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**Biospecimen Child Blood Instrument**

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| --- | --- |
| **Event:** | 12-Month |
| **Participant:** | Child |
| **Respondent:****Domain:****Type of Document:****Allowable Mode:****Allowable Method:**  | Parent/CaregiverBiospecimenInstrument In PersonCAPI |
| **Recruitment Groups:** **Version:****Release:** | EH, PB, HI1.0MDES 3.0 |

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Biospecimen Child Blood Instrument

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Biospecimen Child Blood Instrument

(TIME\_STAMP\_1) PROGRAMMER INSTRUCTION:

* INSERT DATE/TIME STAMP.

BL0100/(BLOOD\_INTRO). I would like to collect a sample of {CHILD’S NAME/ the child}’s blood. Before I do so, I will explain this collection and ask you some questions.

DATA COLLECTOR INSTRUCTIONS:

* EXPLAIN THE CHILD BLOOD COLLECTION PROTOCOL TO THE PARENT OR CAREGIVER .
* IF THE PARENT OR CAREGIVER REFUSED THE COLLECTION, SELECT REFUSED. OTHERWISE, SELECT CONTINUE.

CONTINUE 1

REFUSED -1

PROGRAMMER INSTRUCTIONS:

* PRELOAD PARTICIPANT ID **(P\_ID)** FOR CHILD AND RESPONDENT ID **(R\_P\_ID)** FOR RESPONDENT (MOTHER, FATHER, OTHER).
* PRELOAD CHILD’S FIRST NAME (**BABY\_FNAME**) AND DISPLAY NAME IN “CHILD’S NAME” THROUGHOUT DOCUMENT.
* USE “the child” IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT IF CHILD’S NAME IS REFUSED OR DON’T KNOW.
* PRELOAD **CHILD\_SEX**.
	+ IF **CHILD\_SEX** = 1, DISPLAY “his” AND “he” IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.
	+ IF **CHILD\_SEX** = 2, DISPLAY “her” AND “she” IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.

DATA COLLECTOR COMPLETED QUESTION:

BL0100A/(RESP\_REL). WHAT IS THE RELATIONSHIP OF THE PARENT OR CAREGIVER TO CHILD?

MOTHER 1

FATHER 2

OTHER -5

PROGRAMMER INSTRUCTIONS:

* IF BLOOD\_INTRO = 1 AND RESP\_REL = 1 OR 2, GO TO HEMOPHILIA.
* IF **BLOOD\_INTRO** = -1 AND **RESP\_REL** = 1 OR 2, GO TO **REFUSAL\_REASON**.
* OTHERWISE, IF **RESP\_REL** = -5, GO TO **RESP\_REL\_OTH**.

BL0100B/(RESP\_REL\_OTH).

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

**PROGRAMMER INSTRUCTIONS:**

* LIMIT TEXT TO 255 CHARACTERS.
* IF **BLOOD\_INTRO** = 1, GO TO **HEMOPHILIA**.
* OTHERWISE, GO TO **REFUSAL\_REASON**.

BL0100C/(REFUSAL\_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.

CHILD HAS FEVER/OTHER ILLNESS 1 **(BL2000)**

OTHER -5

REFUSED -1 **(BL2000)**

DON’T KNOW -2 **(BL2000)**

**BL0100D/(REFUSAL\_REASON\_OTH)**.

SPECIFY\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**(BL2000)**

**PROGRAMMER INSTRUCTION:**

* LIMIT TEXT TO 255 CHARACTERS.

BL0200/(HEMOPHILIA). Has {CHILD’S NAME/the child} been diagnosed with hemophilia or any bleeding disorder?

**DATA COLLECTOR INSTRUCTION:**

* RESPONSE DETERMINES ELIGIBILITY OF CHILD FOR BLOOD DRAW.

YES 1 **(BL1600)**

NO 2

REFUSED -1 **(BL1900)**

DON’T KNOW -2 **(BL1900)**

BL0300/(BLOOD\_THINNER). Has {CHILD’S NAME/the child} taken any blood thinning medication, such as Coumadin or Warfarin?

DATA COLLECTOR INSTRUCTION:

* RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

YES 1 **(BL1600)**

NO 2

REFUSED -1 **(BL1900)**

DON’T KNOW -2 **(BL1900)**

BL0400/(CHEMO). Has {CHILD’S NAME/the child} had cancer chemotherapy within the past 4 weeks?

**DATA COLLECTOR INSTRUCTION:**

* RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

YES 1 **(BL1600)**

NO 2

REFUSED -1 **(BL1900)**

DON’T KNOW -2 **(BL1900)**

BL0500/(BLOOD\_DRAW). In the past, have there been any problems with taking blood from {CHILD’S NAME/the child}?

YES 1

NO 2 **(LAST\_EAT\_ TIME/LAST\_EAT\_TIME\_UNIT/LAST\_EAT\_DATE)**

REFUSED -1 **(LAST\_EAT\_ TIME/LAST\_EAT\_TIME\_UNIT/LAST\_EAT\_DATE)**

DON’T KNOW -2 **(LAST\_EAT\_ TIME/LAST\_EAT\_TIME\_UNIT/LAST\_EAT\_DATE)**

**BL0600/(BLOOD\_DRAW\_PROB)**. What problems did {he/she} have with taking blood in the past?

DATA COLLECTOR INSTRUCTIONS:

* SELECT ALL THAT APPLY.
* PROBE: Any others?

FAINTING 1

HEMATOMA 2

UNCOOPERATIVE/FIGETING/UNCONTROLLABLE CRYING 3

BRUISING 4

OTHER -5

REFUSED -1

DON’T KNOW -2

**PROGRAMMER INSTRUCTIONS:**

* IF **BLOOD\_DRAW\_PROB** = any combination of 1 through 4, go to **LAST\_EAT\_ TIME/LAST\_EAT\_TIME\_UNIT/LAST\_EAT\_DATE**
* IF **BLOOD\_DRAW\_PROB** = any combination of 1 through 4, and -5, go to **BLOOD\_DRAW\_OTH**.
* IF **BLOOD\_DRAW\_PROB** = -5, go to **BLOOD\_DRAW\_OTH**.
* IF **BLOOD\_DRAW\_PROB** = -1 or -2, do not allow any other responses and go to **LAST\_EAT\_ TIME/LAST\_EAT\_TIME\_UNIT/LAST\_EAT\_DATE**.
* **BLOOD\_DRAW\_PROB** can only= -1 or -2; not both.

**BL0600A/(BLOOD\_DRAW\_OTH)**.

**DATA COLLECTOR INSTRUCTION:**

* IF THERE WERE ANY PROBLEMS WITH A PAST BLOOD DRAW THAT ARE NOT LISTED IN THE PREVIOUS QUESTION, RECORD THE PROBLEM BELOW.

SPECIFY:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROGRAMMER INSTRUCTION:**

* LIMIT TEXT TO 255 CHARACTERS.

BL0700/(LAST\_EAT\_TIME/LAST\_EAT\_TIME\_UNIT/LAST\_EAT\_DATE). When was the last time {CHILD’S NAME/the child} had anything to eat or drink other than water?

**DATA COLLECTOR INSTRUCTIONS:**

* RECORD THE LAST TIME CHILD ATE OR DRANK ANYTHING OTHER THAN WATER.
* 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 ATE OR DRANK WAS AT 2:05 PM, RECORD “02:05” AND CHOOSE “PM”.
* RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.

**BL0700A/(LAST\_EAT\_TIME).** LAST TIME ATE OR DRANK – TIME

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

 H H M M

REFUSED -1

DON’T KNOW -2

**BL0700B/(LAST\_EAT\_TIME\_UNIT).** LAST TIME ATE OR DRANK – AM/PM

AM 1

PM 2

**BL0700C/(LAST\_EAT\_DATE).** LAST TIME ATE OR DRANK – DATE

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

 M M D D Y Y Y Y

REFUSED -1

DON’T KNOW -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.

BL1200/(VITAMIN). Has {CHILD’S NAME/the child} taken a dietary supplement such as vitamins or minerals in the last 8 hours?

YES 1

NO 2

REFUSED -1

DON’T KNOW -2

BL1500/(BLOOD\_COMPLETE). Thank you for answering my questions. I am now going to prepare to draw blood.

CONTINUE 1 **(TIME\_STAMP\_2)**

REFUSED -1 **(BL2000)**

**BL1600.** Because {CHILD’S NAME/the child} {has been diagnosed with a bleeding disorder/uses blood thinners/had cancer chemotherapy}, we will not be able to draw {his/her} blood for this study. **(TIME\_STAMP\_5)**

**PROGRAMMER INSTRUCTIONS:**

* DISPLAY “has been diagnosed with a bleeding disorder” IF **HEMOPHILIA**=1.
* DISPLAY “uses blood thinners” IF **BLOOD\_THINNER**=1.
* DISPLAY “had cancer chemotherapy” IF **CHEMO**=1.

