

SPANISH VERSION

**WOMEN'S INTERAGENCY HIV STUDY
METABOLIC STUDY: MS01 SPECIMEN COLLECTION FORM**

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

VISIT #: _____ FORM COMPLETED BY: _____

VERSION DATE **04/01/06**

A1. DATE OF BLOOD DRAW: _____ / _____ / _____
M D Y

A2. ¿Se inyecta usted insulina o toma alguna de las siguientes medicaciones por boca: thiazolidinedione [incluido pioglitazone (Actos) o rosiglitazone (Arandia)] o metformin (Glucophage) para la diabetes, o para controlar el azúcar en su sangre?

YES1
NO.....2

A3. ¿Está usted tomando actualmente alguna otra medicina que le hubieran recetado para la diabetes, o para bajar el azúcar en su sangre?

YES1
NO.....2 **(A6)**

A4. ¿Incluyó alguna de las siguientes?			i. Fecha de la última vez que la tomó	ii. Hora de la última vez que la tomó	iii. AM/PM INDICATOR
	<u>YES</u>	<u>NO</u>			
a. Acarbose (Precose)	1	2 (b)	____/____/____	_ _ : _ _	AM.....1 PM.....2
b. Chlorpropamide (Diabinese)	1	2 (c)	____/____/____	_ _ : _ _	AM.....1 PM.....2
c. Glimepiride (Amaryl)	1	2 (d)	____/____/____	_ _ : _ _	AM.....1 PM.....2
d. Glipizide (Glucotrol)	1	2 (e)	____/____/____	_ _ : _ _	AM.....1 PM.....2
e. Glyburide (Micronase, Diabeta)	1	2 (g)	____/____/____	_ _ : _ _	AM.....1 PM.....2
g. Miglitol (Glyset)	1	2 (h)	____/____/____	_ _ : _ _	AM.....1 PM.....2
h. Orlistat (Xenical)	1	2 (j)	____/____/____	_ _ : _ _	AM.....1 PM.....2
j. Repaglinide (Prandin)	1	2 (l)	____/____/____	_ _ : _ _	AM.....1 PM.....2
l. Starlix (Nateglinide)	1	2 (m)	____/____/____	_ _ : _ _	AM.....1 PM.....2
m. Other SPECIFY: _____	1	2 (A5)	____/____/____	_ _ : _ _	AM.....1 PM.....2

WIHS ID#

A5. IN THE LAST EIGHT (8) HOURS, HAS PARTICIPANT TAKEN ANY OF THE MEDICATIONS LISTED IN QUESTIONS A4a – A4I?

YES1 (PROMPT, BELOW)
NO.....2

PROMPT: IF PARTICIPANT HAS TAKEN ANY OF THE DIABETES MEDICATIONS LISTED IN QUESTIONS A4a – A4I IN THE LAST EIGHT (8) HOURS (A5 = 1), SHE MAY NOT PARTICIPATE IN THE GLUCOSE TOLERANCE TEST (GTT) AT THIS TIME. PLEASE RESCHEDULE THE PARTICIPANT FOR A GLUCOSE TOLERANCE TEST AND COMPLETE A NEW MS01 AT THAT TIME.

A6a. HAND PARTICIPANT ANTIVIRAL PHOTO MEDICATION CARDS. GO THROUGH CARDS WITH PARTICIPANT, SAYING THE NAME OF EACH DRUG ALOUD AND ASKING HER TO TELL YOU “YES” OR “NO” WHETHER SHE HAS TAKEN THIS DRUG IN THE LAST 3 DAYS. CHECK BELOW NEXT TO EACH DRUG PARTICIPANT REPORTS HAVING TAKEN. FOR DRUGS NOT LISTED, CHECK “OTHER ANTI-VIRAL,” RECORD NAME AS STATED BY PARTICIPANT AND FILL IN CORRESPONDING 3-DIGIT DRUG CODE FROM DRUG LIST 1.

Ahora le preguntaré acerca de cualquier medicamento que haya tomado en los últimos tres días para combatir el VIH/SIDA. Además de las medicinas recetadas, diga otros medicamentos que haya tomado como parte de un estudio, incluyendo estudios en los que no sabe si recibió el medicamento. En los últimos tres días, ha tomado usted...

