

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

YES 1 (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.

I’m going to ask about any antiretroviral medications you may have taken **in the last 3 days**. In addition to all your prescribed medications, please include any antiretroviral medications you have taken as part of a research study, including those in which you may have been blinded to the study medication. In the last 3 days, have you taken...

Combination Medications

- 262 Atripla (Sustiva + Viread + Emtriva)
- 227 Combivir (AZT + 3TC)
- 254 Epzicom (Ziagen + Epivir)
- 240 Trizivir (abacavir + AZT + 3TC)
- 253 Truvada (Viread + Emtriva)

Entry Inhibitors

- 233 Fuzeon (T-20, enfuvirtide)
- 265 Selzentry (maraviroc)

Nucleoside/Nucleotide RTIs

- 239 Emtriva (emtricitabine, FTC)
- 204 Epivir (lamivudine, 3-TC)
- 094 Hivid (zalcitabine, ddC)
- 092 Retrovir (AZT, zidovudine, ZDV)
- 147 Videx / Videx EC (didanosine, ddI)
- 234 Viread (tenofovir)
- 159 Zerit (stavudine, d4T)
- 218 Ziagen (abacavir)

Non-Nucleoside RTIs

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

Protease Inhibitors

- 219 Agenerase (amprenavir)
- 238 Aptivus (tipranavir)
- 212 Crixivan (indinavir)
- 210 Invirase or Fortovase (saquinavir)
- 217 Kaletra (lopinavir + ritonavir)
- 249 Lexiva (fosamprenavir)
- 211 Norvir (ritonavir)
- 256 Prezista (TMC-114, darunavir)
- 243 Reyataz (atazanavir)
- 216 Viracept (nelfinavir)

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.

A10. ASK PARTICIPANT TO LIST ALL MEDICATIONS SHE HAS TAKEN IN THE LAST THREE DAYS, AND THE DATE AND 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 | Red-Top (SST) | 4 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. _____ | | | | |

