ | ☐☐☐.☐ *x10$^3$/mm$^3$* | ☐ | ☐☐☐ | OR ☐ |

| | Not done | Absolute Count *cells/mm3* | Severity Grade *If applicable* | AE Log Page # | Not reportable as an AE |
|---|---|---|---|---|---|
| DIFFERENTIAL | ☐ → *Go to item 2.* | | | | |
| 1f. Neutrophils | Not reported ☐ | ☐☐☐☐☐ | ☐ | ☐☐☐ | OR ☐ |
| 1g. Lymphocytes | ☐ | ☐☐☐☐ | ☐ | ☐☐☐ | OR ☐ |
| 1h. Monocytes | ☐ | ☐☐☐☐ | | | |
| 1i. Eosinophils | ☐ | ☐☐☐☐ | | | |
| 1j. Basophils | ☐ | ☐☐☐☐ | | | |



*Staff Initials/Date* _____

**Purpose:**

This form is used to provide data on the participant's baseline and follow-up laboratory test results.

**General Instructions:**

Use this form to report the hematology, differential, and liver and renal function test results as they become available. Do not fax the form to DF/Net until all results are available and the participant has enrolled in the study.

**Item-specific Instructions:**

| | |
|---|---|
| **Initial Specimen Collection Date** | Record the date that the first specimen was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required. |
| **Alternate Collection Date** | This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. |
| **Not done/ Not collected** | Mark this box in the event that a specimen was not collected or if the specimen was collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available in Comments on page 2. |
| **Visit Code** | Record the visit code assigned to this visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes. |
| **Repeat Testing** | If any or all of the lab tests listed on this form are repeated (re-drawn) between the Screening and Enrollment Visit, document the repeated results on the same SLR form assigned Visit Code 1.0. Line through the original result(s), record the new result(s) and the Alternate Collection Date for each repeat test result. |
| **Results Reporting** | • Results should be documented on the form using the units present on the source laboratory results document. If the units present on the form do not match your source results report, contact the MTN-027 Management Team. Note that the following units are equivalent: IU/L = U/L, I/I x 100 = %, $10^9$/L = $10^3$/mm$^3$ = $10^3$/μL<br>For creatinine, only record the result in the units listed on the source document.<br>• If the site lab does not report results to the same level of precision allowed on the form, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%.<br>• It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the form. For example, a lab-reported hemoglobin value of 11.05 g/dL would be recorded as 11.1 g/dL. A lab-reported hemoglobin value of 11.04 g/dL would be recorded as 11.0 g/dL.<br>  • If the site lab does not produce test results in the units used on this form, first perform the conversion, then round the converted result if necessary. |
| Severity Grade | • If any values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the result. If value is below Grade 1, leave the severity grade box blank.<br>• Always compare the severity grade range to the value that was recorded on the form (not thelab-reported value).<br>• When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.<br>  • Treat all missing digits in the lab value as zeros.<br>  • If the lab value falls between two calculated severity grade ranges, assign it the higher grade.<br>  • At Screening/Enrollment, record any Grade 1 or higher lab values on the Pre-existing Conditions form. |

(MTN 027) DF/Net 027 SLR-2 (145)

Visit Code ____ . ____

Participant ID

___ – _____ – ___

*Site Number* *Participant Number* *Chk*

## Safety Laboratory Results



Alternate Collection Date

2. SERUM CHEMISTRIES — Not done/ Not collected ☐ → *Go to item 3.* — dd ___ MMM ___ yy ___

| | Not reported | | Severity Grade *If applicable* | AE Log Page # | Not reportable as an AE |
|---|---|---|---|---|---|
| 2a. AST (SGOT) | ☐ | ____ *U/L* | ☐ | ____ | OR ☐ |
| 2b. ALT (SGPT) | ☐ | ____ *U/L* | ☐ | ____ | OR ☐ |
| 2c. Creatinine | ☐ | ___ . ___ *mg/dL* | ☐ | ____ | OR ☐ |
| 2c1. Calculated creatinine clearance | | ____ *mL/min* | | | |

