



## Adult Blood Instrument

<b>Event Category:</b>	Trigger-Based, Pre-Preg, PV1, PV2; Time-Based, Birth, 6M, 12M, 36M, 60M
<b>Event:</b>	Pre-Preg, PV1, PV2, Birth, 6M, 12M, 36M, 60M
<b>Administration:</b>	N/A
<b>Instrument Target:</b>	Pre-Pregnant Woman; Pregnant Women; Biological Mother; Primary Caregiver
<b>Instrument Respondent:</b>	Pre-Pregnant Woman; Pregnant Women; Biological Mother; Primary Caregiver
<b>Domain:</b>	Biospecimen
<b>Document Category:</b>	Sample Collection
<b>Method:</b>	Data Collector Administered
<b>Mode (for this instrument*):</b>	In-Person, CAI
<b>OMB Approved Modes:</b>	In-Person, CAI
<b>Estimated Administration Time:</b>	13 minutes
<b>Multiple Child/Sibling Consideration:</b>	Per Event
<b>Special Considerations:</b>	N/A
<b>Version:</b>	3.0
<b>MDES Release:</b>	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.

Public reporting burden for this collection of information is estimated to average 13 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593\*). Do not return the completed form to this address.

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# Adult Blood Instrument

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# Adult 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	<ul style="list-style-type: none"> <li>• Limit text to 255 characters</li> </ul>
FIRST NAME AND LAST NAME	30	CHARACTER	<ul style="list-style-type: none"> <li>• Limit text to 30 characters</li> </ul>
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	<ul style="list-style-type: none"> <li>• DISPLAY AS MM/DD/YYYY</li> <li>• STORE AS YYYY-MM-DD</li> <li>• HARD EDITS: MM MUST EQUAL 01 TO 12 DD MUST EQUAL 01 TO 31 YYYY MUST BE BETWEEN 1900 AND CURRENT YEAR.</li> </ul>
TIME VARIABLES	TWO-DIGIT HOUR AND TWO-DIGIT MINUTE, AM/PM DESIGNATION	NUMERIC	<ul style="list-style-type: none"> <li>• HARD EDITS: HOURS MUST BE BETWEEN 00 AND 12; MINUTES MUST BE BETWEEN 00 AND 59</li> </ul>

### **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 BLOOD COLLECTION

(TIME\_STAMP\_BBC\_ST).

### PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP
- PRELOAD PARTICIPANT **P\_ID** AND RESPONDENT **R\_P\_ID**.

**BBC01000/(BLOOD\_INTRO)**. I will now collect a blood sample. I will need to ask you some questions before I collect your blood sample.

### DATA COLLECTOR INSTRUCTIONS

- IF THE PARTICIPANT REFUSES THIS COLLECTION, SELECT REFUSED.
- OTHERWISE SELECT CONTINUE.

Label	Code	Go To
CONTINUE	1	
REFUSED	-2	BLOOD_NO_COLLECT_REASON

### SOURCE

National Children's Study, Legacy Phase

**BBC02000/(HEMOPHILIA)**. Do you have hemophilia or any bleeding disorder?

### DATA COLLECTOR INSTRUCTIONS

- RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

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

### SOURCE

National Children's Study, Legacy Phase

### PROGRAMMER INSTRUCTIONS

- IF **EVENT\_TYPE=18** (BIRTH EVENT)
  - o AND IF **HEMOPHILIA=1** GO TO **BLOOD\_NO\_COLLECT\_REASON**
  - o AND IF **HEMOPHILIA=2** GO TO **TIME\_STAMP\_BBC\_ET**
- OTHERWISE, IF **EVENT\_TYPE ≠ 18**, AND
  - o IF **HEMOPHILIA =1** GO TO **BBC16000**
  - o IF **HEMOPHILIA=-1** OR **-2** GO TO **BBC18000**

**BBC03000/(CHEMO).** Have you 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	BBC17000
NO	2	
REFUSED	-1	BBC18000
DON'T KNOW	-2	BBC18000

**SOURCE**

National Children's Study, Legacy Phase

**BBC04000/(BLOOD\_DRAW).** Have you had any problems with a blood draw in the past?

Label	Code	Go To
YES	1	
NO	2	BBC07000
REFUSED	-1	BBC07000
DON'T KNOW	-2	BBC07000

**SOURCE**

National Children's Study, Legacy Phase

**BBC05000/(BLOOD\_DRAW\_PROB).** What problems have you had with a blood draw in the past?

**DATA COLLECTOR INSTRUCTIONS**

- SELECT ALL THAT APPLY

Label	Code	Go To
FAINTING	1	
LIGHT-HEADEDNESS	2	
HEMATOMA	3	
BRUISING	4	
OTHER	-5	
REFUSED	-1	
DON'T KNOW	-2	

**SOURCE**

National Children's Study, Legacy Phase

**PROGRAMMER INSTRUCTIONS**

- IF BLOOD\_DRAW\_PROB= ANY COMBINATION OF 1 THROUGH 4, GO TO BBC07000.
- IF BLOOD\_DRAW\_PROB= -5 OR ANY COMBINATION OF 1 THROUGH 4, AND -5,



**PROGRAMMER INSTRUCTIONS**

GO TO **BLOOD\_DRAW\_PROB\_OTH**.

- IF **BLOOD\_DRAW\_PROB**= -1 OR -2, DO NOT ALLOW ANY OTHER RESPONSES AND GO TO **BBC07000**.

