Volume VIII

Part 3.
Biospecimen Receipt and Storage Procedures

THE NATIONAL CHILDREN'S STUDY
HEALTH GROWTH ENVIRONMENT

November 30, 2009

Updated Chapter

—Part 3—
Chapter
1

Overview

Biospecimens collected in the home, clinic, and birth settings will be transported to a local Specimen Processing and Shipping Center (SPSC), where they will be receipted electronically in the Biological and Environmental Sample Tracking system (BEST). After receipt, biospecimens will be stored temporarily at the SPSC until they are shipped to the central National Children's Study (NCS) repository or histology laboratory.

Part 3 describes step-by-step procedures for the receipt and temporary local storage of all NCS biospecimen types except blood tubes, which are covered in Part 4. This includes instructions for the documentation of receipt and storage activities using the BEST system. If BEST is unavailable at the time of biospecimen receipt and storage, the appropriate event-specific hard copy backup forms should be used to document receipt and storage data until data can be entered in the system. Sample backup Biospecimen Receipt Forms and field-by-field instructions are located in the appendices at the end of this chapter. Instructions for entering data from backup receipt forms into BEST can be found in the document *Guide to BEST Data Entry from Backup Biospecimen Forms* (located on the NCS Collaboration Portal).

After specimens are receipted in BEST by the biospecimen receipt technician, the system will designate a specific storage unit assignment depending on the specimen type and available space in the unit, given there are available storage units that have been prepared in advance. There are various types of storage units depending on the biospecimen type and storage temperature. Table 1-1 lists the storage units that are used to store biospecimens. A storage unit is defined as a sealable plastic pressure bag (for refrigerated or frozen liquid specimens) or a non-pressurized sealable plastic bag (non-liquid ambient specimens).

Table 1-1. Biospecimen storage units

Storage Unit Name	Storage Unit Type	Designated Storage Unit Contents	Max Specimens per Storage Unit	Storage Condition	Shipping Frequency
Refrigerated Blood	Small Pressure Bag	Blood tubes	12	Refrigerated	Daily
Refrigerated Cord Blood	Small Pressure Bag	Cord blood collection bag	1	Refrigerated	Daily
Refrigerated Placenta Fresh	Large Pressure Bag	Placenta and umbilical cord specimen	1	Refrigerated	Daily
Frozen Mixed	Small Pressure Bag	(P1 Mother) • 1 Urine collection container • 2 Vaginal swab vials • 1 3-mL lavender blood tube (T1 Mother) • 1 Urine collection container • 2 Vaginal swab vials • 1 3-mL lavender blood tube (T3 Mother) • 1 Urine collection container • 2 Urine aliquot vials (Group 2 T3 only) • 2 Vaginal swab vials • 1 PAXgene blood tube (T1 Father) • 1 Urine collection container • 1 3-mL lavender blood tube	6	Frozen	Weekly
Frozen Meconium/Blood	Small Pressure Bag	(Birth) ■ 30-mL meconium vials ■ 3-mL lavender blood tubes	4 (2 meconium and 2 blood tubes)	Frozen	Weekly
Frozen Blood Cards	Ziplock Bag	Protein Saver infant blood spot cards	20	Frozen	Weekly
Frozen Breast milk/Formula	Small Pressure Bag	■ Breast milk collection container ■ Infant formula collection vial	4 (2 breast milk and 2 formula)	Frozen	Weekly
Frozen Urine	Small Pressure Bag	Pregnancy Urine and Infant Urine collection containers	2	Frozen	Weekly

Table 1-1. Biospecimen storage units (continued)

Storage Unit Name	Storage Unit Type	Designated Storage Unit Contents	Max Specimens per Storage Unit	Storage Condition	Shipping Frequency
Frozen 2-Day Saliva	Small Pressure Bag	2-day saliva vials	18 (6 bags x 3 vials each)	Frozen	Weekly
Ambient Blood	Small Pressure Bag	ACD blood tube	1	Ambient	Daily
Ambient Placenta Fixed	Large Pressure Bag	Placenta and umbilical cord specimen in formalin	1	Ambient	Weekly (M-W only)
Ambient Blood Cards	Multi-barrier Pouch	FTA® Mini infant blood spot cards	10	Ambient	Monthly
Ambient Slides	1-Gallon Ziplock Bag	Vaginal slides	50	Ambient	Monthly
Ambient Hair	1-Gallon Ziplock Bag	Hair specimens	50	Ambient	Monthly
Ambient Nails	1-Gallon Ziplock Bag	Toenail specimens	50	Ambient	Monthly
Ambient BNC Saliva	Small Pressure Bag	BNC saliva collection containers	3	Ambient	Monthly

Note: FTA = Flinders Technology Associates

Each storage unit must be visibly labeled on the outside with a bar code label to allow for the identification and electronic tracking of the storage unit in BEST. Before storage units are available for use, they must be prepared and created in the system according to the instructions in the BEST User's Guide. Preparation of storage units entails labeling each type of bag with a preprinted bar code label and creating the storage unit in BEST. It is recommended that the receipt technician or other SPSC staff prepare storage units in advance of receipting specimens to streamline the receipt and storage process.

The length of time biospecimens are stored at the SPSC before shipping depends on the type of biospecimen and storage temperature. Refrigerated specimens are stored until the next daily shipment, frozen specimens are stored for up to 1 week prior to shipping, and ambient specimens (except the ACD blood tube) are stored for up to 1 month prior to shipping. Table 1-2 displays the storage duration at the SPSC for each biospecimen type. To streamline activities at the SPSC and minimize specimen handling, individual storage units will be packed directly in shippers when preparing biospecimen shipments to the repository or histology laboratory.

Table 1-2. Duration of storage by biospecimen type and shipping temperature

Biospecimen Type and Storage Temperature	Duration of Storage at SPSC		
	1 Day	1 Week	1 Month
Refrigerated Specimens*			
Whole and centrifuged blood tubes	X		
Cord blood (CB01)	X		
Placenta and Umbilical Cord (fresh) (PC01)	X		
Frozen Specimens			
3-mL lavender blood tubes* (LP10)		X	
PAXgene blood tubes* (PX10)		X	
Urine (UR01, PU01, BU01; UR02, 4265, 4266 for Group 2 T3 only)		X	
2-day saliva (SL01-SL06)		X	
Vaginal swabs (VS01, VS02)		X	
Protein saver infant blood spot cards (B009)		X	
Meconium (MC01)		X	
Breast milk (BM01)		X	
Infant formula (FM01)		X	
Ambient Specimens			
ACD blood tubes* (AD10)	X		
Placenta and umbilical cord (fixed) (PC01)		X	
FTA Mini infant blood spot cards (B010)			X
Vaginal specimen slides (VL01)			X
BNC saliva (SB01)			X
Hair (HR01)			X
Toenails (NL01)			X

*Receipt and storage procedures for blood tube specimens are described in Part 4.

The procedures presented in Part 3 are organized by chapters according to biospecimen type. Receipt and storage procedures for the following types of biospecimens can be found in the following chapters. The event types for which each specimen will be received at the SPSC are indicated.