Alternate Collection Date

3. DIPSTICK URINALYSIS TESTS — Not done/ Not collected ☐ → *End of form.* — dd ___ MMM ___ yy ___

| | Not done | *negative* | *positive* |
|---|---|---|---|
| 3a. Leukocyte esterase (LE) | ☐ | ☐ | ☐ |
| 3b. Nitrites | ☐ | ☐ | ☐ |

| | *negative* | *trace* | *1+* | *2+* | *3+* | *4+* | Severity Grade *If applicable* | AE Log Page # | Not reportable as an AE |
|---|---|---|---|---|---|---|---|---|---|
| 3c. Protein | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ____ | OR ☐ |
| 3d. Glucose | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ____ | OR ☐ |

Comments: _____

_____

_____

Version 2.0, 01-MAY-15

_____
*Staff Initials/Date*

**Purpose:**

This form is used to provide data on the participant's baseline and follow-up laboratory test results.

**General Instructions:**

Use this form to report the hematology, differential, and liver and renal function test results as they become available.

Do not fax the form to DF/Net until all results are available and the participant has enrolled in the study.

**Item-specific Instructions:**

| | |
|---|---|
| **Alternate Collection Date** | This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. |
| **Not done/ Not collected** | Mark this box in the event that a specimen was not collected or if the specimen was collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available in Comments on page 2. |
| **Visit Code** | Record the visit code assigned to this visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes. |
| **Repeat Testing** | If any or all of the lab tests listed on this form are repeated (re-drawn) between the Screening and Enrollment Visit, document the repeated results on the same SLR form assigned Visit Code 1.0. Line through the original result(s), record the new result(s) and the Alternate Collection Date for each repeat test result. |
| **Item 2c1** | When calculating the participant's creatinine clearance use the age and weight of the participant at the time the blood specimen is drawn. If the participant was not weighed at the visit when the blood specimen was drawn, but was weighed at a previous visit (within the allowable window for creatinine clearance per the SSP Manual), record the weight from the previous visit. Also, record in the "Alternative Collection Date" boxes the date of the previous visit when the participant was weighed. If the participant has a creatinine value but cannot have her creatinine clearance calculated (due to missing weight data), line through the response boxes and initial and date. |
| **Item 3** | If a dipstick urinalysis was done, but a given result was not reported, mark the "not done" box. |
| **Items 3a-3b** | If the result is negative or trace, mark the 'negative' box. If the result is 1+ or greater, mark the 'positive' box. |
| **Item 3d** | Grade the severity of the urine glucose value according to the "Proteinuria, random collection" row of the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events.* |

