

Child Blood Instrument

|  |  |
| --- | --- |
| Event Category: | Time-Based |
| Event: | 12M, 36M, 60M |
| Administration: | N/A |
| Instrument Target: | Child |
| Instrument Respondent: | Primary Caregiver |
| Domain: | Biospecimen |
| Document Category: | Sample Collection |
| Method: | Data Collector Administered |
| Mode (for this instrument\*): | In-Person, CAI |
| OMB Approved Modes: | In-Person, CAI |
| Estimated Administration Time: | 13 minutes |
| Multiple Child/Sibling Consideration: | Per Child |
| Special Considerations: | N/A |
| Version: | 2.0 |
| MDES Release: | 4.0 |

\*This instrument is OMB-approved for multi-mode administration but this version of the instrument is designed for administration in this/these mode(s) only.

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Child Blood Instrument

TABLE OF CONTENTS

[GENERAL PROGRAMMER INSTRUCTIONS: 1](#_Toc371078026)

[BIOSPECIMEN CHILD BLOOD INSTRUMENT 3](#_Toc371078027)

[BLOOD COLLECTION 10](#_Toc371078028)

[BLOOD CENTRIFUGATION 16](#_Toc371078029)

[PREPARATION FOR BLOOD TUBE TRANSPORT 21](#_Toc371078030)

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Child Blood Instrument

GENERAL PROGRAMMER INSTRUCTIONS:

WHEN PROGRAMMING INSTRUMENTS, VALIDATE FIELD LENGTHS AND TYPES AGAINST THE MDES TO ENSURE DATA COLLECTION RESPONSES DO NOT EXCEED THOSE OF THE MDES. SOME GENERAL ITEM LIMITS USED ARE AS FOLLOWS:

|  |  |  |  |
| --- | --- | --- | --- |
| **DATA ELEMENT FIELDS** | **MAXIMUM CHARACTERS PERMITTED** | **DATA TYPE** | **PROGRAMMER INSTRUCTIONS** |
| ADDRESS AND EMAIL FIELDS | 100 | CHARACTER |  |
| UNIT AND PHONE FIELDS | 10 | CHARACTER |  |
| \_OTH AND COMMENT FIELDS | 255 | CHARACTER | * Limit text to 255 characters |
| FIRST NAME AND LAST NAME | 30 | CHARACTER | * Limit text to 30 characters |
| ALL ID FIELDS | 36 | CHARACTER |  |
| ZIP CODE | 5 | NUMERIC |  |
| ZIP CODE LAST FOUR | 4 | NUMERIC |  |
| CITY | 50 | CHARACTER |  |
| DOB AND ALL OTHER DATE FIELDS (E.G., DT, DATE, ETC.) | 10 | NUMERIC  CHARACTER | * DISPLAY AS MM/DD/YYYY * STORE AS YYYY-MM-DD * HARD EDITS:   MM MUST EQUAL 01 TO 12  DD MUST EQUAL 01 TO 31  YYYY MUST BE BETWEEN 1900 AND CURRENT YEAR. |
| TIME VARIABLES | TWO-DIGIT HOUR AND TWO-DIGIT MINUTE, AM/PM DESIGNATION | NUMERIC | * HARD EDITS:   HOURS MUST BE BETWEEN 00 AND 12;  MINUTES MUST BE BETWEEN 00 AND 59 |

**Instrument Guidelines for Participant and Respondent IDs:**

PRENATALLY, THE **P\_ID** IN THE MDES HEADER IS THAT OF THE PARTICIPANT (E.G. THE NON-PREGNANT WOMAN, PREGNANT WOMAN, OR THE FATHER).

POSTNATALLY, A RESPONDENT ID WILL BE USED IN ADDITION TO THE PARTICIPANT ID BECAUSE SOMEBODY OTHER THAN THE PARTICIPANT MAY BE COMPLETING THE INTERVIEW. FOR EXAMPLE, THE PARTICIPANT MAY BE THE CHILD AND THE RESPONDENT MAY BE THE MOTHER, FATHER, OR ANOTHER CAREGIVER. THEREFORE, MDES VERSION 2.2 AND ALL FUTURE VERSIONS CONTAIN A **R\_P\_ID** (RESPONDENT PARTICIPANT ID) HEADER FIELD FOR EACH POST-BIRTH INSTRUMENT. THIS WILL ALLOW ROCs TO INDICATE WHETHER THE RESPONDENT IS SOMEBODY OTHER THAN THE PARTICIPANT ABOUT WHOM THE QUESTIONS ARE BEING ASKED.