Chapter 2 Urine Receipt and Storage Procedures

2.1 Adult and Infant Urine (P1, T1 mother, T1 father, T3, 6-Month, 12 - Month)

Chapter 3 Vaginal Specimen Receipt and Storage Procedures (P1, T1 mother, T3)

Chapter 4 Saliva Receipt and Storage Procedures

4.1 Adult 2-Day Saliva (T1 mother, T3, 6-Month)

4.2 Blood Not Collected (BNC) Saliva (P1, T1 mother, T1 father, T3)

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Part 3

Appendix 1-A

Non-Blood Biospecimen Receipt Form –
P1, T1, T3

Appendix 1-A.
Non-Blood Biospecimen Receipt Form – P1, T1, T3

National Children's Study
Non-Blood Biospecimen Receipt Form

P1, T1, T3

(Only for use when BEST is not available)

A. Administrative

Assignment ID: ☐☐☐☐☐☐☐☐

Date received at SPSC: ☐☐/☐☐/2 0☐☐ (m m d d y y y y)

Time received ☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m

Received by: ☐☐☐☐☐☐☐☐ (Data collector ID)

B. Specimens Received

Collection Container ID	Collection Container Received	Problem Observed	Time Stored (Storage Temperature)	Storage Unit Number and Location
PU01 Pregnancy Urine	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
UR01 or UR02 Adult Urine	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
UR03 Adult Urine	☐ No ☐ Yes **For Urine 2 Cup Kit Only**	☐ No ☐ Yes, specify: _____	Aliquot 4265 ☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen) Aliquot 4266 ☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____ Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
VS01 Vaginal Swab 1	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

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Appendix 1-A.
Non-Blood Biospecimen Receipt Form – P1, T1, T3 (continued)

Collection Container ID	Collection Container Received	Problem Observed	Time Stored (Storage Temperature)	Collection Container ID
VS02 Vaginal Swab 2	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
VL01 Vaginal Swab Slide	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Ambient)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
HR01 Hair	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Ambient)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
NL01 Toenails	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Ambient)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
SB01 Saliva BNC* *Blood not collected	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Ambient)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
SL01- SL06 Adult 2-Day Saliva	☐ No ☐ Yes (Indicate number of saliva sample) ☐ One ☐ Four ☐ Two ☐ Five ☐ Three ☐ Six	☐ No ☐ Yes, specify: _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

Data collector ID for data entry: ☐☐☐☐☐☐☐☐

Date entered into BEST: ☐☐/☐☐/2 0☐☐
m m d d y y y y

Part 3

Appendix 1-B

Non-Blood Biospecimen Receipt Form – P1, T1, T3: Field-by-Field Instructions

Appendix 1-B.
Non-Blood Biospecimen Receipt Form – P1, T1, T3: Field-by-Field Instructions

NON-BLOOD BIOSPECIMEN RECEIPT FORM: FIELD-BY-FIELD INSTRUCTIONS

This form is only to be used when the Biological and Environmental Sample Tracking system (BEST) is not available and should be completed by the biospecimen receipt technician. It is used to record receipt and storage data for non-blood biospecimens collected at the P1 mother, T1 mother, T1 father, and T3 mother data collection and pick-up visits. Instructions for completing each item on the form are provided in this field-by-field.

After Completing the Form

- *Data collector identification number (ID) for data entry*
  - The data on this from must be entered in BEST once the system becomes available.
  - Record the data collector ID of the person who performs data entry.
- *Date entered in BEST*
  - Record the date the data from the form were entered into BEST.
  - The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).

National Children's Study

Non-Blood Biospecimen Receipt Form

P1, T1, T3

(Only for use when BEST is not available)

A. Administrative

Assignment ID: ☐☐☐☐☐☐☐☐

Date received at SPSC: ☐☐/☐☐/2 0☐☐ (m m d d y y y y)

Time received ☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m

Received by: ☐☐☐☐☐☐☐☐ (Data collector ID)

B. Specimens Received

Collection Container ID	Collection Container Received	Problem Observed	Time Stored (Storage Temperature)	Storage Unit Number and Location
PU01 Pregnancy Urine	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
UR01 or UR02 Adult Urine	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
UR03 Adult Urine	☐ No ☐ Yes **For Urine 2 Cup Kit Only**	☐ No ☐ Yes, specify: _____	Aliquot 4265 ☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
			Aliquot 4266 ☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
VS01 Vaginal Swab 1	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

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Part A: Administrative

- *Assignment ID*
  - Record the appropriate assignment ID in the spaces provided.
  - The assignment ID consists of the first eight characters on the subject label.
- *Date received at SPSC*
  - Record the date the specimens were received at the Specimen Processing and Shipping Center (SPSC)
  - The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
- *Time received*
  - Record the time the specimens were received at the SPSC
  - Be sure to use zeros when necessary while filling the spaces. For example, if the specimens are received at 2:05 p.m., record "02:05."
  - Mark the box to indicate "a.m." or "p.m."
- *Received by*
  - Record the data collector ID of the person who receives the specimens at the SPSC.

Part B: Specimens Received

Record the following information for each specimen that should have been collected or picked up according to the event type.

- *Collection Container Received*
  - Mark the box that corresponds to "No" to indicate that the specimen has not been received.
  - Mark the box that corresponds to "Yes" to indicate that the specimen has been received.
  - For adult 2-day saliva only, mark the box that corresponds to the number of saliva samples collected.

Collection Container ID	Collection Container Received	Problem Observed	Time Stored (Storage Temperature)	Collection Container ID
VS02 Vaginal Swab 2	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
VL01 Vaginal Swab Slide	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Ambient)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
HR01 Hair	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Ambient)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
NL01 Toenails	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Ambient)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
SB01 Saliva BNC* *Blood not collected	☐ No ☐ Yes	☐ No ☐ Yes, specify: _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Ambient)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
SL01- SL06 Adult 2-Day Saliva	☐ No ☐ Yes (Indicate number of saliva sample) ☐ One ☐ Four ☐ Two ☐ Five ☐ Three ☐ Six	☐ No ☐ Yes, specify: _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

Data collector ID for data entry: ☐☐☐☐☐☐☐☐

Date entered into BEST: ☐☐/☐☐/2 0☐☐
m m d d y y y y

- Note that the UR03 Adult Urine specimen will only be received at the SPSC if an Adult Urine 2 Cup Collection Kit was used when collecting the urine specimen.

- *Problem Observed*

  - Mark the box that corresponds to "No" to indicate that there are no problems with the specimen.

  - Mark the box that corresponds to "Yes, specify" to indicate that there was a problem with the specimen, and record a brief description of the problem in the space provided.

- *Time Stored (Storage Temperature)*

  - Record the time the specimen was placed in the appropriate storage location.

  - Note that Urine Aliquots 4265 and 4266 will only be prepared at the SPSC if the UR03 Adult Urine specimen was received.

  - Be sure to use zeros when necessary while filling the spaces. For example, if the specimen is stored at 2:05 p.m., record "02:05."

  - Mark the box to indicate "a.m." or "p.m."

- *Storage Unit Number and Location*

  - Record the storage unit ID number that appears on the pressure bag or other storage bag the specimens are stored in.

  - Record the location of the storage unit.

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Part 3

Appendix 1-C

Birth Biospecimen Receipt Form

Appendix 1-C.
Birth Biospecimen Receipt Form

National Children's Study
Birth Biospecimen Receipt Form

(Only for use when BEST is not available)

A. Administrative

Assignment ID: ☐☐☐☐☐☐☐☐☐

Date received at SPSC: ☐☐/☐☐/2☐☐☐ (m m d d y y y y)

Time received ☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m

Received by: ☐☐☐☐☐☐☐☐ (Data collector ID)

B. Specimens Received

Collection Container ID	Collection Container Received	Problem Observed	Time Stored (Storage Temperature)	Storage Unit Number and Location
Cord Blood	☐ No ☐ Yes	☐ No ☐ Yes If yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Refrigerated)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
Placenta Umbilical Cord	☐ No ☐ Yes	☐ No ☐ Yes, If yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Refrigerated)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
Infant Blood Spot Card (FTA)	☐ No ☐ Yes	☐ No ☐ Yes If yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Ambient)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
Infant Blood Spot Card (903)	☐ No ☐ Yes	☐ No ☐ Yes If yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

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Appendix 1-C.
Birth Biospecimen Receipt Form (continued)

Collection Container ID	Collection Container Received	Problem Observed	Time Stored (Storage temperature)	Storage Bag Number and Location
Meconium	☐ No ☐ Yes	☐ No ☐ Yes If yes, specify: _____ _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

Data collector ID for data entry: ☐☐☐☐☐☐☐☐

Date entered into BEST: ☐☐/☐☐/2☐☐☐
m m d d y y y y

Part 3

Appendix 1-D

Birth Biospecimen Receipt Form: Field-by-Field Instructions

Appendix 1-D.
Birth Biospecimen Receipt Form: Field-by-Field Instructions

BIRTH BIOSPECIMEN RECEIPT FORM: FIELD-BY-FIELD INSTRUCTIONS

This form is to be used only when the Biological and Environmental Sample Tracking system (BEST) is not available, and it should be completed by the biospecimen receipt technician. It is used to record receipt and storage data for non-blood biospecimens collected at the birth data collection and pick-up visits. Instructions for completing each item on the form are provided in this field-by-field.

After Completing the Form

- *Data collector identification number (ID) for data entry*
  - The data on this from must be entered in BEST once the system becomes available.
  - Record the data collector ID of the person who performs data entry.
- *Date entered in BEST*
  - Record the date the data from the form were entered into BEST.
  - The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).

National Children's Study

Birth Biospecimen Receipt Form

(Only for use when BEST is not available)

A. Administrative

Assignment ID: ☐☐☐☐☐☐☐☐

Date received at SPSC: ☐☐/☐☐/2☐☐☐ (m m d d y y y y)

Time received ☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m

Received by: ☐☐☐☐☐☐☐☐ (Data collector ID)

B. Specimens Received

Collection Container ID	Collection Container Received	Problem Observed	Time Stored (Storage Temperature)	Storage Unit Number and Location
Cord Blood	☐ No ☐ Yes	☐ No ☐ Yes If yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Refrigerated)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
Placenta Umbilical Cord	☐ No ☐ Yes	☐ No ☐ Yes, If yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Refrigerated)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
Infant Blood Spot Card (FTA)	☐ No ☐ Yes	☐ No ☐ Yes If yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Ambient)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
Infant Blood Spot Card (903)	☐ No ☐ Yes	☐ No ☐ Yes If yes, specify: _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

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Part A: Administrative

- *Assignment ID*
  - Record the appropriate assignment ID in the spaces provided.
  - The assignment ID consists of the first eight characters on the subject label.
- *Date received at SPSC*
  - Record the date the specimens were received at the Specimen Processing and Shipping Center (SPSC).
  - The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
- *Time received*
  - Record the time the specimens were received at the SPSC.
  - Be sure to use zeros when necessary while filling the spaces (e.g., if the specimen is received at 2:05 p.m., record "02:05").
  - Mark the box to indicate "a.m." or "p.m."
- *Received by*
  - Record the data collector ID of the person who receives the specimens at the SPSC.

Part B: Specimens Received

Record the following information for each specimen that should have been collected or picked up according to the event type.

- *Collection Container Received*
  - Mark the box that corresponds to "No" to indicate that the specimen has not been received.
  - Mark the box that corresponds to "Yes" to indicate that the specimen has been received.

Collection Container ID	Collection Container Received	Problem Observed	Time Stored (Storage temperature)	Storage Bag Number and Location
Meconium	☐ No ☐ Yes	☐ No ☐ Yes If yes, specify: _____ _____	☐☐:☐☐ ☐ a.m. ☐ p.m. h h m m (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

Data collector ID for data entry: ☐☐☐☐☐☐☐☐

Date entered into BEST: ☐☐/☐☐/2☐☐☐
m m d d y y y y

■

Problem Observed

- Mark the box that corresponds to "No" to indicate that there are no problems with the specimen.
- Mark the box that corresponds to "Yes" to indicate that there was a problem with the specimen.
- When the box that corresponds to "Yes" has been marked, record a brief description of the problem in the space provided.

- *Time Stored (Storage Temperature)*
  - Record the time the specimen was placed in the appropriate storage location.
  - Be sure to use zeros when necessary while filling the spaces (e.g., if the specimen is stored at 2:05 p.m., record "02:05").
  - Mark the box to indicate "a.m." or "p.m."
- *Storage Unit Number and Location*
  - Record the storage unit ID number that appears on the pressure bag or other storage bag the specimens are stored in.
  - Record the location of the storage unit.

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Part 3

Appendix 1-E

Biospecimen Receipt Form—1-Month

Appendix 1-E.
Biospecimen Receipt Form—1-Month

National Children's Study
Biospecimen Receipt Form - 1-Month

(Only for use when BEST is not available)

A. Administrative

Assignment ID: ☐☐☐☐☐☐☐☐☐

Date received at SPSC: ☐☐/☐☐/2☐☐☐ (m m d d y y y y)

Time received ☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m

Received by: ☐☐☐☐☐☐☐☐ (Data collector ID)

B. Specimens Received

Collection Container ID	Collection Container Received	Problem Observed	Time Stored (Storage Temperature)	Storage Unit Number and Location
Breast Milk	☐ No ☐ Yes	☐ No ☐ Yes If yes, specify: _____ _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
Infant Formula	☐ No ☐ Yes	☐ No ☐ Yes, If yes, specify: _____ _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

Data collector ID for data entry: ☐☐☐☐☐☐☐☐

Date entered into BEST: ☐☐/☐☐/2☐☐☐ (m m d d y y y y)

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Part 3

Appendix 1-F

Biospecimen Receipt Form—1-Month: Field-by-Field Instructions

Appendix 1-F.
Biospecimen Receipt Form—1-Month: Field-by-Field Instructions

BIOSPECIMEN RECEIPT FORM—1-MONTH: FIELD-BY-FIELD INSTRUCTIONS

This form is to be used only when the Biological and Environmental Sample Tracking system (BEST) is not available, and it should be completed by the biospecimen receipt technician. It is used to record receipt and storage data for non-blood biospecimens collected at the 1-month pick-up visit. Instructions for completing each item on the form are provided in this field-by-field.

After Completing the Form

- *Data collector identification number (ID) for data entry*
  - The data on this from must be entered in BEST once the system becomes available.
  - Record the data collector ID of the person who performs data entry.
- *Date entered in BEST*
  - Record the date the data from the form were entered into BEST.
  - The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).

National Children's Study

Biospecimen Receipt Form - 1-Month

(Only for use when BEST is not available)

A. Administrative

Assignment ID: ☐☐☐☐☐☐☐☐

Date received at SPSC: ☐☐/☐☐/2☐☐☐ (m m d d y y y y)

Time received ☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m

Received by: ☐☐☐☐☐☐☐☐ (Data collector ID)

B. Specimens Received

Collection Container ID	Collection Container Received	Problem Observed	Time Stored (Storage Temperature)	Storage Unit Number and Location
Breast Milk	☐ No ☐ Yes	☐ No ☐ Yes If yes, specify: _____ _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
Infant Formula	☐ No ☐ Yes	☐ No ☐ Yes, If yes, specify: _____ _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

Data collector ID for data entry: ☐☐☐☐☐☐☐☐

Date entered into BEST: ☐☐/☐☐/2☐☐☐ (m m d d y y y y)

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Part A: Administrative

- *Assignment ID*
  - Record the appropriate assignment ID in the spaces provided.
  - The assignment ID consists of the first eight characters on the subject label.
- *Date received at SPSC*
  - Record the date the specimens were received at the Specimen Processing and Shipping Center (SPSC).
  - The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
- *Time received*
  - Record the time the specimens were received at the SPSC.
  - Be sure to use zeros when necessary while filling the spaces (e.g., if the specimen is received at 2:05 p.m., record "02:05").
  - Mark the box to indicate "a.m." or "p.m."
- *Received by*
  - Record the data collector ID of the person who receives the specimens at the SPSC.

Part B: Specimens Received

Record the following information for each specimen that should have been collected or picked up according to the event type.

- *Collection Container Received*
  - Mark the box that corresponds to "No" to indicate that the specimen has not been received.
  - Mark the box that corresponds to "Yes" to indicate that the specimen has been received.

National Children's Study

Biospecimen Receipt Form - 1-Month

(Only for use when BEST is not available)

A. Administrative

Assignment ID: ☐☐☐☐☐☐☐☐

Date received at SPSC: ☐☐/☐☐/2☐☐☐ (m m d d y y y y)

Time received ☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m

Received by: ☐☐☐☐☐☐☐☐ (Data collector ID)

B. Specimens Received

Collection Container ID	Collection Container Received	Problem Observed	Time Stored (Storage Temperature)	Storage Unit Number and Location
Breast Milk	☐ No ☐ Yes	☐ No ☐ Yes If yes, specify: _____ _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
Infant Formula	☐ No ☐ Yes	☐ No ☐ Yes, If yes, specify: _____ _____	☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

Data collector ID for data entry: ☐☐☐☐☐☐☐☐

Date entered into BEST: ☐☐/☐☐/2☐☐☐ (m m d d y y y y)

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Problem Observed

- Mark the box that corresponds to "No" to indicate that there are no problems with the specimen.
- Mark the box that corresponds to "Yes" to indicate that there was a problem with the specimen.
- When the box that corresponds to "Yes" has been marked, record a brief description of the problem in the space provided.

- *Time Stored (Storage Temperature)*
  - Record the time the specimen was placed in the appropriate storage location.
  - Be sure to use zeros when necessary while filling the spaces (e.g., if the specimen is stored at 2:05 p.m., record "02:05").
  - Mark the box to indicate "a.m." or "p.m."
- *Storage Unit Number and Location*
  - Record the storage unit ID number that appears on the pressure bag or other storage bag the specimens are stored in.
  - Record the location of the storage unit.

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New Appendix

Part 3

Appendix 1-G

Biospecimen Receipt Form—6-Month

Appendix 1-G.
Biospecimen Receipt Form—6-Month

National Children's Study
Biospecimen Receipt Form – 6-Month

(Only for use when BEST is not available)

A. Administrative

Date received at SPSC: ☐☐/☐☐/2 0☐☐ (m m d d y y y y)

Time received: ☐☐:☐☐ (h h m m) ☐ a.m. ☐ p.m.

Received by: ☐☐☐☐☐☐☐☐ (Data collector ID)

6-Month Primary Caregiver Assignment ID: ☐☐☐☐☐☐☐☐

B. Specimens Received

Collection Container ID/ Assignment ID	Collection Container Received	Problem Observed	Time Stored (Storage Temperature)	Storage Unit Number and Location
BU01 Infant Urine Infant Urine Bag Kit ID: ☐☐☐☐☐☐☐☐☐ 6-Month Child Assignment ID: ☐☐☐☐☐☐☐☐	☐ N/A ☐ No ☐ Yes	☐ No ☐ Yes If yes—specify: _____ _____ _____	☐☐:☐☐ (h h m m) ☐a.m. ☐p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
SL01- SL06 Adult 2-Day Saliva Adult 2-Day Saliva Kit ID: ☐☐☐☐☐☐☐☐☐ 6-Month Alternate Caregiver Assignment ID: ☐☐☐☐☐☐☐☐	☐ N/A ☐ No ☐ Yes (Indicate number of saliva samples) ☐ One ☐ Four ☐ Two ☐ Five ☐ Three ☐ Six	☐ No ☐ Yes If yes—specify: _____ _____ _____	☐☐:☐☐ (h h m m) ☐a.m. ☐p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

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Appendix 1-G.
Biospecimen Receipt Form—6-Month (continued)

Collection Container ID/ Assignment ID	Collection Container Received	Problem Observed	Time Stored (Storage Temperature)	Storage Unit Number and Location
SL01- SL06 Adult 2-Day Saliva Adult 2-Day Saliva Kit ID: ☐☐☐☐☐☐☐☐☐☐	☐ N/A ☐ No ☐ Yes (Indicate number of saliva samples) ☐ One ☐ Four ☐ Two ☐ Five ☐ Three ☐ Six	☐ No ☐ Yes If yes—specify: _____ _____ _____	☐☐:☐☐ ☐a.m. ☐p.m. h h m m (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
BM01 Breast Milk Breast Milk Kit ID: ☐☐☐☐☐☐☐☐☐☐	☐ N/A ☐ No ☐ Yes	☐ No ☐ Yes If yes—specify: _____ _____ _____	☐☐:☐☐ ☐a.m. ☐p.m. h h m m (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
FM01 Infant Formula Infant Formula Kit ID: ☐☐☐☐☐☐☐☐☐☐	☐ N/A ☐ No ☐ Yes	☐ No ☐ Yes If yes—specify: _____ _____ _____	☐☐:☐☐ ☐a.m. ☐p.m. h h m m (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

Data collector ID for data entry: ☐☐☐☐☐☐☐☐ **Date entered into BEST:** ☐☐/☐☐/2☐☐☐
m m d d y y y y

New Appendix

Part 3

Appendix 1-H

Biospecimen Receipt Form—6-Month: Field-by-Field Instructions

Appendix 1-H.
Biospecimen Receipt Form—6-Month: Field-by-Field Instructions

BIOSPECIMEN RECEIPT FORM—6-MONTH: FIELD-BY-FIELD INSTRUCTIONS

This form is to be used only when the Biological and Environmental Sample Tracking system (BEST) is not available, and it should be completed by the biospecimen receipt technician. It is used to record receipt and storage data for biospecimens collected at the 6-month visit. Instructions for completing each item on the form are provided in this field-by-field.

After Completing the Form

- *Data collector identification number (ID) for data entry*
  - The data on this form must be entered into BEST once the system becomes available.
  - Record the data collector ID of the person who performs data entry.
- *Date entered into BEST*
  - Record the date the data from the form were entered into BEST.
  - The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).

National Children's Study

Biospecimen Receipt Form – 6-Month

(Only for use when BEST is not available)

A. Administrative

Date received at SPSC: ☐☐/☐☐/2 0☐☐ (m m / d d / y y y y)

Time received: ☐☐:☐☐ (h h : m m) ☐ a.m. ☐ p.m.

Received by: ☐☐☐☐☐☐☐☐ (Data collector ID)

6-Month Primary Caregiver Assignment ID: ☐☐☐☐☐☐☐☐

B. Specimens Received

Collection Container ID/ Assignment ID	Collection Container Received	Problem Observed	Time Stored (Storage Temperature)	Storage Unit Number and Location
BU01 Infant Urine Infant Urine Bag Kit ID: ☐☐☐☐☐☐☐☐☐ 6-Month Child Assignment ID: ☐☐☐☐☐☐☐☐	☐ N/A ☐ No ☐ Yes	☐ No ☐ Yes If yes—specify: _____ _____ _____	☐☐:☐☐ (h h : m m) ☐a.m. ☐p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
SL01- SL06 Adult 2-Day Saliva Adult 2-Day Saliva Kit ID: ☐☐☐☐☐☐☐☐☐ 6-Month Alternate Caregiver Assignment ID: ☐☐☐☐☐☐☐☐	☐ N/A ☐ No ☐ Yes (Indicate number of saliva samples) ☐ One ☐ Four ☐ Two ☐ Five ☐ Three ☐ Six	☐ No ☐ Yes If yes—specify: _____ _____ _____	☐☐:☐☐ (h h : m m) ☐a.m. ☐p.m. (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

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Part A: Administrative

- *Date received at SPSC*
  - Record the date the specimens were received at the Specimen Processing and Shipping Center (SPSC).
  - The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
- *Time received*
  - Record the time the specimens were received at the SPSC.
  - Be sure to use zeros when necessary while filling the spaces (e.g., if the specimen is received at 2:05 p.m., record "02:05").
  - Mark the box to indicate "a.m." or "p.m."
- *Received by*
  - Record the data collector ID of the person who receives the specimens at the SPSC.
- *6-Month Primary Caregiver Assignment ID*
  - Record the appropriate assignment ID in the spaces provided.
  - The assignment ID consists of the first eight characters on the subject label.
  - In addition to the breast milk or infant formula sample, one set of adult 2-day saliva specimens will be associated with the Primary Caregiver assignment.

Part B: Specimens Received

Record the following information for each specimen that should have been collected or picked up according to the visit type.

- *Collection Container ID/Assignment ID*
  - For each specimen type that is received, record the collection kit ID in the spaces provided. The kit ID is the 9-character alphanumeric sequence that precedes the specimen ID on the collection container label (i.e., BA1234567-BU01).
  - When applicable, record the appropriate assignment ID in the spaces provided. The assignment ID consists of the first eight characters on the subject label. Be sure to correctly record the correct assignment ID that is associated with each specimen.

Collection Container ID/ Assignment ID	Collection Container Received	Problem Observed	Time Stored (Storage Temperature)	Storage Unit Number and Location
SL01- SL06 Adult 2-Day Saliva Adult 2-Day Saliva Kit ID: ☐☐☐☐☐☐☐☐☐	☐ N/A ☐ No ☐ Yes (Indicate number of saliva samples) ☐ One ☐ Four ☐ Two ☐ Five ☐ Three ☐ Six	☐ No ☐ Yes If yes—specify: _____ _____ _____	☐☐:☐☐ ☐a.m. ☐p.m. h h m m (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
BM01 Breast Milk Breast Milk Kit ID: ☐☐☐☐☐☐☐☐☐	☐ N/A ☐ No ☐ Yes	☐ No ☐ Yes If yes—specify: _____ _____ _____	☐☐:☐☐ ☐a.m. ☐p.m. h h m m (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____
FM01 Infant Formula Infant Formula Kit ID: ☐☐☐☐☐☐☐☐☐	☐ N/A ☐ No ☐ Yes	☐ No ☐ Yes If yes—specify: _____ _____ _____	☐☐:☐☐ ☐a.m. ☐p.m. h h m m (Frozen)	Unit: ☐☐☐☐☐☐☐☐☐☐ Location: _____

Data collector ID for data entry: ☐☐☐☐☐☐☐☐

Date entered into BEST: ☐☐/☐☐/2 0☐☐
m m d d y y y y

- *Collection Container Received*
  - Mark the box that corresponds to "N/A" to indicate that receipt of this type of specimen is not applicable for this visit. For example, the infant urine specimen may not be collected at the same visit that the adult 2-day saliva specimens are picked up.
  - Mark the box that corresponds to "No" to indicate that the specimen has not been received.
  - Mark the box that corresponds to "Yes" to indicate that the specimen has been received.
  - For adult 2-day saliva specimens, indicate the number of saliva vials that were received for that assignment.
- *Problem Observed*
  - Mark the box that corresponds to "No" to indicate that there are no problems with the specimen/s.
  - Mark the box that corresponds to "Yes" to indicate that there was a problem with the specimen/s.
  - When the box that corresponds to "Yes" has been marked, record a brief description of the problem in the space provided.
- *Time Stored (Storage Temperature)*
  - Record the time the specimen was placed in the appropriate storage location.
  - Be sure to use zeros when necessary while filling the spaces (e.g., if the specimen is stored at 2:05 p.m., record "02:05").
  - Mark the box to indicate "a.m." or "p.m."
- *Storage Unit Number and Location*
  - Record the storage unit ID number that appears on the pressure bag or other storage bag the specimens are stored in.
  - Record the location of the storage unit.

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Updated Chapter

—Part 3—
Chapter
2

Urine Receipt and Storage Procedures

2.1 Adult and Infant Urine

This section describes the procedures for receipt and storage of adult and infant urine specimens at the Specimen Processing and Shipping Center (SPSC).

Urine specimens will be transported on dry ice to the SPSC, where they will be electronically receipted and stored at -30° C until they are shipped weekly to the central NCS repository (see Part 5 of this volume for biospecimen shipping procedures). With the exception of pregnancy urine and infant urine specimens, each urine specimen will be stored in a pressure bag together with frozen vaginal swabs (for mother visits) and frozen blood specimens collected from the same study participant at one study visit (i.e., the Frozen Mixed storage unit. Pregnancy urine and infant urine specimens will be stored together in the Frozen Urine storage unit and up to two specimens may be stored in the same unit.

Receipt and storage data will be documented using the Biological and Environmental Sample Tracking system (BEST). For detailed BEST user information, please refer to the BEST User's Guide.

Note: These receipt and storage procedures are for Group 1 *only*. For Group 2 urine receipt and storage procedures, please refer to Part 3 Addendum A (at the end of this part).

2.1.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to receipt and store urine specimens at the SPSC:

- Laboratory coat
- Gloves

- Dry ice glove
- Small pressure bag, prelabeled
- Computer with bar code scanner.

The following form is required to receipt and store urine specimens:

- Completed Biospecimen Transmittal Form.

Receipt and storage data will be documented in BEST. If BEST is not available, then the appropriate hard copy backup Biospecimen Receipt Form must be used to document receipt and storage data (see the appendices in Chapter 3 of Part 1 for forms and field-by-field instructions for each study event). In this case, because a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store each specimen. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST. Instructions for entering data from backup receipt forms into BEST can be found in the document *Guide to BEST Data Entry from Backup Biospecimen Forms* (located on the NCS Collaboration Portal).

2.1.2 Procedures for Receipt and Storage of Adult and Infant Urine Specimens

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following basic procedures are for the receipt and storage of adult and infant urine specimens. Refer to the BEST User's Guide for detailed instructions on how to complete the biospecimen receipt and storage process using BEST.

1. Put on a lab coat and gloves.
2. Log in to BEST.
3. If you have not already done so, wand the subject label on the Biospecimen Transmittal Form by using the bar code scanner. Once you have accessed and confirmed the correct assignment, follow the steps outlined in the BEST User's Guide to complete the following activities in BEST:

- Record and update visit parameters
- Check out storage units
- Receipt specimens
- Assign specimens to specific storage units.

4. Be sure to wear the dry ice glove when removing the urine collection container from the dry ice chamber of the biospecimen transport cooler.

5. After the urine specimen has been receipted in BEST, place the urine specimen in the assigned pressure bag, keeping the container within the biohazard transport bag. Do not seal the pressure bag until the time the shipment is prepared.

6. Store the pressure bag in the freezer storage bin. If the pressure bag contains a frozen blood tube (i.e., a Frozen Mixed storage unit), the pressure bag should be stored *on its side*.

7. For storage units with blood tubes, the pressure bag should be stored on its side until the 3-ml lavender tube or PAXgene tube is frozen to reduce the possibility of tube breakage. Once the blood is frozen, the pressure bag may be placed in an upright position and should be kept frozen until the shipment to the repository is prepared. For shipping procedures for frozen specimens, see Chapter 3 of Part 5 in this volume.

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Updated Chapter

—Part 3—
Chapter
3

Vaginal Specimen Receipt and Storage Procedures

This chapter describes the procedures for receipt and storage of vaginal slide and swab specimens at the Specimen Processing and Shipping Center (SPSC).

Vaginal slides will be transported at ambient temperature to the SPSC, where they will be electronically receipted and stored at ambient temperature until they are shipped monthly to the central NCS repository (see Part 5 of this volume for biospecimen shipping procedures).

Vaginal swabs will be transported on dry ice to the SPSC, where they will be electronically receipted and stored at -30° C until they are shipped weekly to the central NCS repository (see Part 5 of this volume for biospecimen shipping procedures). Vaginal swab vials will be stored in a pressure bag together with frozen urine and frozen blood specimens collected from the same study participant at one study visit. The pressure bag used to store the specimens in the freezer then will be used to ship the specimens.

Receipt and storage data will be documented using the Biological and Environmental Sample Tracking system (BEST). For detailed BEST user information, please refer to the BEST User's Guide.

3.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to receipt and store vaginal specimens at the SPSC:

- Laboratory coat
- Gloves
- Dry ice glove
- Small pressure bag, prelabeled

- Ambient Ziplock storage bag, prelabeled
- Computer with bar code scanner.

The following form is required to receipt and store vaginal specimens:

- Completed Biospecimen Transmittal Form.

Receipt and storage data will be documented in BEST. If BEST is not available, then the appropriate hard copy backup Non-Blood Biospecimen Receipt Form must be used to document receipt and storage data (see Appendices 1-A and 1-B for form and field-by-field instructions for each study event). In this case, because a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store each vial. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST. Instructions for entering data from backup receipt forms into BEST can be found in the document *Guide to BEST Data Entry from Backup Biospecimen Forms* (located on the NCS Collaboration Portal).

3.2 Procedures for Receipt and Storage of Vaginal Specimens

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following provides basic procedures for the receipt and storage of vaginal specimens. Refer to the BEST User's Guide for detailed instructions on how to complete the biospecimen receipt and storage process using BEST.

1. Put on a lab coat and gloves.
2. Log in to BEST.
3. If you have not already done so, wand the subject label on the Biospecimen Transmittal Form by using the bar code scanner. Once you have accessed and confirmed the correct assignment, follow the steps outlined in the BEST User's Guide to complete the following activities in BEST:
   - Record and update visit parameters

- Check out storage units
- Receipt specimens
- Assign specimens to specific storage units.

To receipt and store *vaginal swab vials*:

1. Be sure to wear the dry ice glove when removing the plastic biohazard transport bag containing the vaginal swab vials from the dry ice chamber of the biospecimen transport cooler.
2. After the vaginal swab vials have been receipted in BEST, place the vaginal swab vials in the assigned pressure bag, keeping the vials within the biohazard transport bag. Do not seal the pressure bag until the time the shipment is prepared.
3. Store the pressure bag in the freezer storage bin. If the pressure bag contains a frozen blood tube (i.e., a Frozen Mixed storage unit), the pressure bag should be stored *on its side*.
4. For storage units with blood tubes, the pressure bag should be stored on its side until the 3ml lavender tube is frozen to reduce the possibility of tube breakage. Once the 3ml lavender tube is frozen, the pressure bag may be placed in an upright position and should be kept frozen until the shipment to the repository is prepared. For shipping procedures for frozen specimens, see Chapter 3 of Part 5 in this volume.

To receipt and store the *vaginal slide*:

1. Remove the cardboard slide holder from the ambient transport bag. Do not remove the slide from the cardboard slide holder when receipting the specimen.
2. After the slide has been receipted in BEST, place the vaginal slide in the assigned Ziplock storage bag and seal the bag.
3. Keep the storage bag at ambient temperature until the shipment to the repository is prepared. For shipping procedures for ambient specimens, see Chapter 4 of Part 5 in this volume.

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Updated Chapter

—Part 3—
Chapter
4

Saliva Receipt and Storage Procedures

4.1 Adult 2-Day Saliva

This section describes the procedures for receipt and storage of adult 2-day saliva specimens at the Specimen Processing and Shipping Center (SPSC). Adult 2-day saliva specimens will be transported on dry ice to the SPSC, where they will be electronically receipted and stored at -30° C until they are shipped weekly to the central NCS repository (see Part 5 of this volume for biospecimen shipping procedures).

Two-day saliva specimens will be stored in a pressure bag together with other 2-day saliva specimens collected from other study participants. The pressure bag used to store the specimens in the freezer then will be used to ship the specimens.

Receipt and storage data will be documented using the Biological and Environmental Sample Tracking system (BEST). For detailed BEST user information, please refer to the BEST User's Guide.

4.1.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to receipt and store adult 2-day saliva specimens at the SPSC:

- Laboratory coat
- Gloves
- Dry ice glove
- Small pressure bag, prelabeled
- Computer with bar code scanner.

The following form is required to receipt and store 2-day saliva specimens:

- Completed Biospecimen Transmittal Form.

Receipt and storage data will be documented in BEST. If BEST is not available, then the appropriate hard copy backup Biospecimen Receipt Form must be used to document receipt and storage data (see the appendices in Chapter 3 of Part 1 for forms and field-by-field instructions for each study event). In this case, because a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store each tube. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST. Instructions for entering data from backup receipt forms into BEST can be found in the document *Guide to BEST Data Entry from Backup Biospecimen Forms* (located on the NCS Collaboration Portal).

4.1.2 Step-by-Step Procedures for Receipt and Storage of Adult 2-Day Saliva Specimens

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following provides basic procedures for the receipt and storage of adult 2-day saliva specimens. Refer to the BEST User's Guide for detailed instructions on how to complete the biospecimen receipt and storage process using BEST.

1. Put on a lab coat and gloves.
2. Log in to BEST.
3. If you have not already done so, wand the subject label on the Biospecimen Transmittal Form by using the bar code scanner. Once you have accessed and confirmed the correct assignment, follow the steps outlined in the BEST User's Guide to complete the following activities in BEST:
   - Record and update visit parameters
   - Check out storage units
   - Receipt specimens

– Assign specimens to specific storage units.

4. Be sure to wear the dry ice glove when removing the biohazard bag containing the 2-day saliva collection vials from the dry ice chamber of the biospecimen transport cooler.

5. After the saliva specimens have been receipted in BEST, place the biohazard transport bag containing the saliva collection vials in the assigned pressure bag. Do not seal the pressure bag until the time the shipment is prepared.

6. Store the pressure bag in the freezer storage bin.

7. Keep the pressure bag in the freezer until the shipment to the repository is prepared. For shipping procedures for frozen specimens, see Chapter 3 of Part 5 in this volume.

4.2 Adult Blood Not Collected (BNC) Saliva

This section describes the procedures for receipt and storage of adult BNC saliva specimens at the SPSC. BNC saliva will be collected at study visits only if participants have refused or are unable to provide blood specimens.

Saliva BNC specimens will be transported at ambient temperature to the SPSC, where they will be electronically receipted and stored at ambient temperature until they are shipped monthly to the central NCS repository (see Part 5 of this volume for biospecimen shipping procedures).

BNC saliva specimens will be stored in a pressure bag together with other BNC saliva specimens collected from other study participants. The pressure bag used to store the specimens at ambient temperature will then be used to ship the specimens.

Receipt and storage data will be documented using BEST. For detailed BEST user information, please refer to the BEST User's Guide.

4.2.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to receipt and store BNC saliva specimens at the SPSC:

- Laboratory coat
- Gloves
- Small pressure bag, prelabeled
- Computer with bar code scanner.

The following form is required to receipt and store BNC saliva specimens:

- Completed Biospecimen Transmittal Form.

Receipt and storage data will be documented in BEST. If BEST is not available, then the appropriate hard copy backup Non-Blood Biospecimen Receipt Form must be used to document receipt and storage data (see Appendices 1-A and 1-B for form and field-by-field instructions for each study event). In this case, because a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store each tube. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST. Instructions for entering data from backup receipt forms into BEST can be found in the document *Guide to BEST Data Entry from Backup Biospecimen Forms* (located on the NCS Collaboration Portal).

4.2.2 Step-by-Step Procedures for Receipt and Storage of BNC Saliva Specimens

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following provides basic procedures for the receipt and storage of BNC saliva specimens. Refer to the BEST User's Guide for detailed instructions on how to complete the biospecimen receipt and storage process using BEST.

1. Put on a lab coat and gloves.

2. Log in to BEST.

3. If you have not already done so, wand the subject label on the Biospecimen Transmittal Form by using the bar code scanner. Once you have accessed and confirmed the correct assignment, follow the steps outlined in the BEST User's Guide to complete the following activities in BEST:

   – Record and update visit parameters

   – Check out storage units

   – Receipt specimens

   – Assign specimens to specific storage units.

4. Remove the plastic biohazard transport bag containing the Oragene saliva collection container from the ambient transport bag.

5. After the saliva specimen has been receipted in BEST, place the biohazard transport bag containing the saliva collection container in the assigned pressure bag. Do not seal the pressure bag until the time the shipment is prepared.

6. Keep the pressure bag at ambient temperature until the shipment to the repository is prepared. For shipping procedures for ambient specimens, see Chapter 4 of Part 5 in this volume.

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Hair Receipt and Storage Procedures

This chapter describes the procedures for receipt and storage of hair specimens at the Specimen Processing and Shipping Center (SPSC). Hair specimens will be transported at ambient temperature to the SPSC, where they will be electronically receipted and stored at ambient temperature until they are shipped monthly to the central NCS repository (see Part 5 for biospecimen shipping procedures).

Hair specimens will be stored in their original collection bag, inside a larger ambient plastic storage bag together with hair specimens collected from other study participants. The plastic storage bag used to store the specimens then will be used to ship the specimens.

Receipt and storage data will be documented using the Biological and Environmental Sample Tracking (BEST) system. For detailed BEST user information, please refer to the BEST User's Guide.

5.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to receipt and store hair specimens at the SPSC:

- Laboratory coat
- Gloves
- Ambient Ziplock storage bag, prelabeled
- Computer with bar code scanner.

The following form is required to receipt and store hair specimens:

- Completed Biospecimen Transmittal Form.

Receipt and storage data will be documented in BEST. If BEST is not available, then the appropriate hard copy backup Biospecimen Receipt Form must be used to document receipt and storage data (see the appendices in Chapter 3 of Part 1 for forms and field-by-field instructions). In this case, because a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store each specimen. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST. Instructions for entering data from backup receipt forms into BEST can be found in the document *Guide to BEST Data Entry from Backup Biospecimen Forms* (located on the NCS Collaboration Portal).

5.2 Procedures for Receipt and Storage of Hair Specimens

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following basic procedures are for the receipt and storage of hair specimens. Refer to the BEST User's Guide for detailed instructions on how to complete the biospecimen receipt and storage process using BEST.

1. Put on a lab coat and gloves.
2. Log in to BEST.
3. If you have not already done so, wand the subject bar code label on the Biospecimen Transmittal Form by using the bar code scanner. Once you have accessed and confirmed the correct assignment, follow the steps outlined in the BEST User's Guide to complete the following activities in BEST:
   - Record and update visit parameters
   - Check out storage units
   - Receipt specimens
   - Assign specimens to specific storage units
4. Remove the plastic specimen collection bag containing the hair specimen from the insulated transport bag. Do not remove the specimen from the plastic collection bag.

5. After the hair specimen has been receipted in BEST, place the specimen collection bag containing the hair specimen in the assigned Ziplock storage bag and seal the bag.

6. Keep the storage bag at ambient temperature until the shipment to the repository is prepared. For shipping procedures for ambient specimens, see Chapter 4 of Part 5 of this volume.

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Toenail Receipt and Storage Procedures

This chapter describes the procedures for receipt and storage of toenail specimens at the Specimen Processing and Shipping Center (SPSC). Toenail specimens will be transported at ambient temperature to the SPSC, where they will be electronically receipted and stored at ambient temperature until they are shipped monthly to the central NCS repository (see Part 5 of this volume for biospecimen shipping procedures).

Toenail specimens will be stored in their original collection bag, inside a larger ambient plastic storage bag together with toenail specimens collected from other study participants. The plastic bag used to store the specimens then will be used to ship the specimens.

Receipt and storage data will be documented using the Biological and Environmental Sample Tracking (BEST) system. For detailed BEST user information, please refer to the BEST User's Guide.

6.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to receipt and store toenail specimens at the SPSC:

- Laboratory coat
- Gloves
- Ambient Ziplock storage bag, prelabeled
- Computer with bar code scanner.

The following form is required to receipt and store hair specimens:

- Completed Biospecimen Transmittal Form

Receipt and storage data will be documented in BEST. If BEST is not available, then the appropriate hard copy backup Non-Blood Biospecimen Receipt Form must be used to document receipt and storage data (see Appendices 1-A and 1-B for form and field-by-field instructions). In this case, because a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store each specimen. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST. Instructions for entering data from backup receipt forms into BEST can be found in the document *Guide to BEST Data Entry from Backup Biospecimen Forms* (located on the NCS Collaboration Portal).

6.2 Procedures for Receipt and Storage of Toenail Specimens

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following basic procedures are for the receipt and storage of toenail specimens. Refer to the BEST User's Guide for detailed instructions on how to complete the biospecimen receipt and storage process using BEST.

1. Put on a lab coat and gloves.
2. Log in to BEST.
3. If you have not already done so, wand the subject bar code label on the Biospecimen Transmittal Form by using the bar code scanner. Once you have accessed and confirmed the correct assignment, follow the steps outlined in the BEST User's Guide to complete the following activities in BEST:
   - Record and update visit parameters
   - Check out storage units
   - Receipt specimens
   - Assign specimens to specific storage units.
4. Remove the plastic specimen collection bag containing the toenail specimen from the insulated transport bag. Do not remove the specimen from the plastic collection bag.

5. After the toenail specimen has been receipted in BEST, place the specimen collection bag containing the toenail specimen in the assigned Ziplock storage bag and seal the bag.

6. Keep the storage bag at ambient temperature until the shipment to the repository is prepared. For shipping procedures for ambient specimens, see Chapter 4 of Part 5 of this volume.

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Cord Blood Receipt and Storage Procedures

7.1 Cord Blood

This section describes the procedures for receipt and storage of cord blood specimens at the Specimen Processing and Shipping Center (SPSC).

Cord blood specimens will be transported at refrigerated temperature to the SPSC, where they will be electronically receipted and stored at 2–8 °C until they are shipped in the next daily overnight shipment to the central National Children's Study (NCS) repository (see Part 5 of this volume for biospecimen shipping procedures). Each cord blood collection bag will be stored within a pressure bag, which then will be used to ship the specimen.

Receipt and storage data will be documented using the Biological and Environmental Sample Tracking system (BEST). For detailed BEST user information, please refer to the BEST User's Guide.

7.1.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to receipt and store cord blood specimens at the SPSC:

- Laboratory coat
- Gloves
- Small pressure bag, prelabeled
- Computer with bar code scanner.

The following form is required to receipt and store cord blood specimens:

- Completed Biospecimen Transmittal Form- Birth Specimens.

Receipt and storage data will be documented in BEST. If BEST is not available, then the hard copy, backup Birth Biospecimen Receipt Form must be used to document receipt and storage data (see Appendices 1-C and 1-D of this part and volume for form and field-by-field instructions). In this case, when a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store each cord blood collection bag. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST. Instructions for entering data from backup receipt forms into BEST can be found in the document *Guide to BEST Data Entry from Backup Biospecimen Forms* (located on the NCS Collaboration Portal).

7.1.2 Procedures for Receipt and Storage of Cord Blood Specimens

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following basic procedures are for the receipt and storage of cord blood specimens. Refer to the BEST User's Guide for detailed instructions on how to complete the biospecimen receipt and storage process using BEST.

If the cord blood bag or biohazard transport bag is labeled with the mother's or child's name, remove any information that can personally identify a study participant before you store the specimen and ship it to the NCS repository. Specimens should be labeled with only the specimen identification number (ID) label from the collection kit and should never identify a participant by name.

1. Put on a lab coat and gloves.
2. Log in to BEST.
3. If you have not already done so, wand the child subject label on the Biospecimen Transmittal Form- Birth Specimens by using the bar code scanner. Once you have accessed and confirmed the correct assignment, follow the steps outlined in the BEST User's Guide to complete the following activities in BEST:
   - Record and update visit parameters
   - Check out storage units

- Receipt specimens
- Assign specimens to specific storage units.

4. Remove the biohazard transport bag containing the cord blood collection bag from the biospecimen transport cooler. Do not remove the cord blood collection bag from the plastic biohazard transport bag.

5. After the cord blood specimen has been receipted in BEST, place the cord blood bag in the assigned pressure bag, keeping the bag within the biohazard transport bag. Do not seal the pressure bag until the time the shipment is prepared.

6. Store the pressure bag in the refrigerator.

7. The pressure bag should be refrigerated until the shipment to the repository is prepared. For shipping procedures for refrigerated specimens, see Chapter 2 of Part 5 in this volume.

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Placenta and Umbilical Cord Receipt and Storage Procedures

8.1 Placenta and Umbilical Cord

This section describes the procedures for receipt and storage of placenta and umbilical cord specimens at the Specimen Processing and Shipping Center (SPSC). Throughout this chapter, the term *placenta* is used to refer to the placenta, the placental membrane, and umbilical cord.

Fresh placenta specimens will be transported at refrigerated temperature to the SPSC, where they will be electronically receipted and stored at 2–8 °C until they are shipped in the next daily overnight shipment to the central National Children's Study (NCS) histology laboratory (see Part 5 of this volume for biospecimen shipping procedures). Fixed placenta specimens will be transported at ambient temperature to the SPSC, where they will be electronically receipted and stored at ambient temperature until they are shipped in the next weekly shipment to the central NCS histology laboratory. Each double-bagged placenta specimen will be stored within a pressure bag, which then will be used to ship the specimen. Once specimens arrive at the central NCS histology laboratory they will be photographed, weighed, measured, fixed, and sectioned; paraffin blocks and slides will be stored at the NCS repository.

Receipt and storage data will be documented using the Biological and Environmental Sample Tracking system (BEST). For detailed BEST user information, please refer to the BEST User's Guide.

8.1.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to receipt and store placenta specimens at the SPSC:

- Laboratory coat
- Gloves

- Goggles or face shield (optional)
- Large pressure bag, prelabeled
- Small pressure bag, prelabeled (if partial tissue)
- Extra 12” x 12” resealable formalin resistant polyethylene bags (secondary bags)
- Extra 250 mL absorbent pads (fresh specimens) or 80 mL formalin-resistant absorbent pads (fixed specimens)
- 10 percent bleach solution
- Chux pads
- Paper towels
- Biohazard waste container
- Computer with bar code scanner.

The following form is required to receipt and store placenta specimens:

- Completed Biospecimen Transmittal Form–Birth Specimens.

Receipt and storage data will be documented in BEST. If BEST is not available, the hard copy backup Birth Biospecimen Receipt Form must be used to document receipt and storage data (see Appendices 1-C and 1-D in this part and volume for form and field-by-field instructions). In this case, when a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store the specimen. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST. Instructions for entering data from backup receipt forms into BEST can be found in the document *Guide to BEST Data Entry from Backup Biospecimen Forms* (located on the NCS Collaboration Portal).

If the primary or secondary polyethylene bag is labeled with the mother’s or child’s name, remove any information that can personally identify a study participant before you store the specimen and ship it to the NCS histology laboratory. Specimens should be labeled with only the specimen identification number (ID) label from the collection kit and should never identify a participant by name.

8.1.2 Procedures for Receipt and Storage of Placenta Specimens

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following basic procedures are for the receipt and storage of fresh and fixed placenta specimens. Refer to the BEST User's Guide for detailed instructions on how to complete the biospecimen receipt and storage process using BEST.

1. Put on a lab coat, gloves, and goggles or a face shield, if needed.
2. Log in to BEST.
3. If you have not already done so, wand the mother's subject label on the Biospecimen Transmittal Form–Birth Specimens by using the bar code scanner. Once you have accessed and confirmed the correct assignment, follow the steps outlined in the BEST User's Guide to complete the following activities in BEST:
   - Record and update visit parameters
   - Check out storage units
   - Receipt specimens
   - Assign specimens to specific storage units.
4. Cover the workspace with Chux pads.
5. Remove the double-bagged specimen from the biospecimen transport cooler, being careful not to disturb the tissue and to keep the placenta as flat as possible. The specimen should be enclosed by two sealed formalin resistant polyethylene bags.
6. Place the double-bagged specimen on top of the Chux pads.
7. Gently press the primary bag to check for a complete seal. With the primary bag completely sealed, gently maneuver the placenta and umbilical cord to get it to lie flat with no curved edges. Gently press the secondary bag to check for a complete seal. With the secondary bag completely sealed, reposition the placental tissue in the bag to smooth out curves or wrinkles.
8. Ensure no leaks are present in either the primary or secondary bag. If a leak is present, place the double-bagged placenta inside another 12" x 12" polyethylene bag. *Never remove the placenta from the primary and secondary bags.*
9. If an absorbent pad is not present inside the secondary bag or if the existing pad is soiled, place a new 250 mL absorbent pad inside the bag.

10. After the placenta specimen has been receipted in BEST, carefully place the double- or triple-bagged specimen inside the assigned pressure bag.

11. For fixed specimens, place a formalin resistant absorbent pad inside the pressure bag.

12. Do not seal the pressure bag until the time the shipment is prepared.

13. For *fresh* placenta specimens:

    – Store the pressure bag in the refrigerator.

    – The pressure bag should be refrigerated until the shipment to the NCS histology laboratory is prepared. If the shipment is scheduled to be picked up within 2 hours, the shipment may be prepared immediately after receipting the specimen. For shipping procedures for refrigerated placenta specimens, see Chapter 2 of Part 5 in this volume.

14. For *fixed* placenta specimens:

    – Store the pressure bag at ambient temperature.

    – The pressure bag should be kept at ambient temperature until the shipment to the NCS histology laboratory is prepared. For shipping procedures for ambient placenta specimens, see Chapter 4 of Part 5 in this volume.

15. Clean all surface areas thoroughly with 10 percent bleach solution and put used paper towels, Chux pads, and other contaminated materials in the biohazard waste container.

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Infant Blood Spot Card Receipt and Storage Procedures

9.1 Infant Blood Spot Cards

This section describes the procedures for receipt and storage of infant blood spot cards at the Specimen Processing and Shipping Center (SPSC).

Infant blood spot cards will be transported ambient to the SPSC, where they will be electronically receipted and stored until they are shipped to the central National Children's Study (NCS) repository (see Part 5 of this volume for biospecimen shipping procedures). Flinders Technological Associates (FTA®) Mini blood spot cards will be stored at ambient temperature and will be shipped monthly to the central NCS repository. Protein Saver blood spot cards will be stored at -30 °C and will be shipped weekly to the central NCS repository.

Receipt and storage data will be documented using the Biological and Environmental Sample Tracking system (BEST). For detailed BEST user information, please refer to the BEST User's Guide.

9.1.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to receipt and store infant blood spot cards at the SPSC:

- Laboratory coat
- Powder-free gloves
- