

Biospecimen Adult Urine Instrument

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| --- | --- |
| **Event:** | Pregnancy Visit 1, Pregnancy Visit 2, Birth |
| **Participant:** | Pregnant or Non-Pregnant Woman |
| **Domain:** | Biospecimen |
| **Type of Document:** | Data Collection Instrument |
| **Recruitment Groups:** | EH, PB, HI, PBS  |
| **Version:** | 1.1 |
| **Release:** | MDES 3.3 |

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Biospecimen Adult Urine Instrument

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BIOSPECIMEN URINE COLLECTION 1

Biospecimen Adult Urine Instrument
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Biospecimen URINE COLLECTION

**(TIME\_STAMP\_1) PROGRAMMER INSTRUCTION:**

* INSERT DATE/TIME STAMP

UR0900/(URINE\_INTRO). You will now collect a urine sample. I will need to ask you some questions before you collect your urine sample.

CONTINUE 1

REFUSED -1 **(TIME\_STAMP\_2)**

UR1000/(LT\_URINE\_1/LT\_URINE\_2/LT\_URINE\_3). When did you last urinate?

DATA COLLECTOR INSTRUCTIONS:

* RECORD DATE AS “MMDDYYYY.”
* RECORD THE TIME AS HH:MM. BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY AND TO MARK THE BOX TO CHOOSE “AM” OR “PM”. FOR EXAMPLE, IF TIME OF LAST URINATION WAS AT 2:05 PM RECORD “02:05” AND CHOOSE “PM”.

**UR1000A/(LT\_URINE\_1).** LAST URINATION – DATE

|\_\_\_|\_\_\_| / |\_\_\_|\_\_\_| / |\_\_\_|\_\_\_|\_\_\_|\_\_\_|

 M M D D Y Y Y Y

**UR1000B/(LT\_URINE\_2).** LAST URINATION – TIME

|\_\_\_|\_\_\_| : |\_\_\_|\_\_\_|

 H H M M

REFUSED -1

DON’T KNOW -2

**UR1000C/(LT\_URINE\_3).** LAST URINATION – AM/PM

AM. 1

PM. 2

REFUSED -1

DON’T KNOW -2

PROGRAMMER INSTRUCTIONS:

* HARD EDIT: INCLUDE HARD EDIT IF HOUR OR MINUTES ARE NOT 2 DIGITS (FILL THE SPACE WITH 0 AS NECESSARY)
* HARD EDIT: INCLUDE HARD EDIT IF HOUR IS NOT BETWEEN 01 AND 12
* HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59
* FORMAT DATE AS YYYYMMDD
* HARD EDIT: INCLUDE HARD EDIT IF MONTH IS NOT BETWEEN 01 AND 12.
* HARD EDIT: INCLUDE HARD EDIT IF DAY IS NOT BETWEEN 01 AND 31.
* HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2011.

UR1100/(LT\_EAT\_DRINK\_1/LT\_EAT\_DRINK\_2/LT\_EAT\_DRINK\_3). When was the last time you had anything to eat or drink other than water?

DATA COLLECTOR INSTRUCTIONS:

* RECORD THE LAST TIME PARTICIPANT ATE OR DRANK OTHER THAN WATER.
* THE TWO DIGIT MONTH, THE TWO DIGIT DAY, AND THE FOUR DIGIT YEAR SHOULD BE RECORDED. RECORD DATE AS “MMDDYYYY.”
* RECORD THE TIME AS HH:MM. BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY AND TO MARK THE BOX TO CHOOSE “AM” OR “PM”. FOR EXAMPLE, IF THE LAST TIME PARTICIPANT ATE OR DRANK WAS AT 2:05 PM RECORD “02:05” AND CHOOSE “PM”.
* **UR1100A/(LT\_\_EAT**\_**DRINK\_1).** LAST TIME ATE OR DRANK – DATE

