

Biospecimen Child Urine Collection Instrument

|  |  |
| --- | --- |
| **Event:** | 6-Month, 12-Month |
| **Participant:** | Child |
| **Respondent:** | Parent/Caregiver |
| **Domain:** | Biospecimen |
| **Type of Document:** | Data Collection Instrument |
| **Allowable Mode:** | In-Person |
| **Allowable Method:** | CAPI |
| **Recruitment Groups:** | EH, PB, HI |
| **Version:** | 1.0 |
| **Release:** | MDES 3.0 |

This page intentionally left blank.

Biospecimen Child Urine Collection Instrument

**TABLE OF CONTENTS**

BIOSPECIMEN URINE COLLECTION 1

Biospecimen Child Urine Collection Instrument

Biospecimen URINE COLLECTION

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

* INSERT DATE/TIME STAMP.

PROGRAMMER INSTRUCTIONS:

* PRELOAD PARTICIPANT ID (**P\_ID**) FOR CHILD AND RESPONDENT ID (**R\_P\_ID**) FOR RESPONDENT.
* PRELOAD CHILD’S FIRST NAME (**BABY\_FNAME**) AND DISPLAY NAME FOR “CHILD’S NAME” THROUGHOUT DOCUMENT.
* USE “the child” IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT IF CHILD’S NAME IS REFUSED.

CUP0100/(URINE\_INTRO). I would like to collect a sample of {CHILD’S NAME/the child}’s urine. Before I do so, I will explain this collection and ask you some questions.

DATA COLLECTOR INSTRUCTIONS:

* EXPLAIN THE CHILD URINE COLLECTION PROTOCOL TO THE PARENT OR CAREGIVER.
* BE SURE TO INFORM THE PARENT OR CAREGIVER THAT:
  + SHE/HE NEEDS TO BE PRESENT WHILE THE BAG IS APPLIED AND REMOVED FROM THE CHILD.
  + THE ADHESIVE ON THE BAG MAY CAUSE A MILD IRRITATION.
* RECORD AGREEMENT OR REFUSAL TO COLLECT URINE SPECIMEN.

CONTINUE 1

REFUSED -1

CUP0100A/(RESP\_REL). WHAT IS THE RELATIONSHIP OF THE PARENT OR CAREGIVER TO THE CHILD?

MOTHER 1

FATHER 2

OTHER -5

**PROGRAMMER INSTRUCTIONS:**

* IF **URINE\_INTRO** = 1 AND **RESP\_REL** = 1 OR 2, GO TO **COLLECTION\_METHOD**.
* IF **URINE\_INTRO** = -1 AND **RESP\_REL** = 1 OR 2, GO TO **REFUSE\_REASON**.
* OTHERWISE, IF **RESP\_REL** = -5, GO TO **RESP\_REL\_OTH**.

**CUP0100B/(RESP\_REL\_OTH).**

SPECIFY\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROGRAMMER INSTRUCTIONS:**

* LIMIT TEXT TO 255 CHARACTERS.
* IF **URINE\_INTRO** = 1, GO TO **COLLECTION\_METHOD**.
* OTHERWISE, GO TO **REFUSE\_REASON**.

CUP0100C/(REFUSE\_REASON). I am sorry that you have chosen not to participate in this collection. Can you tell me why?

DATA COLLECTOR INSTRUCTION:

* ENTER REASON FOR REFUSAL. SPECIFY IF OTHER THAN ALLERGIC REACTION/IRRITATION OR DIAPER RASH.

CONCERN ABOUT ALLERGIC REACTION/SKIN IRRITATION 1 **(CUP0150)**

CHILD HAS A DIAPER RASH 2 **(CUP0150)**

OTHER -5

REFUSED -1

DON’T KNOW -2

**CUP0100D/(REFUSE\_REASON\_OTH)**

SPECIFY\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **(CUP0150)**

PROGRAMMER INSTRUCTION:

* LIMIT TEXT TO 255 CHARACTERS.