**A REMINDER:**

ALL RESPONDENTS MUST BE CONSENTED AND HAVE RECORDS IN THE PERSON, PARTICIPANT, PARTICIPANT\_CONSENT AND LINK\_PERSON\_PARTICIPANT TABLES, WHICH CAN BE PRELOADED INTO EACH INSTRUMENT. ADDITIONALLY, IN POST-BIRTH QUESTIONNAIRES WHERE THERE IS THE ABILITY TO LOOP THROUGH A SET OF QUESTIONS FOR MULTIPLE CHILDREN, IT IS IMPORTANT TO CAPTURE AND STORE THE CORRECT CHILD **P\_ID** ALONG WITH THE LOOP INFORMATION. IN THE MDES VARIABLE LABEL/DEFINITION COLUMN, THIS IS INDICATED AS FOLLOWS: **EXTERNAL IDENTIFIER: PARTICIPANT ID FOR CHILD DETAIL.**

BIOSPECIMEN CHILD BLOOD INSTRUMENT

**(TIME\_STAMP\_BCB\_ST).**

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * INSERT DATE/TIME STAMP. * PRELOAD PARTICIPANT ID **(P\_ID)** FOR CHILD AND RESPONDENT ID **(R\_P\_ID)** FOR ADULT CAREGIVER. * PRELOAD CHILD'S FIRST NAME AND DISPLAY NAME IN **C\_FNAME** THROUGHOUT INSTRUMENT * OTHERWISE, IF **C\_FNAME** = -1 OR -2, DISPLAY "the child" IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT. * IF **CHILD\_SEX** IN PARTICIPANT VERIFICATION QUESTIONNAIRE = 1, DISPLAY "his", "he", OR "himself" IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT. * IF **CHILD\_SEX** IN PARTICIPANT VERIFICATION QUESTIONNAIRE = 2, DISPLAY "her", "she", OR "herself" IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT. |

**BCB01000/(BLOOD\_INTRO).** I would like to collect a sample of {C\_FNAME/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 ADULT CAREGIVER. * IF THE ADULT CAREGIVER REFUSED THE COLLECTION, SELECT REFUSED. OTHERWISE, SELECT CONTINUE. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| CONTINUE | 1 | HEMOPHILIA |
| REFUSED | -1 |  |

|  |
| --- |
| SOURCE |
| National Children’s Study, Vanguard  Phase (12M Child Blood) |

**BCB04000/(REFUSAL\_REASON).** I am sorry that you have chosen not to participate in this collection. Can you tell me why?

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * ENTER REASON FOR REFUSAL. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| CHILD HAS FEVER/OTHER ILLNESS | 1 | BCB21000 |
| OTHER | -5 |  |
| REFUSED | -1 | BCB21000 |
| DON'T KNOW | -2 | BCB21000 |

|  |
| --- |
| SOURCE |
| National Children’s Study, Legacy Phase (Modified) (6M Child) |

**BCB05000/(REFUSAL\_REASON\_OTH).** SPECIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| --- |
| SOURCE |
| National Children’s Study, Legacy Phase (Modified) (6M Child) |

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| --- |
| PROGRAMMER INSTRUCTIONS |
| * GO TO **BCB21000.** |

**BCB06000/(HEMOPHILIA).** Has {C\_FNAME/the child} been diagnosed with hemophilia or any bleeding disorder?

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * RESPONSE DETERMINES ELIGIBILITY OF CHILD FOR BLOOD DRAW. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| YES | 1 | BCB19000 |
| NO | 2 |  |
| REFUSED | -1 | BCB20000 |
| DON'T KNOW | -2 | BCB20000 |

|  |
| --- |
| SOURCE |
| National Children’s Study, Vanguard  Phase  Modified (Adult Blood)  National Children's Study, Legacy Phase |

**BCB08000/(CHEMO).** Has {C\_FNAME/the child} had cancer chemotherapy within the past 4 weeks?

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| YES | 1 | BCB19000 |
| NO | 2 |  |
| REFUSED | -1 | BCB20000 |
| DON'T KNOW | -2 | BCB20000 |

|  |
| --- |
| SOURCE |
| National Children’s Study, Vanguard Phase  Modified (Adult Blood)  National Children's Study, Legacy Phase |

**BCB09000/(LAST\_BLOOD\_DR AW).** Has {C\_FNAME/the child} had blood drawn in the last 24 hours?

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| YES | 1 | BCB19000 |
| NO | 2 |  |
| REFUSED | -1 | BCB20000 |
| DON'T KNOW | -2 | BCB20000 |

|  |
| --- |
| SOURCE |
| New |

**BCB10000/(BLOOD\_DRAW).** Has {C\_FNAME/the child} had any problems with a blood draw in the past?

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| YES | 1 |  |
| NO | 2 | BCB13000 |
| REFUSED | -1 | BCB13000 |
| DON'T KNOW | -2 | BCB13000 |

|  |
| --- |
| SOURCE |
| National Children’s Study, Vanguard Phase  Modified (Adult Blood)  National Children's Study, Legacy Phase |