(MTN 027) DF/Net 027

Participant ID

| | | | – | | | | | – | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |

*Site Number* *Participant Number* *Chk*

Exam Date

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

*dd* *MMM* *yy*

☐ no normal variants or abnormal findings observed

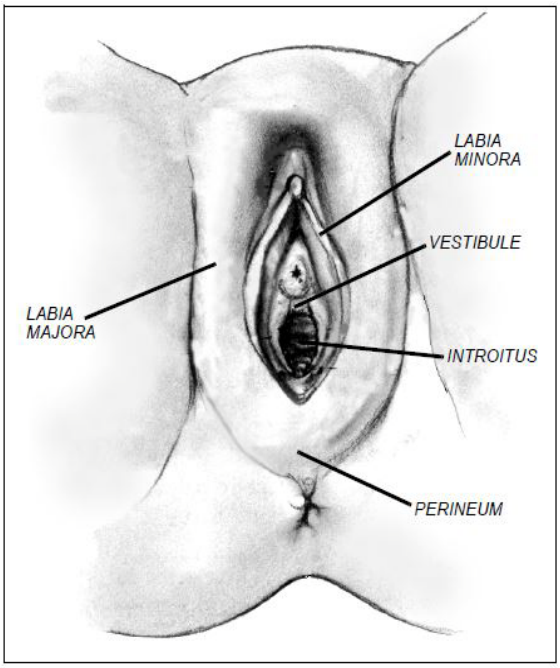
**Speculum Type (screening only)**

*Pederson* ☐ *Graves* ☐ *Cusco* ☐

**Speculum Size (screening only)**

*small* ☐ *medium* ☐ *large* ☐

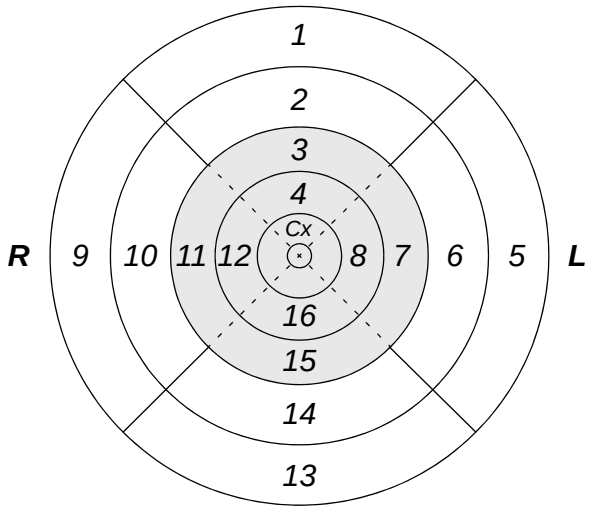
## *External Genitalia*




## Legend for Vagina/Cervix

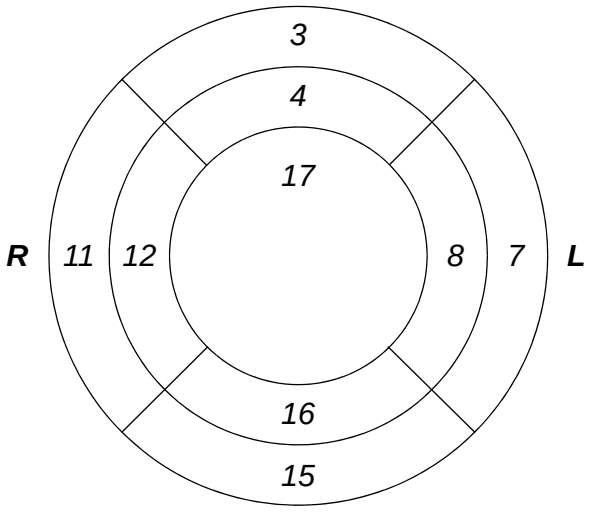
1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina, proximal half
11. Right lateral fornix
12. Cervical trunk, right lateral
13. Posterior vagina, distal half
14. Posterior vagina, proximal half
15. Posterior fornix
16. Cervical trunk, post
17. Cervical face

## *Vagina: Anterior*




***Posterior***

## *Cervix: Anterior*




***Posterior***

Version 1.0, 01-APR-15

*Staff Initials/Date*

**Purpose:**

This form is used to document all variants of normal and all abnormal findings observed during study pelvic exams (screening through termination/study exit).

**General Instructions:**

This form is completed at the Screening Visit, the Enrollment Visit, at all scheduled study visits, and whenever a pelvic exam is clinically indicated during the study. This is a non-DataFax form and should not be faxed to DF/Net DataFax. Transcribe information onto the appropriate Pelvic Exam DataFax form for submission to DataFax and store this form in the participant's chart notes..

**Item-specific Instructions:**

| | |
|---|---|
| **Findings** | All variants of normal (normal findings) and all abnormal findings must be documented on this form. Variants of normal need only be recorded on this form, and not on any of the Pelvic Exam DataFax forms. The following findings are considered normal variants:<br>• anatomic variants<br>• gland openings<br>• Nabothian cysts<br>• mucus retention cysts<br>• Gartner's duct cysts<br>• blood vessel changes other than disruption<br>• skin tags<br>• scars<br>• cervical ectopy<br>If there are no variants of normal or abnormal findings observed mark the "no normal variants or abnormal findings observed" box. |
| **Documenting findings on the cervix:** | If helpful, draw the os in the center of the diagram labeled "Cervix" (lower right corner). |