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 M M D D Y Y Y Y

**UR1100B/(LT**\_**EAT\_DRINK\_2)).** LAST TIME ATE OR DRANK – TIME

|\_\_\_|\_\_\_| : |\_\_\_|\_\_\_|

 H H M M

REFUSED -1

DON’T KNOW -2

**UR1100C/(LT\_EAT\_DRINK\_3).** LAST TIME ATE OR DRANK – AM/PM

AM 1

PM. 2

REFUSED -1

DON’T KNOW -2

PROGRAMMER INSTRUCTIONS:

* HARD EDIT: INCLUDE HARD EDIT IF HOUR OR MINUTES ARE NOT 2 DIGITS (FILL THE SPACE WITH 0 AS NECESSARY)
* HARD EDIT: INCLUDE HARD EDIT IF HOUR IS NOT BETWEEN 01 AND 12
* HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59
* FORMAT DATE AS YYYYMMDD
* HARD EDIT: INCLUDE HARD EDIT IF MONTH IS NOT BETWEEN 01 AND 12.
* HARD EDIT: INCLUDE HARD EDIT IF DAY IS NOT BETWEEN 01 AND 31.
* HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2011.

UR1200/(ATE\_MEAT). How much of what you ate was beef, pork, tuna, or salmon?

NONE 1

Less than one quarter of the meal 2

One quarter to one half of the meal 3

Less than three quarters of the meal 4

Three quarters to all of the meal 5

All of the meal 6

REFUSED -1

DON’T KNOW -2

UR1300/(CREATINE\_SUPP). Do you take creatine supplements?

DATA COLLECTOR INSTRUCTIONS:

* IF THE PARTICIPANT ASKS, EXPLAIN THAT CREATINE SUPPLEMENTS ARE OFTEN TAKEN BY ATHLETES WISHING TO GAIN MUSCLE MASS.

YES 1

NO … 2

REFUSED -1

DON’T KNOW -2

DATA COLLECTOR INSTRUCTIONS:

* READ URINE COLLECTION INSTRUCTIONS TO THE PARTICIPANT.
* PREPARE THE WORK AREA WHILE THE PARTICIPANT IS COLLECTING SPECIMEN.
* PUT ON LAB COAT AND GLOVES.

UR1500/(SPECIMEN\_STATUS). URINE COLLECTION STATUS

DATA COLLECTOR INSTRUCTIONS:

* THANK THE PARTICIPANT FOR THEIR SAMPLE (OR FOR TRYING IF NO SAMPLE WAS COLLECTED).
* ENTER THE STATUS OF THE URINE COLLECTION

COLLECTED 1 **(SPECIMEN\_ID)**

NOT COLLECTED 2

**UR1600A/(SPECIMEN\_COMMENTS).** URINE COLLECTION TECHNICAL COMMENTS

DATA COLLECTOR INSTRUCTIONS:

* ENTER THE REASON THE SAMPLE WAS NOT COLLECTED. SELECT ONLY ONE RESPONSE.
* IF THE PARTICIPANT HAS A PHYSICAL LIMITATION THAT PREVENTS HIM/HER FROM PROVIDING A URINE SPECIMEN CHOOSE “PHYSICAL LIMITATION”.
* IF PARTICIPANT BECOMES ILL DURING THE VISIT AND IS UNABLE TO PROVIDE A URINE SPECIMEN OR HAS AN EMERGENCY THAT REQUIRES TERMINATION OF THE VISIT BEFORE A URINE SPECIMEN IS COLLECTED CHOOSE “PARTICIPANT ILL/EMERGENCY”.
* IF THE COLLECTION EQUIPMENT WAS NOT AVAILABLE AND URINE SAMPLE WAS NOT COLLECTED CHOOSE “COLLECTION EQUIPMENT NOT AVAILABLE.”
* IF THE URINE SAMPLE QUANTITY WAS NOT SUFFICIENT FOR ANALYSIS CHOOSE “QUANTITY NOT SUFFICIENT.”
* IF THERE WAS A LANGUAGE ISSUE DUE TO THE PARTICIPANT’S PRIMARY LANGUAGE BEING SPANISH CHOOSE “LANGUAGE ISSUE, SPANISH”
* IF THERE WAS A LANGUAGE ISSUE DUE TO THE PARTICIPANT’S PRIMARY LANGUAGE BEING A LANGUAGE OTHER THAN SPANISH CHOOSE “LANGUAGE ISSUE, NON SPANISH.”
* IF THE PARTICIPANT HAS A COGNITIVE DISABILITY THAT PREVENTS HIM/HER FROM UNDERSTANDING THE INSTRUCTIONS AND PROVIDING A URINE SPECIMEN CHOOSE “COGNITIVE DISABILITY.”
* IF THERE WAS NOT A SUFFICENT AMOUNT OF TIME FOR THE URINE SPECIMEN COLLECTION CHOOSE “NO TIME.”