**BBC06000/(BLOOD\_DRAW\_PROB\_OTH)**.

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

**DATA COLLECTOR INSTRUCTIONS**

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

**SOURCE**

National Children’s Study, Legacy Phase

**BBC07000**. 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 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 PARTICIPANT ATE OR DRANK WAS AT 2:05PM 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, 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 – AM/PM

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	

**BBC08000/(COFFEE\_TEA).** Have you had sweetener or milk added to a drink, such as coffee or tea, in the last 8 hours?

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

**SOURCE**

National Children's Study, Legacy Phase

**BBC09000/(ALCOHOL).** Have you had alcohol such as beer, wine, or liquor in the last 8 hours?

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

**SOURCE**

National Children's Study, Legacy Phase

**BBC10000/(COUGH\_COLD).** Have you chewed gum, or used breath mints, lozenges, cough drops, or other cough or cold remedies in the last 8 hours?

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

**SOURCE**

National Children's Study, Legacy Phase

**BBC11000/(LAXATIVE).** Have you used antacid, laxatives, or anti-diarrheal medication in the last 8 hours?

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

**SOURCE**

National Children's Study, Legacy Phase

**BBC12000/(VITAMIN).** Have you 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	

**SOURCE**

National Children's Study, Legacy Phase

**BBC13000/(DIABETES).** Has a doctor ever told you that you had diabetes?

**INTERVIEWER INSTRUCTIONS**

- IF RESPONDENT IS PREGNANT, PROBE: "THIS INCLUDES GESTATIONAL DIABETES."

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

**SOURCE**

National Children's Study, Legacy Phase

**DATA COLLECTOR INSTRUCTIONS**

IF THE PARTICIPANT IS PREGNANT, PROBE: "This includes gestational diabetes."

**BBC14000/(INSULIN).** Have you taken any insulin in the last 8 hours?

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

**SOURCE**

National Children's Study, Legacy Phase

**BBC15000/(BLOOD\_COMPLETE).** Thank you for answering my questions. I am now going to prepare to draw your blood

Label	Code	Go To
CONTINUE	1	TIME_STAMP_BBC_ET
REFUSED	-1	BLOOD_NO_COLLECT_REASON

**SOURCE**

National Children's Study, Legacy Phase

**BBC16000.** Because you have hemophilia, we will not be able to draw your blood for this study.**SOURCE**

New

**PROGRAMMER INSTRUCTIONS**

- GO TO BLOOD\_NO\_COLLECT\_REASON

**BBC17000.** Because you've had chemotherapy recently, we will not be able to draw your blood at this time.**SOURCE**

New

**PROGRAMMER INSTRUCTIONS**

- GO TO BLOOD\_NO\_COLLECT\_REASON

**BBC18000.** Because you do not know or declined to answer questions about your {hemophilia/chemotherapy status} we will not be able to draw your blood at this time.

<b>SOURCE</b>
New

<b>PROGRAMMER INSTRUCTIONS</b>
<ul style="list-style-type: none"> <li>GO TO <b>BLOOD_NO_COLLECT_REASON</b></li> <li>IF <b>HEMOPHILIA</b>= -1 OR -2, DISPLAY "hemophilia".</li> <li>IF <b>CHEMO</b> = -1 OR -2, DISPLAY "chemotherapy status".</li> </ul>

**BBC19000/(BLOOD\_NO\_COLLECT\_REASON).** RECORD THE MAIN REASON THE SPECIMEN WAS NOT COLLECTED.

<b>DATA COLLECTOR INSTRUCTIONS</b>
<ul style="list-style-type: none"> <li>SELECT ONLY ONE REASON.</li> </ul>

Label	Code	Go To
PARTICIPANT REFUSAL	1	BBC21000
HEMATOMA	2	BBC21000
NO SUITABLE VEIN	3	BBC21000
BRUISING	4	BBC21000
VEIN COLLAPSTED DURING PROCEDURE	5	BBC21000
LIGHT-HEADEDNESS	6	BBC21000
PHYSICAL LIMITATION	7	BBC21000
COGNITIVE DISABILITY	8	BBC21000
HEMOPHILIA	9	BBC21000
CANCER CHEMOTHERAPY	10	BBC21000
NO TIME	11	BBC21000
OTHER	-5	
DON'T KNOW	-2	BBC21000

**BBC20000/(BLOOD\_NO\_COLLECTION\_REASON\_OTH).** SPECIFY:  
\_\_\_\_\_

**BBC21000.** That's fine. Thank you.

<b>SOURCE</b>
New

<b>PROGRAMMER INSTRUCTIONS</b>
<ul style="list-style-type: none"> <li>GO TO <b>BLOOD_DRAW_COMMENT</b></li> </ul>

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

<b>PROGRAMMER INSTRUCTIONS</b>
<ul style="list-style-type: none"> <li>INSERT DATE/TIME STAMP</li> </ul>

## BLOOD COLLECTION

(TIME\_STAMP\_BC\_ST).

### PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP

BC01000/(BLOOD\_INST). BLOOD DRAW INSTRUCTIONS

### DATA COLLECTOR INSTRUCTIONS

- CONFIRM THAT BLOOD TUBES ARE LABELED AND NOT EXPIRED PRIOR TO COLLECTION OF SAMPLE.
- BE SURE TO EMPLOY UNIVERSAL PRECAUTIONS AND WEAR PPE TO PREVENT EXPOSURE TO INFECTIOUS DISEASES AT ALL TIMES WHEN HANDLING BIOLOGICAL SPECIMENS.
- BE SURE TO EXPLAIN EACH PROCEDURE BEING PERFORMED.
- ONCE IN AN AREA WITH ADEQUATE LIGHT AND A FLAT, CLEAN SURFACE FREE OF FOOD, CLUTTER AND DISTRACTIONS, BEGIN SET UP.
- IDEALLY THE PREP AREA SHOULD BE NEAR A PLACE WHERE THE PARTICIPANT CAN SIT WITH HER/HIS ARM STRETCHED OUT ON A FLAT SURFACE.
- DRAPE A CHUX PAD OVER SURFACES WHERE THE PARTICIPANT WILL PUT HER/HIS ARM.
- STOP DRAWING BLOOD IF BRUISING OCCURS. CONTINUE AFTER THREE MINUTES ONLY WITH VERBAL PERMISSION OF PARTICIPANT.
- ONCE COLLECTION IS COMPLETE, REMOVE THE NEEDLE AND APPLY GAUZE.
- COLLECTION TUBES SHOULD BE DRAWN IN THE FOLLOWING ORDER:
  - o IF PRE-PREGNANCY VISIT:
    - 3mL Lavender top, prescreened (LP10)
    - 10mL Red top (RD10)
    - 10mL Red top (RD11)
    - 6mL Lavender top (LV15)
  - o IF PREGNANCY VISIT 1
    - 8.5mL Red/gray top SST (SS10)
    - 10mL Red top (RD10)
    - 5mL Clear top PPT (PP10)
    - 6mL Lavender top (LV15)
    - 8.5mL Yellow top ACD (AD10)
  - o IF PREGNANCY VISIT 2
    - 6mL Royal blue top, Serum (RS10)
    - 8.5mL Red/gray top SST (SS10)
    - 10mL Red top (RD10)
    - 5mL Clear top PPT (PP10)
    - 6mL Lavender top (LV15)
    - 2.5mL Clear top PAXgene™ (PX10)
  - o IF BIRTH EVENT
    - 3mL Lavender top, prescreened (LP10)
    - 10mL Red top (RD15)
    - 10mL Red top (RD10)
    - 6mL Lavender top (LV15)

**DATA COLLECTOR INSTRUCTIONS**

- o IF 6-MONTH EVENT
  - 6mL Royal blue top, serum (RS30)
  - 8.5mL Red/gray top SST (SS30)
  - 10mL Red top (RD30)
  - 5mL Clear top PPT (PP30)
  - 6mL Lavender top (LV30)
  - 2.5mL Clear top PAXgene™ (PX30)
- o IF 12-MONTH VISIT
  - 3mL Lavender top, prescreened (LP40)
  - 10mL Red top (RD30)
  - 10mL Red top (RD31)
  - 6mL Lavender top (LV30)
- o IF 36-MONTH VISIT
  - 3mL Lavender top, prescreened (LP40)
  - 8.5mL Red/gray top SST (SS30)
  - 10mL Red top (RD30)
  - 6mL Lavender top (LV30)
  - 2.5mL Clear top PAXgene™ (PX30)
- o IF 60-MONTH VISIT
  - 3mL Lavender top, prescreened (LP40)
  - 6mL Royal blue top, serum (RS30)
  - 8.5mL Red/gray top SST (SS30)
  - 10mL Lavender top (LV50)

**BC02000.** Thank you for your blood sample. Please hold this gauze on your arm with mild pressure.

**DATA COLLECTOR INSTRUCTIONS**

- CHECK IF CLOTTING HAS OCCURRED AND APPLY BANDAGE OVER GAUZE.
- IF NECESSARY, INSTRUCT PARTICIPANT TO RAISE ARM ABOVE HEAD FOR TWO MINUTES WITHOUT BENDING ELBOW TO PREVENT THE FORMATION OF A HEMATOMA.

**PROGRAMMER INSTRUCTIONS**

- IF **EVENT\_TYPE=18** (BIRTH EVENT), GO TO **NCS\_BLOOD\_TUBE**
- OTHERWISE, GO TO **TUBE\_STATUS**

**BC03000/(NCS\_BLOOD\_TUBE).** WERE NCS-PROVIDED BLOOD TUBES USED FOR THE SPECIMEN COLLECTION?

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

**BC04000/(NCS\_NEEDLE).** WAS AN NCS-PROVIDED NEEDLE USED FOR THE SPECIMEN COLLECTION?

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

**BC05000/(NUM\_CONTAINERS\_COLLECT).** HOW MANY COLLECTION CONTAINERS WERE COLLECTED (1-4)?

|\_\_|  
NUMBER OF COLLECTION CONTAINERS COLLECTED

**BC06000/(TUBE\_STATUS).** BLOOD TUBE COLLECTION STATUS FOR {TUBE\_TYPE}

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> <li>• ENTER STATUS OF <b>TUBE_TYPE</b>.</li> <li>• 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.</li> <li>• SELECT "SHORT DRAW" TO INDICATE THAT THE BLOOD TUBE WAS FILLED TO LESS THAN 3/4 OF THE DESIRED CAPACITY.</li> <li>• SELECT "NO DRAW" TO INDICATE THAT THE BLOOD TUBE WAS NOT COLLECTED.</li> </ul>

