

WOMEN'S INTERAGENCY HIV STUDY
QUESTION BY QUESTION SPECIFICATIONS
FORM 31: SPECIMENS COLLECTED DURING THE PHYSICAL EXAM

SECTION A. URINE SPECIMENS

- A1. Indicate whether or not a urine specimen was collected for a pregnancy test. If “YES,” go to **Question A1a** and record the date. If collection was indicated but not done, record “NO” and specify the reason why the specimen was not collected. If not applicable, circle code “3.”

During follow up there are only three reasons why a urine pregnancy test is not applicable: if the participant is (1) s/p hysterectomy or (2) s/p bilateral oophorectomy or (3) greater than 50 years of age. Otherwise, urine pregnancy tests are required routinely on all participants, including those currently pregnant, during follow up.

- a. If urine was collected for a pregnancy test, record the date of collection in MM/DD/YY format.
 - b. Indicate if the pregnancy test result was positive, negative, or indeterminate.
- A2. Indicate whether or not a urine specimen was collected for the central repository. If “YES,” go to **Question A2a** and record the date. If collection was indicated but not done, record “NO” and specify the reason why the specimen was not collected. If not applicable, circle code “3.” Urine for the repository should be collected at odd visits. Circle “N/A” only if the visit is even.
- a. If urine was collected for the repository, record the date of collection in MM/DD/YY format.
 - b. If urine was collected for the repository, record the time of collection in HH:MM format.

**VISIT 36, VISIT 40, VISIT 44: COLLECT URINE FOR REPOSITORY FOR SUPERNATANT.
VISIT 38, VISIT 42, VISIT 46: COLLECT URINE FOR REPOSITORY FOR SUPERNATANT & PELLETT.
SAMPLE CAN BE KEPT AT ROOM TEMPERATURE FOR LOCAL TESTS CONDUCTED WITHIN 4 TO 6 HOURS. OTHERWISE KEEP SAMPLE AT 4°C UNTIL PROCESSING.**

- B1. Indicate whether or not a hair specimen was collected. A hair specimen should be collected from ALL HIV-positive women who have reported antiretroviral medication use since her last study visit. If “YES,” go to **Question B1a**. If “NO,” specify the reason why the specimen was not collected and go to **Section C**.

Circle “N/A” if the participant is HIV-1 negative or HIV-positive and not reporting antiretroviral medication use since the last study visit (F22MED, Question B2).

PROMPT: IF PARTICIPANT IS ON A REGIMEN THAT CONTAINS TENOFOVIR (DRUG CODES 262, 253, 280, 287, 234), ASK IF PARTICIPANT IS WILLING TO HAVE 100 STRANDS OF HAIR COLLECTED. IF PARTICIPANT IS ON A REGIMEN THAT DOES NOT INCLUDE TENOFOVIR, PREFERS NOT TO DONATE 100 STRANDS, OR DONATED 100 STRANDS AT HER LAST VISIT, COLLECT 30-40 STRANDS OF HAIR AS PER USUAL PROTOCOL.

NOTE: *Tenofovir-containing regimens include the following drug codes: 234 (Viread), 253 (Truvada), 262 (Atripla), 280 (Complera), and 287 (Stribild).*

- a. Indicate whether or not the participant is on a tenofovir-containing regimen. If she is NOT, then collect 30-40 strands of hair and skip to **Question B1d**.

- b. Indicate whether the visit is EVEN-NUMBERED, or if the participant's last visit was missed or abbreviated. If "yes," then proceed to **Question B1c**. If "no," then collect 30-40 strands of hair and skip to **Question B1d**.
- c. Indicate whether or not the participant is willing to donate 100 strands of hair. If she IS, then collect 100 strands and proceed to **Question B1d**. If she is NOT, then collect 30-40 strands of hair and proceed to **Question B1d**.
- d. If a hair sample was obtained, circle "1" to indicate that it was taken from the occipital region of the scalp. Circle "3" if the sample was taken from the nape or base of the participant's neck. Circle "2" if the sample was taken from somewhere else and then specify the location.
- e. Record the date the hair specimen was collected in MM/DD/YY format.

SECTION C. GYN SPECIMENS

- C1a. Indicate if any gynecological specimens were collected from the participant. If no gynecological specimens were collected, specify why not, and then end the form.
- b. Record the date the gynecological specimens were collected in MM/DD/YY format.
- C2. Indicate whether or not a minimum of 6 ml of CVL fluid was collected by circling the appropriate response code. If "YES," go to **Question C2a** and enter the time of collection. If "NO," specify the reason why the CVL specimen was not collected.

IF CVL WILL NOT BE PROCESSED WITHIN ONE HOUR OF COLLECTION, KEEP SAMPLE AT LESS THAN 10°C TO PREVENT MICROBIAL GROWTH.

- C3. Indicate whether or not a slide for bacterial vaginosis gram stain was collected by circling the appropriate response code. If "YES," go to **Question C4**. If "NO", specify the reason why the BV gram stain specimen was not collected.
- C4. Indicate whether or not a slide for Pap smear was collected by circling the appropriate response code. If "YES," go to **Question C5**. If "NO", specify the reason why the Pap smear specimen was not collected. If a Pap smear is not necessary, due to five years of normal Pap results, circle "3" for "N/A." If the participant is part of the CCSS (Cervical Cancer Screening Substudy), circle "2" for "NO," and write "in CCSS" in the specify field.
- C5. Indicate whether or not a cervical swab for HPV DNA was collected by circling the appropriate response code. This swab should be collected from all women during WIHS IV starting at visit 31. If the participant is part of the CCSS (Cervical Cancer Screening Substudy), circle "2" for "NO," and write "in CCSS" in the specify field.
- C6. Indicate whether or not a swab for trichomonas culture was collected by circling the appropriate response code. If "YES," circle code "1" and skip to **Question C7**. If your site is performing trichomonas cultures and the swab was not collected, circle code "2" and specify the reason why the swab for trichomonas culture was not collected.

NOTE: This is an optional test. If your site is not performing trichomonas cultures, circle code "3" (N/A).

- C7. Indicate whether or not liquid Pap specimens for the CCSS were collected. If the participant is not a part of the CCSS, circle "3" for "NA" and end the form. If the participant is part of the substudy, but the specimen was not collected, circle "2" for "NO" and specify the reason the specimen was not collected. If the specimen was collected, circle "1" for "YES" and skip to **Question C7a** to indicate the number of specimens collected.