**BL1900.** Because you do not know or declined to answer questions about {CHILD’S NAME/the child’s} {hemophilia/use of blood thinners/chemotherapy status}, we will not be able to draw {his/her} blood for this study. **(TIME\_STAMP\_5)**

**PROGRAMMER INSTRUCTIONS:**

* DISPLAY “hemophilia” IF **HEMOPHILIA** = -1 OR -2.
* DISPLAY “use of blood thinners” IF **BLOOD\_THINNER** = -1 OR -2.
* DISPLAY “chemotherapy status” IF **CHEMO** = -1 OR -2.

**BL2000.** That’s fine. Thank you for your time.  **(TIME\_STAMP\_5)**

BLOOD COLLECTION

(TIME\_STAMP\_2) PROGRAMMER INSTRUCTION:

* INSERT DATE/TIME STAMP.

BL2100/(BLOOD\_INST). BLOOD DRAW INSTRUCTIONS

**DATA COLLECTOR INSTRUCTIONS:**

* CONFIRM THAT BLOOD TUBES ARE LABELED AND NOT EXPIRED PRIOR TO COLLECTION OF SPECIMEN.
* BE SURE TO EMPLOY UNIVERSAL PRECAUTIONS TO PREVENT EXPOSURE TO INFECTIOUS DISEASES AT ALL TIMES WHEN HANDLING BIOLOGICAL SPECIMENS.BE SURE TO EXPLAIN EACH PART OF PROCEDURE BEING PERFORMED DURING BLOOD COLLECTION.
* STOP DRAWING BLOOD IF BRUISING OCCURS.
* COLLECTION TUBES SHOULD BE DRAWN IN THE FOLLOWING ORDER:
	+ 3mL Lavender Top AA# # # # # # # - LV20
	+ 3mL Red top AA# # # # # # # - RD20
	+ 3mL Red top AA# # # # # # # - RD21
	+ 3mL Lavender top AA# # # # # # # - LV21

BL2100A/(COLLECTION\_LOCATION). COLLECTION LOCATION

**DATA COLLECTOR INSTRUCTION:**

* RECORD WHERE BLOOD COLLECTION OCCURRED.

HOME 1  **(CBLOOD\_COLL\_DATE)**

CLINIC 2  **(CBLOOD\_COLL\_DATE)**

OTHER LOCATION -5

**BL2100B/(COLLECTION\_LOCATION\_OTH).**

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

**PROGRAMMER INSTRUCTION:**

* LIMIT TEXT TO 255 CHARACTERS.

**BL2150/(CBLOOD\_COLL\_DATE).** DATE CHILD BLOOD SPECIMEN COLLECTED

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

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**BL2150A/(CBLOOD\_COLL\_TIME).** TIME CHILD BLOOD SPECIMEN COLLECTED

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

 H H M M

**BL2150B/(CBLOOD\_COLL\_TIME\_UNIT).** TIME CHILD BLOOD SPECIMEN 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 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.

BL2200. Thank you for {CHILD’S NAME/the child}’s blood sample.

**DATA COLLECTOR INSTRUCTION:**

* CHECK IF CLOTTING HAS OCCURRED AND APPLY BAND-AID OVER GAUZE.

**BL2400/(TUBE\_TYPE).** ASSIGN **TUBE\_TYPE**

**PROGRAMMER INSTRUCTIONS:**

* LOOP THROUGH **TUBE\_TYPE, SPECIMEN\_ID, TUBE\_STATUS, TUBE\_COMMENTS** (IFAPPLICABLE) AND **TUBE\_COMMENTS**\_**OTH** (IF APPLICABLE) SEQUENTIALLY FOR EACH OF THE FOUR (4) BLOOD TUBES. THEN GO TO **COLLECTION\_STATUS**.
* DISPLAY CORRECT **TUBE\_TYPE** FOREACH LOOP**:**
	+ IF FIRST CYCLE OF the LOOP, THEN SET **TUBE\_TYPE** = 1 AND DISPLAY “3mL Lavender top (LV20).”
	+ IF SECOND CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 2 AND DISPLAY “3mL Red top (RD20).”
	+ IF THIRD CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 3 AND DISPLAY “3mL Red top (RD21).”
	+ IF FOURTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 4 AND DISPLAY “3mL Lavender top (LV21).”