Label	Code	Go To
FULL DRAW	1	
SHORT DRAW	2	TUBE_COMMENTS
NO DRAW	3	TUBE_COMMENTS

PROGRAMMER INSTRUCTIONS
<ul style="list-style-type: none"> <li>• LOOP THROUGH <b>TUBE_STATUS</b>, <b>SPECIMEN_ID</b>, <b>TUBE_COMMENTS</b>, AND <b>TUBE_COMMENTS_OTH</b> (IF NEEDED) FOR ALL BLOOD TUBES.</li> <li>• DISPLAY CORRECT <b>TUBE_TYPE</b> AS A REFERENCE FOR EACH LOOP: <ul style="list-style-type: none"> <li>o IF <b>EVENT_TYPE</b> = 11 (PRE-PREGNANCY VISIT) <ul style="list-style-type: none"> <li>▪ AND IF FIRST CYCLE OF THE LOOP, THEN SET <b>TUBE_TYPE</b>=1 DISPLAY "3mL Lavender top, prescreened (LP10)"</li> <li>▪ AND IF SECOND CYCLE OF THE LOOP, THEN SET <b>TUBE_TYPE</b>=2, DISPLAY "10mL Red top (RD10)"</li> <li>▪ AND IF THIRD CYCLE OF THE LOOP, THEN SET <b>TUBE_TYPE</b>=3 DISPLAY "10mL Red top (RD11)"</li> <li>▪ AND IF FOURTH CYCLE OF THE LOOP, THEN SET <b>TUBE_TYPE</b>=4 DISPLAY "6mL Lavender top (LV15)"</li> </ul> </li> <li>o IF <b>EVENT_TYPE</b> = 13 (PREGNANCY VISIT 1) <ul style="list-style-type: none"> <li>▪ AND IF FIRST CYCLE OF THE LOOP, THEN SET <b>TUBE_TYPE</b>=5 DISPLAY "8.5mL Red/gray top SST (SS10)"</li> <li>▪ AND IF SECOND CYCLE OF THE LOOP, THEN SET <b>TUBE_TYPE</b>=2, DISPLAY "10mL Red top (RD10)"</li> <li>▪ AND IF THIRD CYCLE OF THE LOOP, THEN SET <b>TUBE_TYPE</b>=6 DISPLAY "5mL Clear top PPT (PP10)"</li> <li>▪ AND IF FOURTH CYCLE OF THE LOOP, THEN</li> </ul> </li> </ul> </li> </ul>



## PROGRAMMER INSTRUCTIONS

- SET **TUBE\_TYPE**=4 DISPLAY "6mL Lavender top (LV15)"
  - AND IF FIFTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=7, DISPLAY "8.5mL Yellow top ACD (AD10)"
- o IF **EVENT\_TYPE** = 15 (PREGNANCY VISIT 2)
  - AND IF FIRST CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=8, DISPLAY "6mL Royal blue top, Serum (RS10)"
  - AND IF SECOND CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=5, DISPLAY "8.5mL Red/gray top SST (SS10)"
  - AND IF THIRD CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=2, DISPLAY "10mL Red top (RD10)"
  - AND IF FOURTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=6, DISPLAY "5mL Clear top PPT (PP10)"
  - AND IF FIFTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=4, DISPLAY "6mL Lavender top (LV15)"
  - AND IF SIXTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=9, DISPLAY "2.5mL Clear top PAXgene™ (PX10)"
- o IF **EVENT\_TYPE** = 18 (BIRTH EVENT):
  - AND IF FIRST CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=1 DISPLAY "3mL Lavender top, prescreened (LP10)"
  - AND IF SECOND CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=10, DISPLAY "10mL Red top (RD15)"
  - AND IF THIRD CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=2 DISPLAY "10mL Red top (RD10)"
  - AND IF FOURTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=4 DISPLAY "6mL Lavender top (LV15)"
- o IF **EVENT\_TYPE** = 24 (6-MONTH EVENT)
  - AND IF FIRST CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=11, DISPLAY "6mL Royal blue top, serum (RS30)"
  - AND IF SECOND CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=12, DISPLAY "8.5mL Red/gray top SST (SS30)"
  - AND IF THIRD CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=13, DISPLAY "10mL Red top (RD30)"
  - AND IF FOURTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=14, DISPLAY "5mL Clear top PPT (PP30)"
  - AND IF FIFTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=15, DISPLAY "6mL Lavender top (LV30)"
  - AND IF SIXTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=16, DISPLAY "2.5mL Clear top PAXgene™ (PX30)"
- o IF **EVENT\_TYPE** = 27 (12-MONTH VISIT)
  - AND IF FIRST CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=17, DISPLAY "3mL Lavender top, prescreened (LP40)"
  - AND IF SECOND CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=13, DISPLAY "10mL Red top (RD30)"
  - AND IF THIRD CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=18, DISPLAY "10mL Red top (RD31)"
  - AND IF FOURTH CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=15, DISPLAY "6mL Lavender top (LV30)"
- o IF **EVENT\_TYPE** = 37 (36-MONTH VISIT)
  - AND IF FIRST CYCLE OF THE LOOP, THEN SET **TUBE\_TYPE**=17,



**PROGRAMMER INSTRUCTIONS**

- IF **TUBE\_TYPE**=11, DISPLAY "6mL Royal blue top, serum (RS30)" AND FORMAT AS: A A # # # # # # - RS30.
- IF **TUBE\_TYPE**=12, DISPLAY "8.5mL Red/gray top SST (SS30)" AND FORMAT AS: A A # # # # # # - SS30.
- IF **TUBE\_TYPE**=13, DISPLAY "10mL Red top (RD30)" AND FORMAT AS: A A # # # # # # - RD30.
- IF **TUBE\_TYPE**=14, DISPLAY "5mL Clear top PPT (PP30)" AND FORMAT AS: A A # # # # # # - PP30.
- IF **TUBE\_TYPE**=15 , DISPLAY "6mL Lavender top (LV30)" AND FORMAT AS: A A # # # # # # - LV30.
- IF **TUBE\_TYPE**=16, DISPLAY "2.5mL Clear top PAXgene™ (PX30)" AND FORMAT AS: A A # # # # # # - PX30.
- IF **TUBE\_TYPE**=17, DISPLAY "3mL Lavender top, prescreened (LP40)" AND FORMAT AS: A A # # # # # # - LP40.
- IF **TUBE\_TYPE**=18, DISPLAY "10mL Red top (RD31)" AND FORMAT AS: A A # # # # # # - RD31.
- IF **TUBE\_TYPE**=19, DISPLAY "10mL Lavender top (LV50)" AND FORMAT AS: A A # # # # # # - LV50.

**BC09000/(TUBE\_COMMENTS).** REASON BLOOD TUBE NOT COLLECTED OR DRAW WAS SHORT FOR {TUBE\_TYPE}

**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	
OTHER	-5	
REFUSED	-1	
DON'T KNOW	-2	

**PROGRAMMER INSTRUCTIONS**

- DISPLAY CORRECT **TUBE\_TYPE**:
  - o IF **TUBE\_TYPE**=1 DISPLAY "3mL Lavender top, prescreened (LP10)"
  - o IF **TUBE\_TYPE**=2, DISPLAY "10mL Red top (RD10)"
  - o IF **TUBE\_TYPE**=3 DISPLAY "10mL Red top (RD11)"
  - o IF **TUBE\_TYPE**=4 DISPLAY "6mL Lavender top (LV15)"
  - o IF **TUBE\_TYPE**=5 DISPLAY "8.5mL Red/gray top SST (SS10)"
  - o IF **TUBE\_TYPE**=6 DISPLAY "5mL Clear top PPT (PP10)"
  - o IF **TUBE\_TYPE**=7, DISPLAY "8.5mL Yellow top ACD (AD10)"
  - o IF **TUBE\_TYPE**=8, DISPLAY "6mL Royal blue top, Serum (RS10)"

### PROGRAMMER INSTRUCTIONS

- o IF **TUBE\_TYPE**=9, DISPLAY "2.5mL Clear top PAXgene™ (PX10)"
- o IF **TUBE\_TYPE**=10, DISPLAY "10mL Red top (RD15)"
- o IF **TUBE\_TYPE**=11, DISPLAY "6mL Royal blue top, serum (RS30)"
- o IF **TUBE\_TYPE**=12, DISPLAY "8.5mL Red/gray top SST (SS30)"
- o IF **TUBE\_TYPE**=13, DISPLAY "10mL Red top (RD30)"
- o IF **TUBE\_TYPE**=14, DISPLAY "5mL Clear top PPT (PP30)"
- o IF **TUBE\_TYPE**=15, DISPLAY "6mL Lavender top (LV30)"
- o IF **TUBE\_TYPE**=16, DISPLAY "2.5mL Clear top PAXgene™ (PX30)"
- o IF **TUBE\_TYPE**=17, DISPLAY "3mL Lavender top, prescreened (LP40)"
- o IF **TUBE\_TYPE**=18, DISPLAY "10mL Red top (RD31)"
- o IF **TUBE\_TYPE**=19, DISPLAY "10mL Lavender top (LV50)"
- IF **TUBE\_COMMENTS** = ANY COMBINATION OF 1 THROUGH 7, AND
  - o IF FIRST THROUGH SECOND TO LAST LOOP, GO TO **TUBE\_STATUS** TO LOOP THROUGH REMAINING BLOOD SPECIMENS.
  - o IF FINAL LOOP, GO TO **COLLECTION\_LOCATION**.
- IF **TUBE\_COMMENTS** = -5 OR ANY COMBINATION OF 1 THROUGH 7 AND -5, GO TO **TUBE\_COMMENTS\_OTH**.
- IF **TUBE\_COMMENTS** = -1 OR -2, DO NOT ALLOW SELECTION OF ANY OTHER RESPONSES AND
  - o IF FIRST THROUGH SECOND TO LAST LOOP, GO TO **TUBE\_STATUS** TO LOOP THROUGH REMAINING BLOOD SPECIMENS.
  - o IF FINAL LOOP, GO TO **COLLECTION\_LOCATION**.

BC10000/(**TUBE\_COMMENTS\_OTH**). \_\_\_\_\_

### DATA COLLECTOR INSTRUCTIONS

- IF THERE ARE ANY OTHER REASONS THE {**TUBE\_TYPE**} WAS NOT COLLECTED OTHER THAN THOSE LISTED IN THE PREVIOUS QUESTION, ENTER THEM IN THE SPACE PROVIDED.

### PROGRAMMER INSTRUCTIONS

- DISPLAY CORRECT **TUBE\_TYPE**:
  - o IF **TUBE\_TYPE**=1 DISPLAY "3mL Lavender top, prescreened (LP10)"
  - o IF **TUBE\_TYPE**=2, DISPLAY "10mL Red top (RD10)"
  - o IF **TUBE\_TYPE**=3 DISPLAY "10mL Red top (RD11)"
  - o IF **TUBE\_TYPE**=4 DISPLAY "6mL Lavender top (LV15)"
  - o IF **TUBE\_TYPE**=5 DISPLAY "8.5mL Red/gray top SST (SS10)"
  - o IF **TUBE\_TYPE**=6 DISPLAY "5mL Clear top PPT (PP10)"
  - o IF **TUBE\_TYPE**=7, DISPLAY "8.5mL Yellow top ACD (AD10)"
  - o IF **TUBE\_TYPE**=8, DISPLAY "6mL Royal blue top, Serum (RS10)"
  - o IF **TUBE\_TYPE**=9, DISPLAY "2.5mL Clear top PAXgene™ (PX10)"
  - o IF **TUBE\_TYPE**=10, DISPLAY "10mL Red top (RD15)"
  - o IF **TUBE\_TYPE**=11, DISPLAY "6mL Royal blue top, serum (RS30)"
  - o IF **TUBE\_TYPE**=12, DISPLAY "8.5mL Red/gray top SST (SS30)"
  - o IF **TUBE\_TYPE**=13, DISPLAY "10mL Red top (RD30)"
  - o IF **TUBE\_TYPE**=14, DISPLAY "5mL Clear top PPT (PP30)"
  - o IF **TUBE\_TYPE**=15, DISPLAY "6mL Lavender top (LV30)"
  - o IF **TUBE\_TYPE**=16, DISPLAY "2.5mL Clear top PAXgene™ (PX30)"

**PROGRAMMER INSTRUCTIONS**

- o IF **TUBE\_TYPE**=17, DISPLAY "3mL Lavender top, prescreened (LP40)"
- o IF **TUBE\_TYPE**=18, DISPLAY "10mL Red top (RD31)"
- o IF **TUBE\_TYPE**=19, DISPLAY "10mL Lavender top (LV50)"
- IF FIRST THROUGH SECOND TO LAST LOOP, GO TO **TUBE\_STATUS** TO LOOP THROUGH REMAINING BLOOD SPECIMENS.
- OTHERWISE, GO TO **COLLECTION\_LOCATION**.

**BC11000/(COLLECTION\_LOCATION).** COLLECTION LOCATION

**DATA COLLECTOR INSTRUCTIONS**

- RECORD WHERE BLOOD COLLECTION OCCURRED

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

**BC12000.** DATE ADULT BLOOD WAS COLLECTED.

**DATA COLLECTOR INSTRUCTIONS**

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

(**ABLOOD\_COLL\_MM**) |\_\_|\_\_|  
 M M

(**ABLOOD\_COLL\_DD**) |\_\_|\_\_|  
 D D

(**ABLOOD\_COLL\_YYYY**) |\_\_|\_\_|\_\_|\_\_|  
 Y Y Y Y

**BC13000.** TIME ADULT BLOOD WAS COLLECTED.

**DATA COLLECTOR INSTRUCTIONS**

- RECORD THE TIME THE ADULT BLOOD SAMPLE WAS COLLECTED
- 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 BLOOD SAMPLE WAS COLLECTED AT 2:05PM, RECORD "02:05" AND CHOOSE "PM".

(**ABLOOD\_COLL\_TIME**)  
 |\_\_|\_\_|:|\_\_|\_\_|  
 H H M M

(**ABLOOD\_COLL\_TIME\_UNIT**)

Label	Code	Go To
AM	1	
PM	2	

**BC14000/(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**

- THIS VALUE PROVIDES AN OVERALL STATUS OF BLOOD COLLECTION USING THE **TUBE\_STATUS** (FULL DRAW=1, SHORT DRAW=2, NO DRAW=3) AND **TUBE\_TYPE** (1, 2, 3, 4, 5, 6, 7, 8, 9, AND, 10 DEPENDING ON THE VISIT).
- “COLLECTED” INDICATES THAT ALL BLOOD TUBES ARE 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. THIS CHOICE SHOULD NOT BE SELECTED IF THERE ARE ANY PARTIALLY FILLED TUBES.
- “PARTIALLY COLLECTED” INDICATES THAT AT LEAST ONE, BUT NOT ALL OF THE BLOOD TUBES IS FILLED TO AT LEAST 3/4 OF THE DESIRED CAPACITY OR THAT ALL TUBES WERE FILLED TO LESS THAN 3/4 OF THE DESIRED CAPACITY.
- “NOT COLLECTED” INDICATES THAT NO BLOOD TUBES WERE COLLECTED.
- SET **COLLECTION\_STATUS**=1 IF EACH **TUBE\_TYPE** HAS A **TUBE\_STATUS**=1.
- SET **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.
- SET **COLLECTION\_STATUS** =3 IF EACH **TUBE\_TYPE** HAS A **TUBE\_STATUS**=3.

**BC15000/(OVERALL\_COMMENTS). BLOOD COLLECTION OVERALL COMMENTS**

**DATA COLLECTOR INSTRUCTIONS**

- ENTER REASON BLOOD WAS NOT COLLECTED.

Label	Code	Go To
SAFETY EXCLUSION	1	
PHYSICAL LIMITATION	2	
PARTICIPANT ILL/EMERGENCY	3	
QUANTITY NOT SUFFICIENT	4	
LANGUAGE ISSUE, SPANISH	5	
LANGUAGE ISSUE, NON SPANISH	6	
COGNITIVE DISABILITY	7	
NO TIME	8	
OTHER	-5	
REFUSED	-1	

Label	Code	Go To
DON'T KNOW	-2	

BC16000/(OVERALL\_COMMENTS\_OTH).

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DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> <li>IF THERE ARE ANY OTHER BLOOD COLLECTION COMMENTS NOT LISTED IN THE PREVIOUS QUESTION, ENTER THEM IN THE SPACE PROVIDED.</li> </ul>

PROGRAMMER INSTRUCTIONS
<ul style="list-style-type: none"> <li>GO TO BLOOD_DRAW_COM</li> </ul>

(TIME\_STAMP\_BC\_ET).

PROGRAMMER INSTRUCTIONS
<ul style="list-style-type: none"> <li>INSERT DATE/TIME STAMP</li> </ul>

## BLOOD CENTRIFUGATION

(TIME\_STAMP\_BCZ\_ST).

<b>PROGRAMMER INSTRUCTIONS</b>
--------------------------------

- |  |
|--|
| <ul style="list-style-type: none"> <li>INSERT DATE/TIME STAMP</li> </ul> |
|--|

**BCZ01000/(CENTRIFUGE\_LOCATION).** WILL BLOOD BE CENTRIFUGED AT COLLECTION LOCATION?

<b>DATA COLLECTOR INSTRUCTIONS</b>
------------------------------------

- |  |
|--|
| <ul style="list-style-type: none"> <li>RECORD WHETHER BLOOD WILL BE CENTRIFUGED AT COLLECTION LOCATION,</li> </ul> |
|--|

Label	Code	Go To
YES	1	
NO	2	TIME_STAMP_BCZ_ET

**BCZ02000/(EQUIP\_ID).** EQUIPMENT ID FOR CENTRIFUGE

\_\_\_\_\_

<b>DATA COLLECTOR INSTRUCTIONS</b>
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- |  |
|--|
| <ul style="list-style-type: none"> <li>ENTER EQUIPMENT ID FOR CENTRIFUGE.</li> </ul> |
|--|

**BCZ03000.** TIME CENTRIFUGATION BEGAN

<b>DATA COLLECTOR INSTRUCTIONS</b>
------------------------------------

- |  |
|--|
| <ul style="list-style-type: none"> <li>RECORD THE TIME THE BLOOD TUBES WERE PLACED IN THE CENTRIFUGE.</li> <li>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 BLOOD TUBES WERE PLACED IN THE CENTRIFUGE AT 2:05 PM RECORD "02:05" AND CHOOSE "PM".</li> <li>RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.</li> </ul> |
|--|

(CENTRIFUGE\_TIME) TIME CENTRIFUGATION BEGAN – TIME

								:				
H	H	M	M						M	M		

(CENTRIFUGE\_TIME\_UNIT)

Label	Code	Go To
AM	1	
PM	2	

(CENTRIFUGE\_MM) TIME CENTRIFUGATION BEGAN – DATE: MONTH



|\_|\_|  
M M

(CENTRIFUGE\_DD) TIME CENTRIFUGATION BEGAN – DATE: DAY

|\_|\_|  
D D

(CENTRIFUGE\_YYYY) TIME CENTRIFUGATION BEGAN – DATE: YEAR

|\_|\_|\_|  
Y Y Y Y

BCZ04000. 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 2:05PM RECORD “02:05” AND CHOOSE “PM”.
- RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.

(CENTRIFUGE\_END\_TIME) TIME CENTRIFUGATION ENDED – TIME

|\_|\_|:|\_|\_|  
H H M M

(CENTRIFUGE\_END\_TIME\_UNIT) TIME CENTRIFUGATION ENDED – AM/PM

Label	Code	Go To
AM	-1	
PM	-2	

(CENTRIFUGE\_END\_MM) TIME CENTRIFUGATION ENDED – DATE: MONTH

|\_|\_|  
M M

(CENTRIFUGE\_END\_DD) TIME CENTRIFUGATION ENDED – DATE: DAY

|\_|\_|  
D D

(CENTRIFUGE\_END\_YYYY) TIME CENTRIFUGATION ENDED – DATE: YEAR

|\_|\_|\_|  
Y Y Y Y

**BCZ05000/(CENTRIFUGE\_TEMP\_MEASURE). TEMPERATURE OF CENTRIFUGE**

**DATA COLLECTOR INSTRUCTIONS**

- IF ABLE TO MEASURE TEMPERATURE, THEN SELECT "TEMPERATURE".
- IF NOT ABLE TO MEASURE 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	CENTRIFUGE_TEMP
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	

**BCZ05100/(CENTRIFUGE\_TEMP\_MEASURE\_OTH). SPECIFY OTHER REASON NOT ABLE TO MEASURE TEMPERATURE:**

**PROGRAMMER INSTRUCTIONS**

- GO TO BLOOD\_HEMOLYZE.

**BCZ06000/(CENTRIFUGE\_TEMP). TEMPERATURE OF CENTRIFUGE**

\_\_\_\_.\_\_\_\_ °C

**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.
- RECORD THE TEMPERATURE TO THE FIRST DECIMAL POINT.

**PROGRAMMER INSTRUCTIONS**

- SOFT EDIT: DISPLAY SOFT EDIT IF TEMPERATURE IS < 15.0 °C OR > 25.0 °C

**BCZ07000/(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	

Label	Code	Go To
YES, AT LEAST ONE TUBE HEMOLYZED AND AT LEAST ONE TUBE DID NOT HEMOLYZE	2	
NO, NONE OF THE TUBES HEMOLYZED	3	CENTRIFUGE_COMMENT

BCZ08000/(V1\_TUBE\_HEMOLYZE). INDICATE WHICH TUBE(S) HEMOLYZED

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> <li>SELECT ALL THAT APPLY.</li> </ul>

PROGRAMMER INSTRUCTIONS
<ul style="list-style-type: none"> <li>IF <b>EVENT_TYPE</b> = 11 (PRE-PREGNANCY VISIT), DISPLAY THE FOLLOWING RESPONSE CATEGORIES:  10 mL Red top (RD10)..... 1  10 mL Red top (RD11)..... 2</li> <li>IF <b>EVENT_TYPE</b> = 13 (PREGNANCY VISIT 1), DISPLAY THE FOLLOWING RESPONSE CATEGORIES:10 mL Red top (RD10)..... 1  8.5mL SST (SS10)..... 3  5mL PPT (PP10)..... 4</li> <li>IF <b>EVENT_TYPE</b> = 15 (PREGNANCY VISIT 2), DISPLAY THE FOLLOWING RESPONSE CATEGORIES:10 mL Red top (RD10)..... 1  8.5mL SST (SS10)..... 3  5mL PPT (PP10)..... 4</li> <li>IF <b>EVENT_TYPE</b> = 18 (BIRTH EVENT), DISPLAY THE FOLLOWING RESPONSE CATEGORIES:10 mL Red top (RD15)..... 5  10 mL Red top (RD10)..... 6</li> <li>IF <b>EVENT_TYPE</b> = 24 (6-MONTH EVENT), DISPLAY THE FOLLOWING RESPONSE CATEGORIES:8.5mL SST (SS30)..... 7  10 mL Red top (RD30)..... 8  5mL PPT (PP30)..... 9</li> <li>IF <b>EVENT_TYPE</b> = 27 (12-MONTH VISIT), DISPLAY THE FOLLOWING RESPONSE CATEGORIES:10 mL Red top (RD30)..... 8  10 mL Red top (RD31)..... 10</li> <li>IF <b>EVENT_TYPE</b> = 37 (36-MONTH VISIT), DISPLAY THE FOLLOWING RESPONSE CATEGORIES:8.5mL SST (SS30)..... 7  10 mL Red top (RD30)..... 8</li> <li>IF <b>EVENT_TYPE</b> = XX (60-MONTH VISIT), DISPLAY THE FOLLOWING RESPONSE CATEGORIES:8.5mL SST (SS30)..... 7  10 mL Red top (RD30)..... 8</li> </ul>

Label	Code	Go To
10 mL Red top (RD10)	1	
10 mL Red top (RD11)	2	
8.5mL SST (SS10)	3	
5mL PPT (PP10)	4	
10 mL Red top (RD15)	5	
10 mL Red top (RD19)	6	

Label	Code	Go To
8.5mL SST (SS30)	7	
10 mL Red top (RD30)	8	
5mL PPT (PP30)	9	
10 mL Red top (RD31)	10	

BCZ09000/(CENTRIFUGE\_COMMENT). ENTER CENTRIFUGE COMMENTS.

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> <li>ENTER CENTRIFUGE COMMENTS.</li> </ul>

Label	Code	Go To
NO COMMENTS	1	TIME_STAMP_BCZ_ET
COMMENT	2	

BCZ10000/(CENTRIFUGE\_COMMENT\_OTH).

\_\_\_\_\_

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> <li>ENTER ANY OTHER CENTRIFUGE COMMENTS.</li> </ul>

(TIME\_STAMP\_BCZ\_ET).

PROGRAMMER INSTRUCTIONS
<ul style="list-style-type: none"> <li>INSERT DATE/TIME STAMP</li> </ul>

**PREPARATION FOR BLOOD TUBE TRANSPORT**

(TIME\_STAMP\_PFB\_ST).

<b>PROGRAMMER INSTRUCTIONS</b>
• INSERT DATE/TIME STAMP

**PFB01000/(COLD\_TEMP\_MEASURE).** TEMPERATURE OF REFRIGERATED CHAMBER

<b>DATA COLLECTOR INSTRUCTIONS</b>
<ul style="list-style-type: none"> <li>• PREPARE THE TUBES FOR TRANSPORT IN EITHER THE REFRIGERATED CLAMSHELL OR THE AMBIENT TUBE HOLDER, DEPENDING ON THE TUBE TYPE AND LOCATION OF CENTRIFUGATION.</li> <li>• PLACE A LOWER THRESHOLD (0.0 °C) MONITOR INSIDE THE REFRIGERATED CLAMSHELL AND INSIDE THE AMBIENT TUBE HOLDER (IF APPLICABLE) AND ACTIVATE.</li> <li>• ACTIVATE AN UPPER THRESHOLD (20.0 °C) MONITOR AND AFFIX IT TO THE OUTSIDE OF THE REFRIGERATED CLAMSHELL.</li> <li>• 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.</li> <li>• IF NOT ABLE TO MEASURE TEMPERATURE, THEN SELECT “NOT ABLE TO MEASURE” AND THE REASON THE TEMPERATURE COULD NOT BE RECORDED.</li> <li>• IF THERE ARE NOT ANY TUBES THAT REQUIRE REFRIGERATED TRANSPORT TEMPERATURES, THEN SELECT “NOT APPLICABLE”.</li> </ul>

Label	Code	Go To
TEMPERATURE	1	COLD_TEMP
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

**PFB01100/(COLD\_TEMP\_MEASURE\_OTH).**

SPECIFY:

\_\_\_\_\_

<b>PROGRAMMER INSTRUCTIONS</b>
• GO TO COLD_THRESHOLD_LOW.

**PFB02000/(COLD\_TEMP).** RECORD TEMPERATURE OF REFRIGERATED CHAMBER

|\_|\_|\_|. |\_| °C

**DATA COLLECTOR INSTRUCTIONS**

- RECORD THE TEMPERATURE OF THE REFRIGERATED CHAMBER OF THE TRANSPORT COOLER.
- ENTER TEMPERATURE IN DEGREES CELSIUS.

**PROGRAMMER INSTRUCTIONS**

- SOFT EDIT: DISPLAY SOFT EDIT IF TEMPERATURE IS = 20.0 °C OR IF = 0.0°C.

**PFB03000/(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	

**PFB04000/(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	

**PFB05000/(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	

**PFB05100/(TRANSPORT\_COMMENT).** TRANSPORT COMMENT

Label	Code	Go To
NO COMMENTS	1	

Label	Code	Go To
COMMENT	2	

PFB05200/(TRANSPORT\_COMMENT\_OTH).  
\_\_\_\_\_

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> <li>ENTER ANY TRANSPORT COMMENT.</li> </ul>

PFB06000/(BLOOD\_DRAW\_COMMENT). BLOOD DRAW OTHER COMMENTS

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> <li>ENTER BLOOD COLLECTION COMMENTS:</li> </ul>

Label	Code	Go To
NO COMMENTS	1	TIME_STAMP_PFB_ET
COMMENT	2	

PFB07000/(BLOOD\_DRAW\_COMMENT\_OTH). \_\_\_\_\_

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> <li>ENTER ANY OTHER BLOOD COLLECTION COMMENTS.</li> </ul>

(TIME\_STAMP\_PFB\_ET).

PROGRAMMER INSTRUCTIONS
<ul style="list-style-type: none"> <li>INSERT DATE/TIME STAMP</li> </ul>