**CUP0150.** That’s fine. Thank you for your time. **(TIME\_STAMP\_2)**

CUP0160/(COLLECTION\_METHOD). HOW WILL THE URINE BE COLLECTED?

DATA COLLECTOR INSTRUCTION:

* MARK THE CHOICE THAT INDICATES HOW THE CHILD’S URINE WILL BE COLLECTED.

NCS PROVIDED URINE BAG 1 **(CUP0200)**

OTHER -5

**CUP0170/(COLLECTION\_METHOD\_OTH)**

SPECIFY \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROGRAMMER INSTRUCTION:**

* LIMIT TEXT TO 255 CHARACTERS.

CUP0200/(LAST\_CHANGE\_DATE/LAST\_CHANGE\_TIME/LAST\_CHANGE\_TIME\_UNIT). When was the last time {CHILD’S NAME/the child}’s diaper was changed?

DATA COLLECTOR INSTRUCTIONS:

* RECORD WHEN DIAPER WAS LAST CHANGED.
* ENTER A TWO-DIGIT MONTH, A TWO-DIGIT DAY, AND A FOUR-DIGIT YEAR.
* 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 CHILD WAS CHANGED WAS AT 2:05 PM, RECORD “02:05” AND CHOOSE “PM.”
* IF RESPONSE WAS DETERMINED TO BE INVALID, ASK QUESTION AGAIN AND PROBE FOR VALID RESPONSE.

**CUP0200A/(LAST\_CHANGE\_DATE).** LAST DIAPER CHANGE - DATE

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

M M D D Y Y Y Y

REFUSED -1

DON’T KNOW -2

**CUP0200B/(LAST\_CHANGE\_TIME).**  LAST DIAPER CHANGE - TIME

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

H H M M

REFUSED -1

DON’T KNOW -2

**CUP0200C/(LAST\_CHANGE\_TIME \_UNIT).**  LAST DIAPER CHANGE – AM/PM

AM. 1

PM. 2

PROGRAMMER INSTRUCTIONS:

* HARD EDIT: INCLUDE HARD EDIT IF HOURS, MINUTES, MONTH OR DAY ARE NOT TWO DIGITS. (FILL THE SPACE WITH 0 AS NECESSARY.)
* HARD EDIT: INCLUDE HARD EDIT IF HOUR OR MONTH IS NOT BETWEEN 01 AND 12.
* HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59.
* 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 < 2012.
* HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.
* FORMAT DATE AS YYYYMMDD.

CUP0300/(LAST\_DRINK\_DATE/LAST\_DRINK\_TIME/LAST\_DRINK\_TIME\_UNIT). When was the last time {CHILD’S NAME/the child} had anything to drink?

DATA COLLECTOR INSTRUCTIONS:

* RECORD THE LAST TIME CHILD DRANK ANYTHING.
* ENTER A TWO-DIGIT MONTH, A TWO-DIGIT DAY, AND A FOUR-DIGIT YEAR.
* 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 CHILD DRANK WAS AT 2:05 PM, RECORD “02:05” AND CHOOSE “PM.”
* IF RESPONSE WAS DETERMINED TO BE INVALID, ASK QUESTION AGAIN AND PROBE FOR VALID RESPONSE.

**CUP0300A/(LAST\_DRINK\_DATE)**. LAST DRINK - DATE

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

M M D D Y Y Y Y

REFUSED -1

DON’T KNOW -2

**CUP0300B/(LAST\_DRINK\_TIME)**. LAST DRINK - TIME

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

H H M M

REFUSED -1

DON’T KNOW -2

**CUP0300C/(LAST\_DRINK\_TIME\_UNIT)**. LAST DRINK – AM/PM

AM 1

PM. 2

PROGRAMMER INSTRUCTIONS:

* HARD EDIT: INCLUDE HARD EDIT IF HOURS, MINUTES, MONTH OR DAY ARE NOT TWO DIGITS. (FILL THE SPACE WITH 0 AS NECESSARY.)
* HARD EDIT: INCLUDE HARD EDIT IF HOUR OR MONTH IS NOT BETWEEN 01 AND 12.
* HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59.HARD EDIT: INCLUDE HARD EDIT IF DAY IS NOT BETWEEN 01 AND 31.
* HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2012.
* HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.
* FORMAT DATE AS YYYYMMDD.