BL2500/(SPECIMEN\_ID). SPECIMEN\_ID FOR {TUBE\_TYPE}

**DATA COLLECTOR INSTRUCTIONS:**

* SCAN {**TUBE\_TYPE**} BARCODE.
* IF THE BARCODE SCANNER IS NOT WORKING, MANUALLY ENTER THE INFORMATION.
* FORMAT SHOULD BE AA # # # # # # # - AA # #

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

**PROGRAMMER INSTRUCTIONS:**

* DISPLAY CORRECT **TUBE\_TYPE** DESCRIPTION IN BRACKETS AND FORMAT FOR **SPECIMEN\_ID** FOR EACH LOOP:
* IF **TUBE\_TYPE** = 1, DISPLAY “3mL Lavender top, (LV20)” AND FORMAT
AA# # # # # # # - LV20.
* IF **TUBE\_TYPE** = 2, DISPLAY “3mL Red top (RD20),” AND FORMAT
AA# # # # # # # - RD20.
* IF **TUBE\_TYPE** = 3, DISPLAY “3mL Red top (RD21),” AND FORMAT
* AA## # # # ## - RD21.
* IF **TUBE\_TYPE** = 4, DISPLAY “3mL Lavender top (LV21),” AND FORMAT
AA# # # # # # # - LV21.

BL2600/(TUBE\_STATUS). {TUBE\_TYPE} BLOOD TUBE COLLECTION STATUS

FULL DRAW 1

SHORT DRAW 2

NO DRAW 3

**DATA COLLECTOR INSTRUCTIONS:**

* ENTER STATUS OF {**TUBE\_TYPE**}BLOOD TUBE.
* SELECT “FULL DRAW” TO INDICATE THAT THE BLOOD TUBE WAS FILLED TO AT LEAST 3/4 OF THE DESIRED CAPACITY. DESIRED CAPACITY IS DEFINED AS FILLED TO THE FILL LINE INDICATED ON THE BLOOD TUBE LABEL.
* SELECT “SHORT DRAW” TO INDICATE THAT THE BLOOD TUBE WAS FILLED TO LESS THAN 3/4 OF THE DESIRED CAPACITY.
* SELECT “NO DRAW” TO INDICATE THAT THE BLOOD TUBE WAS NOT COLLECTED.

**PROGRAMMER INSTRUCTIONS**:

* DISPLAY CORRECT **TUBE\_TYPE** FOR LOOP:
* IF FIRST CYCLE OF the LOOP, THEN **TUBE\_TYPE** = 1, DISPLAY ”3mL Lavender top (LV20)”.
* IF SECOND CYCLE OF THE LOOP, THEN **TUBE\_TYPE** = 2, DISPLAY ”3mL Red top (RD20)”.
* IF THIRD CYCLE OF THE LOOP, THEN **TUBE\_TYPE** = 3, DISPLAY ”3mL Red top (RD21)”.
* IF FOURTH CYCLE OF THE LOOP, THEN **TUBE\_TYPE** = 4, DISPLAY ”3mL Lavender top (LV21)”.
* IF **TUBE\_STATUS** = 2 OR 3, GO TO **TUBE\_COMMENTS**.
* OTHERWISE, IF **TUBE\_STATUS** = 1 AND
	+ **TUBE\_TYPE** = 1, 2, OR 3, GO TO **TUBE\_TYPE** AND LOOP THROUGH REMAINING BLOOD SPECIMENS.
	+ **TUBE\_TYPE** = 4, GO TO **OVERALL\_COMMENTS**.

BL2700/(TUBE\_COMMENTS). REASON {TUBE\_TYPE} BLOOD TUBE NOT COLLECTED OR DRAW WAS SHORT.

