

WOMEN'S INTERAGENCY HIV STUDY

FORM 31: SPECIMENS COLLECTED DURING THE PHYSICAL EXAM

ID LABEL HERE ---> |_| - |_|_| - |_|_|_|_| - |_|

VISIT #: _____ FORM COMPLETED BY: _____

VERSION DATE: **04/01/14**

ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.

SECTION A. URINE TESTS

<u>TEST TYPE</u>	<u>LOCATION</u>	<u>YES</u>	<u>NO</u>	<u>IF NO, SPECIFY REASON</u>	<u>N/A</u>
A1. Pregnancy Test	Exam Site	1* (a)	2	_____ (A2)	3* (A2)
a. DATE OF COLLECTION		___ / ___ / ___	M D Y		
b. RESULT:					
POSITIVE		1			
NEGATIVE		2			
INDETERMINATE		3			
A2. Urine for repository	Freeze locally	1§ (a)	2	_____ (B1)	3§ (B1)
a. DATE OF COLLECTION		___ / ___ / ___	M D Y		
b. Time of collection:				<div style="display: flex; justify-content: space-between; align-items: center;"> ___ : ___ AM.....1 </div> <div style="display: flex; justify-content: space-between; align-items: center;"> PM.....2 </div>	

- * **REQUIRED FOR EVERY WOMAN UNLESS SHE IS : S/P HYSTERECTOMY OR BILATERAL OOPHORECTOMY OR ≥ 50 YEARS OF AGE.**
- § **VISIT 36, VISIT 40, VISIT 44: COLLECT URINE FOR REPOSITORY FOR SUPERNATANT. VISIT 38, VISIT 42, VISIT 46: COLLECT URINE FOR REPOSITORY FOR SUPERNATANT & PELLET. SAMPLE CAN BE KEPT AT ROOM TEMPERATURE FOR LOCAL TESTS CONDUCTED WITHIN 4 TO 6 HOURS. OTHERWISE KEEP SAMPLE AT 4°C UNTIL PROCESSING.**

WIHS ID #

[Empty box for WIHS ID #]

SECTION B. HAIR SPECIMEN

<u>SPECIMEN TYPE</u>	<u>LAB</u>	<u>YES</u>	<u>NO</u>	<u>IF NO, SPECIFY REASON</u>	<u>N/A</u>
B1. Hair	Central	1 (a)	2		(C1) 3 † (C1)

† Circle “N/A” **only** if participant is HIV-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 20-30 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. Is participant on a tenofovir-containing regimen?
 YES 1
 NO 2 (collect 20-30 strands and go to B1d)

- b. IS THIS AN EVEN-NUMBERED VISIT, OR WAS PARTICIPANT’S LAST VISIT MVIS OR ABRV?
 YES 1
 NO 2 (collect 20-30 strands and go to B1d)

- c. Is participant willing to have 100 strands of hair taken?
 YES 1 (collect 100 strands and go to B1d)
 NO 2 (collect 20-30 strands and go to B1d)

- d. From where was the sample taken?
 Occipital region of scalp (preferred) 1 (e)
 Nape / base of neck 3 (e)
 Other regions of scalp..... 2
 SPECIFY: _____

- e. Date hair specimen collected: |__|/|__|/|__|
 M D Y

WIHS ID #

SECTION C. GYN SPECIMENS

C1. a. WERE ANY GYN SPECIMENS COLLECTED?

YES..... 1 (b)
NO..... 2

IF NO, SPECIFY REASON: _____ (END)

b. DATE GYN SPECIMENS COLLECTED: ___/___/___
 M D Y

<u>SPECIMEN TYPE</u>	<u>LAB</u>	<u>YES</u>	<u>NO</u>	<u>IF NO, SPECIFY REASON</u>	<u>N/A</u>
C2. Minimum 6 ml CVL Fluid	Local for Aliquoting and Freezing	1 (a)	2	_____ (C3)	
a.) IF YES, time of collection:		_ _ : _ _		AM.....1	PM.....2

IF CVL WILL NOT BE PROCESSED WITHIN 1 HOUR OF COLLECTION, KEEP SAMPLE AT LESS THAN 10°C TO PREVENT MICROBIAL GROWTH.

C3. Slide for Bacterial Vaginosis Gram Stain	Central	1 (C4)	2	_____	
C4. 1 Glass Slide for Pap Smear	Central	1 (C5)	2	_____	3
C5. 1 Cervical swab for HPV DNA	Central	1 (C6)	2	_____	
C6. <u>Optional</u> : Swab in Diamonds Media for Trichomonas Culture	Exam Site	1 (C7)	2	_____	3
C7. Liquid Pap for CCSS	Central	1 (a)	2	_____ (END)	3 (END)
a.) IF YES, number of specimens:				1 specimen.....1	2 specimens.....2