CUP0350/(CARE\_PRODUCTS). Have you or anyone else used any of the following products on your child's diaper area in the past 24 hours?

DATA COLLECTOR INSTRUCTIONS:

* READ THE CHOICES BELOW TO THE PARTICIPANT AND RECORD THE RESPONSE FOR EACH.
* SELECT ALL THAT APPLY.
* PROBE ANY OTHERS.
* IF THERE ARE ANY OTHER PRODUCTS USED THAT ARE NOT LISTED, SELECT OTHER AND SPECIFY THE PRODUCT TYPE.

Child powder/talc/cornstarch 1

Diaper cream/ointment 2

Vaseline 3

Child wipes 4

Child shampoo/body wash 5

Child lotion 6

Baby oil 7

None 8

REFUSED -1

DON’T KNOW -2

OTHER -5

PROGRAMMER INSTRUCTIONS:

* IF **CARE\_PRODUCTS** = ANY COMBINATION OF 1 THROUGH 7, GO TO **CLEANSE\_METHOD.**
* IF **CARE\_PRODUCTS** = -5 OR ANY COMBINATION OF 1 THROUGH 7 AND -5, GO TO **CARE\_PRODUCTS\_OTH.**
* IF **CARE\_PRODUCTS** = 8, -1 OR -2, DO NOT ALLOW ANY OTHER RESPONSE, AND GO TO **CLEANSE\_METHOD**.
* IF **CARE\_PRODUCTS** = 8, -1 OR -2, DO NO ALLOW SELECTION OF ADDITIONAL RESPONSES.

**CUP0400/(CARE\_PRODUCTS\_OTH).**

SPECIFY \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROGRAMMER INSTRUCTION:**

* LIMIT TEXT TO 255 CHARACTERS.

**DATA COLLECTOR COMPLETED QUESTIONS**

CUP0550/(CLEANSE\_METHOD). HOW WAS THE CHILD’S GENITAL AREA CLEANSED?

DATA COLLECTOR INSTRUCTION:

* MARK THE CHOICE THAT INDICATES HOW THE CHILD’S GENITAL AREA WAS CLEANSED PRIOR TO APPLICATION OF THE COLLECTION BAG.

SOAP AND WATER 1

WATER ONLY … 2

DID NOT CLEANSE 3

CUP0600/(CLEANSE\_DONE\_BY). WHO CLEANSED THE CHILD’S GENITAL AREA?

DATA COLLECTOR INSTRUCTION:

* RECORD WHO CLEANSED THE CHILD. IF OTHER THAN DATA COLLECTOR OR PARENT, SPECIFY.

DATA COLLECTOR 1 **(PLACED\_BAG\_1)**

PARENT/CAREGIVER … 2 **(PLACED\_BAG\_1)**

OTHER -5

**CUP0650/(CLEANSE\_DONE\_BY\_OTH).**

SPECIFY \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROGRAMMER INSTRUCTION:**

* LIMIT TEXT TO 255 CHARACTERS.

**CUP0700/(PLACED\_BAG\_1).** WHO PLACED THE URINE BAG ON THE CHILD?

DATA COLLECTOR INSTRUCTION:

* RECORD WHO PLACED THE URINE BAG ON THE CHILD.

DATA COLLECTOR 1 **(BAG\_2\_USED)**

PARENT/CAREGIVER 2 **(BAG\_2\_USED)**

OTHER -5

PARENT/CAREGIVER REFUSED

BAG PLACEMENT 3 **(CUP2000)**

**CUP0750/(PLACED\_BAG\_1\_OTH).**

SPECIFY \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PROGRAMMER INSTRUCTION:

* LIMIT TEXT TO 255 CHARACTERS

CUP0800/(BAG\_2\_USED) WAS A SECOND BAG USED?

DATA COLLECTOR INSTRUCTION:

* RECORD YES IF A SECOND BAG WAS USED. RECORD NO IF A SECOND BAG WAS NOT USED. RECORD REFUSED IF A SECOND BAG WAS REFUSED.

YES 1

NO 2 **(SPECIMEN\_STATUS)**

PARENT/CAREGIVER REFUSED

BAG PLACEMENT …………………….3 **(TIME\_STAMP\_2)**

**CUP0900/(BAG\_2\_USED\_REASON)** REASON FOR USING SECOND BAG.

FIRST BAG LEAKED 1 **(PLACED\_BAG\_2)**

FIRST BAG TORN/PULLED OFF 2 **(PLACED\_BAG\_2)**

FIRST BAG SPILLED 3 **(PLACED\_BAG\_2)**

BOWEL MOVEMENT 4 **(PLACED\_BAG\_2)**

OTHER -5

**CUP0900A/(BAG\_2\_USED\_REASON\_OTH).**

SPECIFY \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PROGRAMMER INSTRUCTION:

* LIMIT TEXT TO 255 CHARACTERS

**CUP0901/(PLACED\_BAG\_2).** WHO PLACED THE SECOND BAG ON THE CHILD?

DATA COLLECTOR INSTUCTION:

* RECORD WHO PLACED THE SECOND URINE BAG ON THE CHILD.

DATA COLLECTOR 1 **(SPECIMEN\_STATUS)**

PARENT/CAREGIVER 2 **(SPECIMEN\_STATUS)**

**CUP2000**OTHER -5

**CUP0901A/(PLACED\_BAG\_2\_OTH).**

SPECIFY \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PROGRAMMER INSTRUCTION:

* LIMIT TEXT TO 255 CHARACTERS.

**CUP1000/(SPECIMEN\_STATUS).** STATUS OF THE URINE COLLECTION

DATA COLLECTOR INSTRUCTION:

* ENTER THE STATUS OF THE URINE COLLECTION.

COLLECTED 1 **(BAG\_REMOVED \_BY)**

NOT COLLECTED 2

**CUP1600/(NO\_SPECIMEN\_REASON).**

DATA COLLECTOR INSTRUCTIONS:

* ENTER THE REASON WHY SPECIMEN WAS NOT COLLECTED.
* SELECT ONLY ONE RESPONSE.

BAG LEAKED 1 (**COLLECTION\_LOCATION)**

BAG TORN/PULLED OFF 2 (**COLLECTION\_LOCATION)**

BAG SPILLED 3 (**COLLECTION\_LOCATION)**

CONTAINER/CUP SPILLED 4 (**COLLECTION\_LOCATION)**

CUP LEAKED 5 (**COLLECTION\_LOCATION)**

SPECIMEN CONTAMINATED 6 (**COLLECTION\_LOCATION)**

PHYSICAL LIMITATION 7 (**COLLECTION\_LOCATION)**

CAREGIVER ILL/EMERGENCY 8 (**COLLECTION\_LOCATION)**

COLLECTION SUPPLIES MALFUNCTIONED 9 (**COLLECTION\_LOCATION)**

NO URINE TO TRANSFER 10 (**COLLECTION\_LOCATION)**

CHILD ILL/EMERGENCY 11 (**COLLECTION\_LOCATION)**

NO TIME 12 (**COLLECTION\_LOCATION)**

OTHER -5

REFUSED -1 (**COLLECTION\_LOCATION)**

**CUP1600A/(NO\_SPECIMEN\_REASON\_OTH).**

SPECIFY \_\_\_\_\_\_\_\_\_\_\_\_ **(COLLECTION\_LOCATION)**

PROGRAMMER INSTRUCTION:

* LIMIT TEXT TO 255 CHARACTERS.

CUP1650/(BAG\_REMOVED\_BY). WHO REMOVED THE BAG FROM THE CHILD?

DATA COLLECTOR INSTRUCTION:

* RECORD WHO REMOVED THE URINE BAG FROM THE CHILD. IF OTHER THAN DATA COLLECTOR OR PARENT, SPECIFY.

DATA COLLECTOR 1 (**SPECIMEN\_ID)**

PARENT/CAREGIVER … 2 (**SPECIMEN\_ID)**

OTHER -5

**CUP1660/(BAG\_REMOVED\_OTH).**

SPECIFY \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PROGRAMMER INSTRUCTION:

* LIMIT TEXT TO 255 CHARACTERS.

CUP1700/(SPECIMEN\_ID). URINE COLLECTION CUP SPECIMEN ID

DATA COLLECTOR INSTRUCTIONS:

* RECORD URINE COLLECTION CUP SPECIMEN ID.
* FORMAT MUST BE AA # # # # # # #-BU##

|\_\_\_|\_\_\_|\_\_\_|\_\_\_|\_\_\_|\_\_\_|\_\_\_|\_\_\_|\_\_\_|-BU|\_\_\_|\_\_\_|

PROGRAMMER INSTRUCTIONS:

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

**CUP1750/(URINE\_COLLECT\_DATE).** DATE CHILD URINE SPECIMEN WAS COLLECTED

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

M M D D Y Y Y Y

**CUP1750A/(URINE\_COLLECT\_TIME).** TIME CHILD URINE SPECIMEN WAS COLLECTED

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

H H M M

**CUP1750B/(URINE\_COLLECT\_TIME\_UNIT).**  TIME CHILD URINE SPECIMEN WAS COLLECTED – AM/PM

AM. 1

PM. 2

**DATA COLLECTOR INSTRUCTION:**

* RECORD THE DATE AS TWO DIGIT MONTH, TWO DIGIT DAY, AND FOUR DIGIT YEAR.

**PROGRAMMER INSTRUCTIONS:**

* HARD EDIT: INCLUDE HARD EDIT IF HOURS, MINUTES, MONTH OR DAY ARE NOT 2 DIGITS (FILL THE SPACE WITH 0 AS NECESSARY)
* HARD EDIT: INCLUDE HARD EDIT IF HOUR OR MONTH IS NOT BETWEEN 01 AND 12
* HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59.
* HARD EDIT: INCLUDE HARD EDIT IF DAY IS NOT BETWEEN 01 AND 31.
* HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2012.
* HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.
* FORMAT DATE AS YYYYMMDD

CUP1800/(COLLECTION\_LOCATION). WHERE DID THE URINE COLLECTION OCCUR?

DATA COLLECTOR INSTRUCTION:

* RECORD WHERE URINE COLLECTION OCCURRED OR WAS ATTEMPTED.

HOME 1 **(COLLECTION\_COMMENT)**

CLINIC 2 **(COLLECTION\_COMMENT)**

OTHER LOCATION -5

**CUP1900/(COLLECTION\_LOCATION\_OTH).**

SPECIFY\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROGRAMMER INSTRUCTION:**

* LIMIT TEXT TO 255 CHARACTERS.

**CUP1900/(COLLECTION\_COMMENT**). RECORD ANY PROBLEMS OR CONCERNS ABOUT THE COLLECTION.

DATA COLLECTOR INSTRUCTION:

* DOCUMENT ANY PROBLEMS OR CONCERNS ABOUT THE CHILD URINE COLLECTION PROCEDURE.

NO COMMENTS………..1 **(CUP2000)**

COMMENT………………2

**CUP1900A/(COLLECTION\_COMMENT\_OTH).**

SPECIFY\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PROGRAMMER INSTRUCTION:

* LIMIT TEXT TO 255 CHARACTERS.

**CUP2000.** {That’s fine. Thank you for your time./Thank you for your child’s participation in this sample collection.}

PROGRAMMER INSTRUCTIONS:

* IF **PLACED\_BAG\_1** = 3 or **BAG\_2\_USED** = 3, DISPLAY “That’s fine. Thank you for your time.”
* OTHERWISE DISPLAY, “Thank you for your child’s participation in this sample collection.”

**(TIME\_STAMP\_2) PROGRAMMER INSTRUCTION:**

* INSERT DATE/TIME STAMP.