**DATA COLLECTOR INSTRUCTION:**

* ENTER REASONS {**TUBE\_TYPE**} WAS NOT COLLECTED OR DRAW WAS SHORT. SELECT ALL THAT APPLY

EQUIPMENT FAILURE 1

FAINTING 2

LIGHT-HEADEDNESS 3

HEMATOMA 4

BRUISING 5

VEIN COLLAPSED DURING PROCEDURE 6

NO SUITABLE VEIN 7

UNCOOPERATIVE/FIDGETING/UNCOTROLLABLE CRYING 8

PARENT/CAREGIVER REFUSED 9

OTHER -5

**PROGRAMMER INSTRUCTIONS:**

* DISPLAY CORRECT **TUBE\_TYPE** AS REFERENCE FOR LOOP:
* IF FIRST CYCLE OF the LOOP, THEN **TUBE\_TYPE** = 1, DISPLAY ”3mL Lavender top (LV20)”.
* IF SECOND CYCLE OF THE LOOP, THEN **TUBE\_TYPE** = 2, DISPLAY ”3mL Red top (RD20)”.
* IF THIRD CYCLE OF THE LOOP, THEN **TUBE\_TYPE** = 3, DISPLAY ”3mL Red top (RD21)”.
* IF FOURTH CYCLE OF THE LOOP, THEN **TUBE\_TYPE** = 4, DISPLAY ”3mL Lavender top (LV21)”.
* IF **TUBE\_TYPE** = 1, 2, OR 3 AND
	+ **TUBE\_COMMENTS** = ANY COMBINATION OF 1 THROUGH 8, GO TO **TUBE\_TYPE** AND LOOP THROUGH REMAINING BLOOD SPECIMENS.
	+ **TUBE\_COMMENTS** = -5OR ANY COMBINATION OF 1 THROUGH 8 AND -5, GO TO **TUBE\_COMMENTS\_OTH**.
	+ **TUBE\_COMMENTS** =-1 OR -2, DO NOT ALLOW ANY OTHER RESPONSES, GO TO **TUBE\_TYPE** AND LOOP THROUGH REMAINING BLOOD SPECIMENS.
* IF **TUBE\_TYPE** = 4 AND
	+ **TUBE\_COMMENTS** =ANY COMBINATION OF 1 THROUGH 8, GO TO **COLLECTION\_STATUS**.
	+ **TUBE\_COMMENTS** = -5OR ANY COMBINATION OF 1 THROUGH 8 AND -5, GO TO **TUBE\_COMMENTS\_OTH**.
	+ **TUBE\_COMMENTS** = -1 OR -2**,** DO NOT ALLOW ANY OTHER RESPONSES AND GO TO **COLLECTION\_STATUS**.

**BL2700A/(TUBE\_COMMENTS\_OTH)**

SPECIFY

**PROGRAMMER INSTRUCTIONS:**

* LIMIT TEXT TO 255 CHARACTERS.
* IF **TUBE\_TYPE** = 1, 2, OR 3 GO TO **TUBE\_TYPE** AND LOOP THROUGH REMAINING BLOOD SPECIMENS.
* IF **TUBE\_TYPE** = 4, GO TO **COLLECTION\_STATUS**.

BL2800/(COLLECTION\_STATUS). BLOOD TUBE COLLECTION OVERALL STATUS

COLLECTED 1

PARTIALLY COLLECTED 2

NOT COLLECTED 3

**PROGRAMMER INSTRUCTIONS:**

* **COLLECTION\_STATUS** = 1 IF EACH **TUBE\_TYPE** HAS A **TUBE\_STATUS** = 1.
* **COLLECTION\_STATUS** = 2 IF AT LEAST 1 BUT LESS THAN 4 TUBES HAVE A **TUBE\_STATUS** = 1 OR THAT ALL TUBES HAVE A **TUBE\_STATUS** = 2.
* **COLLECTION\_STATUS** = 3 IF EACH TUBE\_TYPE HAS A **TUBE\_STATUS** = 3
* IF **COLLECTION STATUS** = 1 OR 2, GO TO **TIME\_STAMP\_3**.
* OTHERWISE, GO TO **OVERALL\_COMMENTS**.

**BL2900/(OVERALL\_COMMENTS).** BLOOD COLLECTION OVERALL COMMENTS

**DATA COLLECTOR INSTRUCTION:**

* ENTER MAIN REASON BLOOD WAS NOT COLLECTED.

SAFETY EXCLUSION 1 **(BLOOD\_DRAW\_COMMENT)**

PHYSICAL LIMITATION 2 **(BLOOD\_DRAW\_COMMENT)**

CAREGIVER ILL/EMERGENCY 3 **(BLOOD\_DRAW\_COMMENT)**

QUANTITY NOT SUFFICIENT 4 **(BLOOD\_DRAW\_COMMENT)**

CHILD ILL/EMERGENCY 5 **(BLOOD\_DRAW\_COMMENT)**

NO TIME 6 **(BLOOD\_DRAW\_COMMENT)**

PARENT/CAREGIVER REFUSED 7 **(BLOOD\_DRAW\_COMMENT)**

OTHER -5

**BL2900A/(OVERALL\_COMMENTS\_OTH)**

SPECIFY  **(BLOOD\_DRAW\_COMMENT)**

**PROGRAMMER INSTRUCTION:**

* LIMIT TEXT TO 255 CHARACTERS.

BLOOD CENTRIFUGATION

(TIME\_STAMP\_3) PROGRAMMER INSTRUCTION:

* INSERT DATE/TIME STAMP.

BL3000/(CENTRIFUGE\_LOCATION). CENTRIFUGATION LOCATION

* **DATA COLLECTOR INSTRUCTIONS:** RECORD WHERE BLOOD WILL BE CENTRIFUGED.

DEFAULT COLLECTION LOCATION 1 **(EQUIP\_ID)**

SPSC 2 **(TIME\_STAMP\_4)**

OTHER -5

**BL3000A/(CENTRIFUGE\_LOCATION\_OTH).**

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

**PROGRAMMER INSTRUCTION:**

* LIMIT TEXT TO 255 CHARACTERS.