Nucleoside/Nucleotide RTIs

- 204 ___ Eпивir (lamivudine, 3-TC)
218 ___ Ziagen (abacavir)
092 ___ Retrovir (AZT, zidovudine, ZDV)
227 ___ Combivir (AZT + 3TC)
159 ___ Zerit (stavudine, d4T)
094 ___ Hivid (zalcitabine, ddC)
147 ___ Videx / Videx EC (didanosine, ddI)
240 ___ Trizivir (abacavir + AZT + 3TC)
234 ___ Viread (tenofovir)
239 ___ Emtriva (emtricitabine, FTC)
253 ___ Truvada (Viread + Emtriva)
254 ___ Epzicom (Ziagen + Eпивir)

Non-Nucleoside RTIs

- 194 ___ Rescriptor (delavirdine)
220 ___ Sustiva (efavirenz)
191 ___ Viramune (nevirapine)

Protease Inhibitors

- 219 ___ Agenerase (amprenavir)
212 ___ Crixivan (indinavir)
217 ___ Kaletra (lopinavir + ritonavir)
216 ___ Viracept (nelfinavir)
211 ___ Norvir (ritonavir)
210 ___ Invirase or Fortovase (saquinavir)
243 ___ Reyataz (atazanavir)
238 ___ Aptivus (tipranavir)
249 ___ Lexiva (fosamprenavir)

Entry Inhibitors

- 233 ___ Fuzeon (T-20, enfuvirtide)

Other

- 207 ___ Droxia or Hydrea (hydroxyurea)
___ Other anti-viral(s) (from Drug List 1)

Name of Drug:
Name of Drug:

Drug Code: |_|_|_|_|

Drug Code: |_|_|_|_|

b. ENTER THE TOTAL NUMBER OF MEDICATIONS THE PARTICIPANT REPORTED TAKING IN QUESTION A6a: |_|_|

PROMPT: IF QUESTION A6b = 0, SKIP TO QUESTION A8.

A7. **FOR EACH MEDICATION LISTED IN QUESTION A6a, ASK PARTICIPANT THE DATE AND TIME SHE LAST TOOK THAT MEDICATION AND COMPLETE COLUMNS a, b, c AND d.**

START MS01s1

	a. DRUG CODE	b. DATE LAST TAKEN	c. TIME LAST TAKEN	d. AM/PM INDICATOR
i.	_ _ _ _ _	__ __ \ __ __ \ __ __	_ _ _ _ : _ _ _ _	AM.....1 PM.....2
ii.	_ _ _ _ _	__ __ \ __ __ \ __ __	_ _ _ _ : _ _ _ _	AM.....1 PM.....2
iii.	_ _ _ _ _	__ __ \ __ __ \ __ __	_ _ _ _ : _ _ _ _	AM.....1 PM.....2
iv.	_ _ _ _ _	__ __ \ __ __ \ __ __	_ _ _ _ : _ _ _ _	AM.....1 PM.....2
v.	_ _ _ _ _	__ __ \ __ __ \ __ __	_ _ _ _ : _ _ _ _	AM.....1 PM.....2
vi.	_ _ _ _ _	__ __ \ __ __ \ __ __	_ _ _ _ : _ _ _ _	AM.....1 PM.....2

END MS01s1

A8. ¿Cuándo fue la última vez que comió o bebió algo que no fuera agua?

a. DATE: __ __ / __ __ / __ __
 M D Y

b. TIME: |_|_|_|_| : |_|_|_|_| AM.....1
 PM2

A9. En los últimos tres días, ¿Ha usted tomado alguna otra medicina? Favor de incluir medicina que se le haya recetado, que NO hayamos mencionado antes, y medicinas que NO se le haya recetado (medicinas que se puede comprar SIN receta del doctor), y también hierbas, vitaminas, remedios caseros, u otras medicinas alternativas o complementarios.

YES 1
NO 2 (**SECTION B**)

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A10. ASK PARTICIPANT TO LIST ALL MEDICATIONS SHE HAS TAKEN IN THE LAST THREE DAYS, AND THE DATE/TIME SHE LAST TOOK EACH MEDICATION. COMPLETE COLUMNS a, b, c AND d.

START MS01s2

	a. DRUG NAME	b. DATE LAST TAKEN	c. TIME LAST TAKEN	d. AM/PM INDICATOR
i.	_____	___ \ ___ \ ___	_ : _	AM.....1 PM..... 2
ii.	_____	___ \ ___ \ ___	_ : _	AM.....1 PM..... 2
iii.	_____	___ \ ___ \ ___	_ : _	AM.....1 PM..... 2
iv.	_____	___ \ ___ \ ___	_ : _	AM.....1 PM..... 2
v.	_____	___ \ ___ \ ___	_ : _	AM.....1 PM..... 2
vi.	_____	___ \ ___ \ ___	_ : _	AM.....1 PM..... 2

END MS01s2

A10e. ENTER THE TOTAL NUMBER OF MEDICATIONS THE PARTICIPANT REPORTED TAKING IN QUESTION A10a: |_|_|

SECTION B. FIRST BLOOD DRAW (FASTING)