**BCB11000/(BLOOD\_DRAW\_PROB).** What problems did {he/she} have with a blood draw in the past?

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| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * SELECT ALL THAT APPLY. * PROBE:  Any others? |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| FAINTING | 1 |  |
| HEMATOMA | 2 |  |
| UNCOOPERATIVE/FIDGETING/UNCONTROLLABLE CRYING | 3 |  |
| BRUISING | 4 |  |
| OTHER | -5 |  |
| REFUSED | -1 |  |
| DON'T KNOW | -2 |  |

|  |
| --- |
| SOURCE |
| National Children’s Study, Vanguard Phase  Modified (Adult Blood)  National Children's Study, Legacy Phase |

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| PROGRAMMER INSTRUCTIONS |
| * IF **BLOOD\_DRAW\_PROB** = ANY COMBINATION OF 1 THROUGH 4, GO TO **BCB13000.** * IF **BLOOD\_DRAW\_PROB**= -5 OR ANY COMBINATION OF 1 THROUGH 4 AND -5, GO TO **BLOOD\_DRAW\_PROB\_OTH**. * IF **BLOOD\_DRAW\_PROB**= -1 OR -2, DO NOT ALLOW SELECTION OF ADDITIONAL RESPONSES AND GO TO **BCB13000**. |

**BCB12000/(BLOOD\_DRAW\_PROB\_OTH).** SPECIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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| SOURCE |
| National Children’s Study, Vanguard Phase  Modified (Adult Blood)  National Children's Study, Legacy Phase |

**BCB13000.** When was the last time {C\_FNAME/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 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. |

|  |
| --- |
| SOURCE |
| National Children’s Study, Vanguard Phase  Modified (Adult Blood)  National Children's Study, Legacy Phase |

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

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

   H    H      M    M

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| REFUSED | -1 |  |
| DON'T KNOW | -2 |  |

**(LAST\_EAT\_TIME\_UNIT)** LAST TIME ATE OR DRANK – UNIT

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| AM | 1 |  |
| PM | 2 |  |
| REFUSED | -1 |  |
| DON'T KNOW | -2 |  |

**(LAST\_EAT\_MM)** LAST TIME ATE OR DRANK – DATE: MONTH

|\_\_\_|\_\_\_|

   M   M

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| REFUSED | -1 |  |
| DON'T KNOW | -2 |  |

**(LAST\_EAT\_DD)** LAST TIME ATE OR DRANK – DATE: DAY

|\_\_\_|\_\_\_|

   D   D

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| REFUSED | -1 |  |
| DON'T KNOW | -2 |  |

**(LAST\_EAT\_YYYY)** LAST TIME ATE OR DRANK – DATE: YEAR

|\_\_\_|\_\_\_|\_\_\_|\_\_\_|

   Y     Y     Y     Y

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| REFUSED | -1 |  |
| DON'T KNOW | -2 |  |

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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 YEAR ≠ CURRENT YEAR. * HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME. |

**BCB17000/(VITAMIN).** Has {C\_FNAME/the child} taken a dietary supplement such as vitamins or minerals in the last 8 hours?

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| YES | 1 |  |
| NO | 2 |  |
| REFUSED | -1 |  |
| DON'T KNOW | -2 |  |

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| --- |
| SOURCE |
| National Children’s Study, Vanguard Phase  Modified (Adult Blood)  National Children's Study, Legacy Phase |

**BCB18000/(BLOOD\_COMPLETE).** Thank you for answering my questions. I am now going to prepare to draw {C\_FNAME/the child}'s blood.

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| CONTINUE | 1 | TIME\_STAMP\_BCB\_ET |
| REFUSED | -1 | REFUSAL\_REASON |

|  |
| --- |
| SOURCE |
| National Children’s Study, Vanguard Phase  Modified (Adult Blood)  National Children's Study, Legacy Phase |

**BCB19000.** Because {C\_FNAME/the child} {has been diagnosed with a bleeding disorder/had cancer chemotherapy/had blood drawn in the last 24 hours}, we will not be able to draw {his/her} blood for this study.

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| --- |
| SOURCE |
| National Children’s Study, Vanguard Phase  Modified (Adult Blood)  National Children's Study, Legacy Phase |

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| PROGRAMMER INSTRUCTIONS |
| * DISPLAY “has been diagnosed with a bleeding disorder” IF **HEMOPHILIA**=1. * DISPLAY “had cancer chemotherapy” IF **CHEMO**=1. * DISPLAY “had blood drawn in the last 24 hours” IF **LAST\_BLOOD\_DRAW**=1. * GO TO **BCB21000**. |

**BCB20000.** Because you do not know or declined to answer questions about {C\_FNAME/the child}’s {hemophilia/chemotherapy status/blood drawn in last 24 hours}, we will not be able to draw {his/her} blood for this study.

|  |
| --- |
| SOURCE |
| National Children’s Study, Vanguard Phase  Modified (Adult Blood)  National Children's Study, Legacy Phase |

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| PROGRAMMER INSTRUCTIONS |
| * DISPLAY “hemophilia” IF **HEMOPHILIA** = -1 OR-2. * DISPLAY “chemotherapy status” IF **CHEMO** = -1OR -2. * DISPLAY “blood drawn in last 24 hours” IF **LAST\_BLOOD\_DRAW**= -1 OR -2. |

**BCB21000.** That’s fine. Thank you for your time.

|  |
| --- |
| SOURCE |
| National Children’s Study, Vanguard Phase  Modified (Adult Blood)  National Children's Study, Legacy Phase |

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * GO TO **BLOOD\_DRAW\_COMMENT**. |

**(TIME\_STAMP\_BCB\_ET).**

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * INSERT DATE/TIME STAMP. |

BLOOD COLLECTION

**(TIME\_STAMP\_BC\_ST).**

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * INSERT DATE/TIME STAMP. |

**BC01000/(BLOOD\_INST).** BLOOD DRAW INSTRUCTIONS

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| --- |
| 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**:**   + IF 12 MONTH VISIT     - 3mL Lavender top, prescreened (LP20)     - 3mL Red top (RD20)     - 3mL Red top (RD21)     - 3mL Lavender top (LV21)   + IF 36 MONTH VISIT     - 3mL Lavender top, prescreened (LP20)     - 3.5mL Gold top SST (SS20)     - 5mL Red top (RD22)     - 4mL Lavender top (LV22)     - 2.5mL Clear top PAXgene™ (PX20)   + IF 60 MONTH VISIT     - 3mL Lavender top, prescreened (LP20)     - 6mL Royal blue top, serum (RS20)     - 5mL Gold top SST (SS22)     - 4mL Lavender top (LV22) |

**BC02000/(COLLECTION\_LOCATION).** COLLECTION LOCATION

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * RECORD WHERE BLOOD COLLECTION OCCURRED. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| HOME | 1 | BC04000 |
| CLINIC | 2 | BC04000 |
| HOSPITAL | 3 | BC04000 |
| OTHER | -5 |  |

**BC03000/(COLLECTION\_LOCATION\_OTH).** SPECIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**BC04000.** DATE CHILD BLOOD SPECIMEN COLLECTED

|  |
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| DATA COLLECTOR INSTRUCTIONS |
| * RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR. |

**(CBLOOD\_COLL\_MM)** |\_\_\_|\_\_\_|

   M    M

**(CBLOOD\_COLL\_DD)** |\_\_\_|\_\_\_|

  D     D

**(CBLOOD\_COLL\_YYYY)** |\_\_\_|\_\_\_|\_\_\_|\_\_\_|

   Y     Y    Y     Y

**BC05000.** TIME CHILD BLOOD SPECIMEN COLLECTED

|  |
| --- |
| 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 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’. |

**(CBLOOD\_COLL\_TIME)** |\_\_\_|\_\_\_|:|\_\_\_|\_\_\_|

   H    H       H     H

**(CBLOOD\_COLL\_TIME\_UNIT)** TIME CHILD BLOOD SPECIMEN COLLECTED – AM/PM

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| AM | 1 |  |
| PM | 2 |  |

**BC07000.** Thank you for {C\_FNAME/the child}’s blood sample.

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| DATA COLLECTOR INSTRUCTIONS |
| * CHECK IF CLOTTING HAS OCCURRED AND APPLY BANDAGE OVER GAUZE. |

**BC08000/(TUBE\_STATUS).** {**TUBE\_TYPE**} BLOOD TUBE COLLECTION STATUS

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| FULL DRAW | 1 |  |
| SHORT DRAW | 2 | TUBE\_COMMENTS |
| NO DRAW | 3 | TUBE\_COMMENTS |

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| --- |
| 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. |

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| PROGRAMMER INSTRUCTIONS |
| * LOOP THROUGH  **TUBE\_STATUS, SPECIMEN\_ID, TUBE\_COMMENTS** (IF APPLICABLE) AND **TUBE\_COMMENTS\_OTH**(IF APPLICABLE) SEQUENTIALLY FOR EACH OF THE FOUR (4) OR FIVE (5) BLOOD TUBES. * DISPLAY CORRECT **TUBE\_TYPE** FOR LOOP: * IF **EVENT\_TYPE**= 27 (12 MONTH VISIT):   + IF FIRST CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 1, DISPLAY ”3mL Lavender top, prescreened (LP20)”.   + IF SECOND CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 2, DISPLAY ”3mL Red top (RD20)”.   + IF THIRD CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 3, DISPLAY ”3mL Red top (RD21)”.   + IF FOURTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 4, DISPLAY ”3mL Lavender top (LV21)”. * IF **EVENT\_TYPE**= 37 (36 MONTH VISIT):   + IF FIRST CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**= 1, DISPLAY ”3mL Lavender top, prescreened (LP20)”.   + IF SECOND CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 5, DISPLAY ”3.5mL Gold top SST (SS20)”.   + IF THIRD CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 6, DISPLAY ”5mL Red top (RD22)”.   + IF FOURTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 7, DISPLAY ”4mL Lavender top (LV22)”.   + IF FIFTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 8, DISPLAY ”2.5mL Clear top PAXgene™ (PX20)”. * IF **EVENT\_TYPE**= XX (60 MONTH VISIT):   + IF FIRST CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 1 AND DISPLAY “3mL Lavender top, prescreened (LP20).”   + IF SECOND CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 9 AND DISPLAY “6mL Royal blue top, serum (RS20).”   + IF THIRD CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 10 AND DISPLAY “5mL Gold top SST (SS22).”   + IF FOURTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE** = 7 AND DISPLAY “4mL Lavender top (LV22).” |

**BC09000/(SPECIMEN\_ID).** ENTER SPECIMEN ID FOR {**TUBE\_TYPE**}

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| DATA COLLECTOR INSTRUCTIONS |
| * SCAN {**TUBE\_TYPE**} BARCODE. * IF THE BARCODE SCANNER IS NOT WORKING, RECORD THE INFORMATION. |

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| PROGRAMMER INSTRUCTIONS |
| * DISPLAY CORRECT **TUBE\_TYPE** AND REFERENCE FORMAT FOR **SPECIMEN\_ID** FOR EACH LOOP.   + IF **TUBE\_TYPE**= 1, DISPLAY ”3mL Lavender top, prescreened (LP20)” AND FORMAT AS A A # # # # # # # - LP20.   + IF **TUBE\_TYPE** = 2, DISPLAY ”3mL Red top (RD20)” AND FORMAT AS A A # # # # # # # - RD20.   + IF **TUBE\_TYPE** = 3, DISPLAY ”3mL Red top (RD21)” AND FORMAT AS A A # # # # # # # - RD21.   + IF **TUBE\_TYPE** = 4, DISPLAY ”3mL Lavender top (LV21)” AND FORMAT AS A A # # # # # # # - LV21.   + IF **TUBE\_TYPE** = 5, DISPLAY ”3.5mL Gold top SST (SS20)” AND FORMAT AS A A # # # # # # # - SS20.   + IF **TUBE\_TYPE** = 6, DISPLAY ”5mL Red top (RD22)” AND FORMAT AS A A # # # # # # # - RD22.   + IF **TUBE\_TYPE** = 7, DISPLAY ”4mL Lavender top (LV22)” AND FORMAT AS A A # # # # # # # - LV22.   + IF **TUBE\_TYPE** = 8, DISPLAY ”2.5mL Clear top PAXgene™ (PX20)” AND FORMAT AS A A # # # # # # # - PX20.   + IF **TUBE\_TYPE**= 9, DISPLAY “6mL Royal blue top, serum (RS20)” AND FORMAT AS A A # # # # # # # - RS20.   + IF **TUBE\_TYPE**= 10, DISPLAY “5mL Gold top SST (SS22)" AND FORMAT AS A A # # # # # # # - SS22. |

**BC11000/(TUBE\_COMMENTS).** REASON {**TUBE\_TYPE**} BLOOD TUBE NOT COLLECTED OR DRAW WAS SHORT.

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| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * ENTER REASONS {**TUBE\_TYPE**} WAS NOT COLLECTED OR DRAW WAS SHORT. * SELECT ALL THAT APPLY. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| EQUIPMENT FAILURE | 1 |  |
| FAINTING | 2 |  |
| LIGHT-HEADEDNESS | 3 |  |
| HEMATOMA | 4 |  |
| BRUISING | 5 |  |
| VEIN COLLAPSED DURING PROCEDURE | 6 |  |
| NO SUITABLE VEIN | 7 |  |
| UNCOOPERATIVE/FIDGETING/UNCONTROLLABLE CRYING | 8 |  |
| ADULT CAREGIVER REFUSED | 9 |  |
| OTHER | -5 |  |

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * DISPLAY CORRECT **TUBE\_TYPE**   + IF**TUBE\_TYPE** = 1, DISPLAY ”3mL Lavender top, prescreened (LP20)”   + IF **TUBE\_TYPE**= 2, DISPLAY ”3mL Red top (RD20)”   + IF **TUBE\_TYPE**= 3, DISPLAY ”3mL Red top (RD21)”   + IF**TUBE\_TYPE**= 4, DISPLAY ”3mL Lavender top (LV21)”   + IF **TUBE\_TYPE** = 5, DISPLAY ”3.5mL Gold top SST (SS20)”   + IF **TUBE\_TYPE** = 6, DISPLAY ”5mL Red top (RD22)”   + IF **TUBE\_TYPE**= 7, DISPLAY ”4mL Lavender top (LV22)”   + IF **TUBE\_TYPE** = 8, DISPLAY ”2.5mL Clear top PAXgene™ (PX20)”   + IF **TUBE\_TYPE** = 9, DISPLAY “6mL Royal blue top, serum (RS20)”   + IF **TUBE\_TYPE** = 10, DISPLAY “5mL Gold top SST (SS22)" * IF THIS IS NOT THE LAST LOOP, AND   + **TUBE\_COMMENTS** = ANY COMBINATION OF 1 THROUGH 9, GO TO **TUBE\_STATUS** AND LOOP THROUGH REMAINING BLOOD SPECIMENS.   + **TUBE\_COMMENTS** = -5 OR ANY COMBINATION OF 1 THROUGH 9 AND -5, GO TO **TUBE\_COMMENTS\_OTH**. * IF THIS IS THE LAST LOOP, AND   + **TUBE\_COMMENTS** = ANY COMBINATION OF 1 THROUGH 9, GO TO **COLLECTION\_STATUS.**   + **TUBE\_COMMENTS** = -5 OR ANY COMBINATION OF 1 THROUGH 9 AND -5, GO TO **TUBE\_COMMENTS\_OTH.** |

**BC12000/(TUBE\_COMMENTS\_OTH).** SPECIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * IF THIS IS NOT THE LAST LOOP,  GO TO **TUBE\_STATUS** AND LOOP THROUGH REMAINING BLOOD SPECIMENS. * OTHERWISE, GO TO **COLLECTION\_STATUS.** |

**BC13000/(COLLECTION\_STATUS).** BLOOD TUBE COLLECTION OVERALL STATUS

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| COLLECTED | 1 | TIME\_STAMP\_BC\_ET |
| PARTIALLY COLLECTED | 2 | TIME\_STAMP\_BC\_ET |
| NOT COLLECTED | 3 |  |

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * **COLLECTION\_STATUS** = 1 IF EACH **TUBE\_TYPE** HAS A **TUBE\_STATUS** = 1. * **COLLECTION\_STATUS** = 2     + IF **EVENT\_TYPE** = 27 OR XX (60-MONTH VISIT), AND IF AT LEAST 1 BUT LESS THAN 4 TUBES HAVE A **TUBE\_STATUS**= 1 OR ALL TUBES HAVE A **TUBE\_STATUS**= 2.   + IF**EVENT\_TYPE**= 37 AND IF AT LEAST 1 BUT LESS THAN 5 TUBES HAVE A **TUBE\_STATUS**= 1 OR ALL TUBES HAVE A **TUBE\_STATUS**= 2. * **COLLECTION\_STATUS** = 3 IF EACH **TUBE\_TYPE** HAS A **TUBE\_STATUS** =3. |

**BC14000/(OVERALL\_COMMENTS).** BLOOD COLLECTION OVERALL COMMENTS

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * ENTER MAIN REASON BLOOD WAS NOT COLLECTED. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| 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 |
| ADULT CAREGIVER REFUSED | 7 | BLOOD\_DRAW\_COMMENT |
| OTHER | -5 |  |

**BC15000/(OVERALL\_COMMENTS\_OTH).** SPECIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * GO TO **BLOOD\_DRAW\_COMMENT**. |

**(TIME\_STAMP\_BC\_ET).**

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * INSERT DATE/TIME STAMP. |

BLOOD CENTRIFUGATION

**(TIME\_STAMP\_BCF\_ST).**

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * INSERT DATE/TIME STAMP. |

**BCF01000/(CENTRIFUGE\_LOCATION).** CENTRIFUGATION LOCATION

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * RECORD WHERE BLOOD WILL BE CENTRIFUGED. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| DEFAULT COLLECTION LOCATION | 1 | EQUIP\_ID |
| SPSC | 2 | TIME\_STAMP\_BCF\_ET |
| OTHER | -5 |  |

**BCF02000/(CENTRIFUGE\_LOCATION\_OTH).** SPECIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**BCF03000/(EQUIP\_ID).** EQUIPMENT ID FOR CENTRIFUGE

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

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * ENTER EQUIPMENT ID FOR CENTRIFUGE. |

**BCF04000.** DATE AND TIME CENTRIFUGATION BEGAN

|  |
| --- |
| 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 YEAR ≠ CURRENT YEAR. * HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME ARE GREATER THAN CURRENT DATE AND TIME. |

**(CENTRIFUGE\_START\_TIME)** CENTRIFUGE START – TIME

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

  H    H      M    M

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

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| AM | 1 |  |
| PM | 2 |  |

**(CENTRIFUGE\_START\_MM)** CENTRIFUGE START – DATE: MONTH

|\_\_\_|\_\_\_|

  M    M

**(CENTRIFUGE\_START\_DD)** CENTRIFUGE START – DATE: DAY

|\_\_\_|\_\_\_|

  D    D

**(CENTRIFUGE\_START\_YYYY)** CENTRIFUGE START – DATE: YEAR

|\_\_\_|\_\_\_|\_\_\_|\_\_\_|

  Y     Y     Y     Y

|  |
| --- |
| 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. |

**BCF08000.** TIME CENTRIFUGATION ENDED

|  |
| --- |
| 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 YEAR ≠ CURRENT YEAR. * HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME ARE GREATER THAN CURRENT DATE AND TIME OR LESS THAN CENTRIFUGE\_START\_TIME AND/OR CENTRIFUGE\_START\_DATE. |

**(CENTRIFUGE\_END\_TIME)** CENTRIFUGE END – TIME

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

  H    H      M    M

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

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| AM | 1 |  |
| PM | 2 |  |

**(CENTRIFUGE\_END\_MM)** CENTRIFUGE END – DATE: MONTH

|\_\_\_|\_\_\_|

  M    M

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME ARE GREATER THAN CURRENT DATE AND TIME OR LESS THAN **CENTRIFUGE\_START\_TIME** AND/OR **CENTRIFUGE\_START\_DATE**. |

**(CENTRIFUGE\_END\_DD)** CENTRIFUGE END – DATE: DAY

|\_\_\_|\_\_\_|

  D    D

**(CENTRIFUGE\_END\_YYYY)** CENTRIFUGE END – DATE: YEAR

|\_\_\_|\_\_\_|\_\_\_|\_\_\_|

  Y    Y       Y    Y

|  |
| --- |
| 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. |

**BCF12000/(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 |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| TEMPERATURE | 1 | BCF14000 |
| NOT ABLE TO MEASURE-THERMOMETER BROKEN | 2 | BLOOD\_HEMOLYZE |
| NOT ABLE TO MEASURE-THERMOMETER NOT AVAILABLE | 3 | BLOOD\_HEMOLYZE |
| NOT ABLE OT MEASURE-OTHER | -5 |  |

**BCF13000/(CENTRIFUGE\_TEMP\_MEASURE\_OTH).** SPECIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * GO TO **BLOOD\_HEMOLYZE**. |

**BCF14000.** 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. |

**BCF15000/(CENTRIFUGE\_TEMP).** RECORD THE TEMPERATURE TO THE FIRST DECIMAL POINT.

|\_\_\_|\_\_\_| . |\_\_\_| °C

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

**BCF16000/(CENT\_TEMP\_POSNEG).** RECORD WHETHER 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" |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| POSITIVE | 1 |  |
| NEGATIVE | 2 |  |

**BCF17000/(BLOOD\_HEMOLYZE).** DID BLOOD HEMOLYZE?

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * RECORD WHETHER HEMOLYSIS OCCURRED IN ONE OR MORE OF THE BLOOD TUBES. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| 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 | CENTRIFUGE\_COMMENT |

**BCF18000/(V1\_TUBE\_HEMOLYZE).** INDICATE WHICH TUBE(S) HEMOLYZED.

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * SELECT ALL THAT APPLY |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| 3mL Red top (RD20) | 1 |  |
| 3mL Red top (RD21) | 2 |  |
| 3.5mL SST (SS20) | 3 |  |
| 5mL Red top (RD22) | 4 |  |
| 5mL SST (SS22) | 5 |  |

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * DISPLAY THE FOLLOWING RESPONSE CATEGORIES: * IF **EVENT\_TYPE** = 27 (12 MONTH VISIT): 3mL Red top (RD20)................................... .. 1 3mL Red top (RD21)..................................... 2 * IF **EVENT\_TYPE**= 37 (36 MONTH VISIT): 3.5mL SST (SS20)........................................ 3 5mL Red top (RD22)................................... .. 4 * IF **EVENT\_TYPE** = XX (60 MONTH VISIT):5mL Red top (RD22)................................... .. 4   5mL SST (SS22)............................................ 5 |

**BCF19000/(CENTRIFUGE\_COMMENT).** CENTRIFUGE OTHER COMMENTS

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * ENTER CENTRIFUGE COMMENTS. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| NO COMMENTS | 1 | TIME\_STAMP\_BCF\_ET |
| COMMENT | 2 |  |

**BCF20000/(CENTRIFUGE\_COMMENT\_OTH).** SPECIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * ENTER ANY CENTRIFUGE COMMENT. |

**(TIME\_STAMP\_BCF\_ET).**

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * INSERT DATE/TIME STAMP. |

PREPARATION FOR BLOOD TUBE TRANSPORT

**(TIME\_STAMP\_PFB\_ST).**

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * INSERT DATE/TIME STAMP. |

**PFB01000/(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) AND ACTIVATE. * 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” AND THE REASON THE TEMPERATURE COULD NOT BE RECORDED. * IF THERE ARE NOT ANY TUBES THAT REQUIRE REFRIGERATED TRANSPORT TEMPERATURES, THEN SELECT “NOT APPLICABLE.” |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| TEMPERATURE | 1 | PFB03000 |
| 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 |

**PFB02000/(COLD\_TEMP\_MEASURE\_OTH).** SPECIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * GO TO **COLD\_THRESHOLD\_LOW**. |

**PFB03000.** RECORD TEMPERATUREOF REFRIGERATED CHAMBER

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * RECORD THE TEMPERATURE OF THE REFRIGERATED CHAMBER OF THE TRANSPORT COOLER. |

**PFB04000/(COLD\_TEMP).** ENTER TEMPERATURE IN DEGREES CELSIUS.

|\_\_\_|\_\_\_|. |\_\_\_| °C

**PFB05000/(COLD\_TEMP\_POSNEG).** RECORD WHETHER 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." |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| POSITIVE | 1 |  |
| NEGATIVE | 2 |  |

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

**PFB06000/(COLD\_THRESHOLD\_LOW).** STATUS OF REFRIGERATED CHAMBER LOW THRESHOLD MONITOR

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * RECORD STATUS OF THE LOW THRESHOLD MONITOR IN THE REFRIGERATED CHAMBER OF THE TRANSPORT COOLER. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| YES, IN CHAMBER | 1 |  |
| NO, NOT REQUIRED | 2 |  |
| NO, NOT AVAILABLE | 3 |  |

**PFB07000/(COLD\_THRESHOLD\_HIGH).** STATUS OF REFRIGERATED CHAMBER UPPER THRESHOLD MONITOR

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * RECORD STATUS OF THE UPPER THRESHOLD MONITOR IN THE REFRIGERATED COMPARTMENT OF THE COOLER. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| YES, IN CHAMBER | 1 |  |
| NO, NOT REQUIRED | 2 |  |
| NO, NOT AVAILABLE | 3 |  |

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * IF **EVENT\_TYPE**= 27 (12-MONTH VISIT), GO TO **TRANSPORT\_COMMENT**. * OTHERWISE, GO TO **AMBIENT\_THRESHOLD\_LOW**. |

**PFB08000/(AMBIENT\_THRESHOLD\_LOW).** STATUS OF AMBIENT LOW THRESHOLD MONITOR

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * RECORD STATUS OF THE LOW THRESHOLD MONITOR IN THE AMBIENT COMPARTMENT OF THE COOLER. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| YES, IN CHAMBER | 1 |  |
| NO, NOT REQUIRED | 2 |  |
| NO, NOT AVAILABLE | 3 |  |

**PFB09000/(TRANSPORT\_COMMENT).** TRANSPORT COMMENT

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| NO COMMENTS | 1 | BLOOD\_DRAW\_COMMENT |
| COMMENT | 2 |  |

**PFB10000/(TRANSPORT\_COMMENT\_OTH).** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * ENTER ANY TRANSPORT COMMENT. |

**PFB11000/(BLOOD\_DRAW\_COMMENT).** ADDITIONAL BLOOD DRAW COMMENT

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * ENTER ANY ADDITIONAL BLOOD COLLECTION COMMENTS. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| NO COMMENTS | 1 | TIME\_STAMP\_PFB\_ET |
| COMMENT | 2 |  |

**PFB12000/(BLOOD\_DRAW\_COMMENT\_OTH).** SPECIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**(TIME\_STAMP\_PFB\_ET).**

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * INSERT DATE/TIME STAMP. |