PHYSICAL LIMITATION 1 **(TIME\_STAMP\_2)**

PARTICIPANT ILL/ EMERGENCY 2 (**TIME\_STAMP\_2)**

COLLECTION EQUIPMENT NOT AVAILABLE 3 (**TIME\_STAMP\_2)**

QUANTITY NOT SUFFICIENT 4 (**TIME\_STAMP\_2)**

LANGUAGE ISSUE, SPANISH 5 (**TIME\_STAMP\_2)**

LANGUAGE ISSUE, NON SPANISH 6 (**TIME\_STAMP\_2)**

COGNITIVE DISABILITY 7 (**TIME\_STAMP\_2)**

NO TIME 8 (**TIME\_STAMP\_2)**

OTHER -5

REFUSED -1 (**TIME\_STAMP\_2)**

DON’T KNOW -2 (**TIME\_STAMP\_2)**

UR1600B/(SPECIMEN\_COMMENT\_OTH). URINE COLLECTION TECHNICAL COMMENT OTHER SPECIFY

DATA COLLECTOR INSTRUCTION:

* IF THERE ARE ANY OTHER URINE COLLECTION TECHNICAL COMMENTS NOT LISTED IN THE PREVIOUS QUESTION, ENTER THE REASON BELOW.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **(TIME\_STAMP\_2)**

PROGRAMMER INSTRUCTION:

* LIMIT FREE TEXT TO 255 CHARACTERS

UR1700/(SPECIMEN\_ID). SPECIMEN ID

DATA COLLECTOR INSTRUCTIONS:

* RECORD URINE COLLECTION CUP SPECIMEN ID WHEN PARTICIPANT RETURNS WITH THE SAMPLE.
* IMMEDIATELY PLACE COLLECTION CUP IN DRY ICE CHAMBER OF THE TRANSPORT COOLER PER TRANSPORT INSTRUCTIONS.
* FORMAT MUST BE AA # # # # # # #-UR##

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PROGRAMMER INSTRUCTIONS:

* CANNOT BE NULL
* HARD EDIT: INCLUDE HARD EDIT IF FORMAT IS NOT AA # # # # # # #-UR## (FORMAT MUST BE AA # # # # # # #-UR##)

UR1800/(COLLECTION\_LOCATION). COLLECTION LOCATION

DATA COLLECTOR INSTRUCTIONS:

* RECORD WHERE URINE COLLECTION OCCURRED.

HOME 1

CLINIC 2

OTHER LOCATION 3

PROGRAMMER INSTRUCTIONS:

* IF STUDY CENTER IS PARTICIPATING IN LOI3-ENV-01-DAND **SPECIMEN\_STATUS** = 1, GO TO **UR\_COLL\_DIFFICULT**.
* OTHERWISE, GO TO **TIME\_STAMP\_2**.

DATA COLLECTOR INSTRUCTIONS:

* ASK THE FOLLOWING QUESTIONS OF THE PARTICIPANT:

UR1900/(UR\_COLL\_DIFFICULT). Was the urine collection difficult for you?

YES 1

NO 2

REFUSED -1

DON’T KNOW -2

UR2000/(UR\_COLL\_EASIER\_COMMENT). Is there anything that would make the urine sample collection easier for you?

COMMENT \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

REFUSED -1

DON’T KNOW -2

PROGRAMMER INSTRUCTION:

* LIMIT FREE TEXT TO 255 CHARACTERS

**(TIME\_STAMP\_2) DATE/TIME STAMP PROGRAMMER INSTRUCTION:**

* INSERT DATE/TIME STAMP