B1. TIME OF FIRST BLOOD DRAW: |_|_| : |_|_| AM.....1
PM2

B2. PHLEBOTOMIST'S INITIALS ___ _

	<u>TEST TYPE</u>	<u>TUBE TYPE</u>	<u>VOLUME</u>	<u>a.) SPECIMEN COLLECTED?</u>		<u>b.) REQUIRED VOLUME COLLECTED?</u>		<u>c.) ESTIMATED VOLUME COLLECTED?</u>
				<u>YES</u>	<u>NO</u>	<u>YES</u>	<u>NO</u>	
B3.	GLUCOSE	Gray Top	2 ml	1	2 (i)	1 (B4)	2	_ _ mls.
		IF NO, SPECIFY REASON		i. _____				
B4.	INSULIN/LIPID PANEL	Red-Top (SST)	4 ml	1	2 (i)	1 (B5)	2	_ _ mls.
		IF NO, SPECIFY REASON		i. _____				
B5.	NMR Lipoprofile	Purple-yellow (EDTA)	5 ml	1	2 (i)	1 (PROMPT)	2	_ _ mls.
		IF NO, SPECIFY REASON		i. _____				

PROMPT: IF QUESTION A2 = 1, SKIP TO PROMPT AT END OF FORM. OTHERWISE, PLEASE HAVE PATIENT DRINK 75G GLUCOSE LOAD WITHIN 5 MINUTES AND CONTINUE WITH SPECIMEN DRAW.

B6. DID THE PARTICIPANT FULLY DRINK GLUCOSE (75G GLUCOSE LOAD)?

YES 1 **(B6a)**
 NO 2

SPECIFY REASON: _____ **(END FORM)**

a. TIME GLUCOSE LOAD ADMINISTERED: |__| |__| : |__| |__| AM 1
 PM 2

SECTION C. SECOND BLOOD DRAW (30 MINUTES)

C1. TIME OF SECOND BLOOD DRAW: |__| |__| : |__| |__| AM 1
 PM 2

C2. PHLEBOTOMIST'S INITIALS _____

	<u>TEST TYPE</u>	<u>TUBE TYPE</u>	<u>VOLUME</u>	<u>a.) SPECIMEN COLLECTED?</u>		<u>b.) REQUIRED VOLUME COLLECTED?</u>		<u>c.) ESTIMATED VOLUME COLLECTED?</u>
				<u>YES</u>	<u>NO</u>	<u>YES</u>	<u>NO</u>	
C3.	GLUCOSE	Gray Top	2 ml	1	2 (i)	1 (C4)	2	__ __ mls.
		IF NO, SPECIFY REASON		i. _____				
C4.	INSULIN	Red-Top (SST)	4 ml	1	2 (i)	1 (D1)	2	__ __ mls.
		IF NO, SPECIFY REASON		i. _____				

SECTION D. THIRD BLOOD DRAW (60 MINUTES)

D1. TIME OF THIRD BLOOD DRAW: |__| |__| : |__| |__| AM 1
 PM 2

D2. PHLEBOTOMIST'S INITIALS _____

	<u>TEST TYPE</u>	<u>TUBE TYPE</u>	<u>VOLUME</u>	<u>a.) SPECIMEN COLLECTED?</u>		<u>b.) REQUIRED VOLUME COLLECTED?</u>		<u>c.) ESTIMATED VOLUME COLLECTED?</u>
				<u>YES</u>	<u>NO</u>	<u>YES</u>	<u>NO</u>	
D3.	GLUCOSE	Gray Top	2 ml	1	2 (i)	1 (E1)	2	__ __ mls.
		IF NO, SPECIFY REASON		i. _____				

SECTION E. FOURTH BLOOD DRAW (120 MINUTES)

E1. TIME OF FOURTH BLOOD DRAW: |_|_| : |_|_| AM.....1
 PM2

E2. PHLEBOTOMIST'S INITIALS _ _ _

	<u>TEST TYPE</u>	<u>TUBE TYPE</u>	<u>VOLUME</u>	<u>a.) SPECIMEN COLLECTED?</u>		<u>b.) REQUIRED VOLUME COLLECTED?</u>		<u>c.) ESTIMATED VOLUME COLLECTED?</u>
				<u>YES</u>	<u>NO</u>	<u>YES</u>	<u>NO</u>	
E3.	GLUCOSE	Gray Top	2 ml	1	2 (i)	1 (E4)	2	_ _ mls.
		IF NO, SPECIFY REASON		i.	_____			
E4.	INSULIN	Red-Top (SST)	4 ml	1	2 (i)	1 (END)	2	_ _ mls.
		IF NO, SPECIFY REASON		i.	_____			

PROMPT: AFTER PROCESSING, SAMPLES FOR INSULIN, GLUCOSE AND LIPIDS WILL BE BATCHED AND THEN SHIPPED TO QUEST DIAGNOSTICS. SAMPLES FOR NMR LIPOPROTEIN WILL BE SHIPPED TO LIPOSCIENCES, INC. SEE THE WIHS MANUAL OF OPERATIONS, SECTION 25, FOR INSTRUCTIONS ON PROCESSING AND SHIPPING.