BL3100/(EQUIP\_ID). EQUIPMENT ID FOR CENTRIFUGE

**DATA COLLECTOR INSTRUCTION:**

* ENTER EQUIPMENT ID FOR CENTRIFUGE.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

BL3125/(CENTRIFUGE\_START\_DATE\_TIME). DATE AND TIME CENTRIFUGATION BEGAN

**DATA COLLECTOR INSTRUCTIONS:**

* RECORD THE TIME THE BLOOD TUBES WERE PLACED IN THE CENTRIFUGE.
* RECORD THE TIME AS HH:MM, BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY AND TO CHOOSE “AM” OR “PM.” FOR EXAMPLE, IF THE BLOOD TUBES WERE PLACED IN THE CENTRIFUGE AT 2:05 PM, RECORD “02:05” AND CHOOSE “PM.”
* RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.

**BL3125A/(CENTRIFUGE\_START\_TIME).** CENTRIFUGE START – TIME

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

 H H M M

**BL3125B/(CENTRIFUGE\_START\_TIME\_UNIT).** CENTRIFUGE START – AM/PM

AM 1

PM 2

**BL3125C/(CENTRIFUGE\_START\_DATE).** CENTRIFUGE START – DATE

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

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**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.

BL3130/(CENTRIFUGE\_END\_DATE\_TIME).TIME CENTRIFUGATION ENDED

**DATA COLLECTOR INSTRUCTIONS:**

* RECORD THE TIME CENTRIFUGATION WAS COMPLETED.
* 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 CENTRIFUGATION WAS COMPLETED AT 2:05 PM, RECORD “02:05” AND CHOOSE “PM.”
* RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.

**BL3130A/(CENTRIFUGE\_END\_TIME).** CENTRIFUGE END – TIME

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

 H H M M

**BL3130B/(CENTRIFUGE\_END\_TIME\_UNIT).** CENTRIFUGE END – AM/PM

AM 1

PM 2

**BL3130C/(CENTRIFUGE\_END\_DATE).** CENTRIFUGE END – DATE

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 M M D D Y Y Y Y

**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 < 2011.
* HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME OR LESS THAN **CENTRIFUGE\_START\_TIME** AND/OR **CENTRIFUGE\_START\_DATE**.
* FORMAT DATE AS YYYYMMDD.

BL3140/(CENTRIFUGE\_TEMP\_MEASURE). TEMPERATURE OF CENTRIFUGE

**DATA COLLECTOR INSTRUCTIONS:**

* IF ABLE TO MEASURE CENTRIFUGE TEMPERATURE, SELECT “TEMPERATURE.”
* IF NOT ABLE TO MEASURE CENTRIFUGE TEMPERATURE, THEN SELECT “NOT ABLE TO MEASURE” AND THE REASON THE TEMPERATURE COULD NOT BE RECORDED.
* OTHERWISE, SELECT OTHER AND SPECIFY

TEMPERATURE 1 **(CENTRIFUGE\_TEMP/**

**CENT\_TEMP\_POSNEG)**

NOT ABLE TO MEASURE – THERMOMETER BROKEN 2 **(BLOOD\_HEMOLYZE)**

NOT ABLE TO MEASURE – THERMOMETER NOT AVAILABLE 3 **(BLOOD\_HEMOLYZE)**

NOT ABLE TO MEASURE – OTHER -5

**BL3140A/(CENTRIFUGE\_TEMP\_MEASURE\_OTH)**.

SPECIFY \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**(BLOOD\_HEMOLYZE)**

**PROGRAMMER INSTRUCTION:**

* LIMIT TEXT TO 255 CHARACTERS.

BL3150/(CENTRIFUGE\_TEMP/CENT\_TEMP\_POSNEG). TEMPERATURE OF CENTRIFUGE

**DATA COLLECTOR INSTRUCTIONS:**

* RECORD THE TEMPERATURE READING ON THE DIGITAL THERMOMETER ATTACHED TO THE CENTRIFUGE AT THE TIME THAT THE BLOOD TUBES ARE REMOVED AFTER CENTRIFUGATION.
* ENTER TEMPERATURE IN DEGREES CELSIUS.

**BL3150A**/(**CENTRIFUGE\_TEMP**). RECORD THE TEMPERATURE TO THE FIRST DECIMAL POINT.

|\_\_\_|\_\_\_| . |\_\_\_| °C

**PROGRAMMER INSTRUCTIONS:**

* SOFT EDIT: DISPLAY SOFT EDIT IF TEMPERATURE IS < 15.0 oC OR > 25.0oC
* SOFT EDIT: DISPLAY SOFT EDIT IF NO VALUE ENTERED IN THE FIRST DECIMAL POINT.

**BL3150B/(CENT\_TEMP\_POSNEG**). RECORD IF THE TEMPERATURE IS A POSITIVE OR NEGATIVE VALUE.

**DATA COLLECTOR INSTRUCTIONS:**

* If temperature is zero or above, record “Positive.”
* If temperature is below zero, record “Negative.”

POSITIVE 1

NEGATIVE 2

BL3160/(BLOOD\_HEMOLYZE). did blood hemolyze?

**DATA COLLECTOR INSTRUCTION:**

* RECORD WHETHER HEMOLYSIS OCCURRED IN ONE OR MORE OF THE BLOOD TUBES.

YES, ALL TUBES HEMOLYZED 1

YES, AT LEAST ONE TUBE HEMOLYZED AND AT
 LEAST ONE TUBE DID NOT HEMOLYZE 2

NO, NONE OF THE TUBES HEMOLYZED 3 **(TIME\_STAMP\_4)**

BL3170/(V1\_TUBE\_HEMOLYZE) INDICATE WHICH TUBE(S) HEMOLYZED.

**DATA COLLECTOR INSTRUCTION:**

* SELECT ALL THAT APPLY:

**(TUBE\_TYPE)**= 1**,** 3mL Lavender top (LV20) 1

**(TUBE\_TYPE)**= 2**,** 3mL Red top (RD20) .. 2

**(TUBE\_TYPE)**= 3, 3mL Red top (RD21) 3

**(TUBE\_TYPE)**= 4**,** 3mL Lavender top (LV21) 4

**PROGRAMMER INSTRUCTION:**

* DISPLAY THE FOLLOWING RESPONSE CATEGORIES:

**(TUBE\_TYPE)**= 1**,** 3mL Lavender top (LV20) 1

**(TUBE\_TYPE)**= 2**,** 3mL Red top (RD20) .. 2

**(TUBE\_TYPE)**= 3, 3mL Red top (RD21) 3

**(TUBE\_TYPE)**=4**,** 3mL Lavender top (LV21) 4

BL3180/(CENTRIFUGE\_COMMENT). CENTRIFUGE OTHER COMMENTS

**DATA COLLECTOR INSTRUCTION:**

* ENTER CENTRIFUGE COMMENTS:

NO COMMENTS 1 **(TIME\_STAMP\_4)**

COMMENT 2

BL3185/(CENTRIFUGE\_COMMENT\_OTH).

**DATA COLLECTOR INSTRUCTION:**

* ENTER ANY CENTRIFUGE COMMENT.

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

**PROGRAMMER INSTRUCTION:**

* LIMIT FREE TEXT TO 255 CHARACTERS.

PREPARATION FOR BLOOD TUBE TRANSPORT

**(TIME\_STAMP\_4) PROGRAMMER INSTRUCTION:**

* INSERT DATE/TIME STAMP.

BL3200/(COLD\_TEMP\_MEASURE). TEMPERATURE OF REFRIGERATED CHAMBER

**DATA COLLECTOR INSTRUCTIONS:**

* PREPARE THE TUBES FOR TRANSPORT IN EITHER THE REFRIGERATED CLAMSHELL OR IN THE AMBIENT TUBE HOLDER, DEPENDING ON THE TUBE TYPE AND LOCATION OF CENTRIFUGATION.
* PLACE A LOWER THRESHOLD (0.0°C) MONITOR INSIDE THE REFRIGERATED CLAMSHELL AND INSIDE THE AMBIENT TUBE HOLDER (IF APPLICABLE).
* ACTIVATE AN UPPER THRESHOLD (20.0°C) MONITOR AND AFFIX IT TO THE OUTSIDE OF THE REFRIGERATED CLAMSHELL.
* IF ABLE TO MEASURE TEMPERATURE, THEN SELECT “TEMPERATURE.” ENTER THE TEMPERATURE OF THE DIGITAL THERMOMETER IN THE TRANSPORT COOLER AT THE TIME THE DATA COLLECTOR PUTS THE SPECIMEN IN THE COOLER.
* IF NOT ABLE TO MEASURE TEMPERATURE, THEN SELECT “NOT ABLE TO MEASURE.”
* IF THERE ARE NOT ANY TUBES THAT REQUIRE REFRIGERATED TRANSPORT TEMPERATURES, THEN SELECT “NOT APPLICABLE.”

TEMPERATURE 1 **(COLD\_TEMP/**

**COLD\_TEMP\_POSNEG)**

NOT ABLE TO MEASURE – THERMOMETER BROKEN 2 (**COLD\_THRESHOLD\_LOW)**

NOT ABLE TO MEASURE – THERMOMETER NOT AVAILABLE 3 (**COLD\_THRESHOLD\_LOW)**

NOT ABLE TO MEASURE – OTHER -5

NOT APPLICABLE -7 **(COLD\_THRESHOLD\_LOW)**

BL3200A/(COLD\_TEMP\_MEASURE\_OTH).

SPECIFY **(COLD\_THRESHOLD\_LOW)**

**PROGRAMMER INSTRUCTION:**

* LIMIT TEXT TO 255 CHARACTERS.

BL3300/(COLD\_TEMP/COLD\_TEMP\_POSNEG). RECORD TEMPERATURE OF REFRIGERATED CHAMBER

**DATA COLLECTOR INSTRUCTION:**

* RECORD THE TEMPERATURE OF THE REFRIGERATED CHAMBER OF THE TRANSPORT COOLER.

**BL3300A/**(**COLD\_TEMP**). ENTER TEMPERATURE IN DEGREES CELSIUS.

|\_\_\_|\_\_\_| . |\_\_\_| °C

**3300B/COLD\_TEMP\_POSNEG**). RECORD IF THE TEMPERATURE IS A POSITIVE OR NEGATIVE VALUE

**DATA COLLECTOR INSTRUCTIONS:**

* If temperature is zero or above, record “Positive.”
* If temperature is below zero, record “Negative.”

POSITIVE 1

NEGATIVE 2

**PROGRAMMER INSTRUCTIONS:**

* SOFT EDIT: DISPLAY SOFT EDIT IF TEMPERATURE IS ≥ 10.0oC OR IF ≤ 0.0oC.
* SOFT EDIT: DISPLAY SOFT EDIT IF NO VALUE ENTERED IN THE FIELD FOLLOWING THE DECIMAL POINT.

BL3400/(COLD\_THRESHOLD\_LOW). STATUS OF REFRIGERATED CHAMBER LOW THRESHOLD MONITOR

**DATA COLLECTOR INSTRUCTION:**

* RECORD STATUS OF THE LOW THRESHOLD MONITOR IN THE REFRIGERATED CHAMBER OF THE TRANSPORT COOLER.

YES, IN CHAMBER 1

NO, NOT REQUIRED 2

NO, NOT AVAILABLE 3

BL3500/(COLD\_THRESHOLD\_HIGH). STATUS OF REFRIGERATED CHAMBER HIGH THRESHOLD MONITOR

**DATA COLLECTOR INSTRUCTION:**

* RECORD STATUS OF THE HIGH THRESHOLD MONITOR IN THE REFRIGERATED COMPARTMENT OF THE COOLER.

YES, IN CHAMBER 1

NO, NOT REQUIRED 2

NO, NOT AVAILABLE 3

PROGRAMMER INSTRUCTIONS:

* IF 12-MONTH VISIT, GO TO TIME\_STAMP\_5.
* OTHERWISE, GO TO AMBIENT\_THRESHOLD\_LOW.

BL3600/(AMBIENT\_THRESHOLD\_LOW). STATUS OF AMBIENT LOW THRESHOLD MONITOR

**DATA COLLECTOR INSTRUCTION:**

* RECORD STATUS OF THE LOW THRESHOLD MONITOR IN THE AMBIENT COMPARTMENT OF THE COOLER.

YES, IN CHAMBER 1

NO, NOT REQUIRED 2

NO, NOT AVAILABLE 3

BL3650/(TRANSPORT\_COMMENT). TRANSPORT COMMENT

NO COMMENTS 1 **(TIME\_STAMP\_5)**

COMMENT 2

BL3660/(TRANSPORT\_COMMENT\_OTH).

**DATA COLLECTOR INSTRUCTION:**

* ENTER ANY TRANSPORT COMMENT.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROGRAMMER INSTRUCTION:**

* LIMIT TEXT TO 255 CHARACTERS.

BL3700/(BLOOD\_DRAW\_COMMENT). ADDITIONAL BLOOD DRAW COMMENT

**DATA COLLECTOR INSTRUCTION:**

* ENTER ANY ADDITIONAL BLOOD COLLECTION COMMENTS:

NO COMMENTS 1 **(TIME\_STAMP\_5)**

COMMENT 2

**BL3750/(BLOOD\_DRAW\_COMMENT\_OTH).**

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

(TIME\_STAMP\_5) PROGRAMMER INSTRUCTION:

* INSERT DATE/TIME STAMP.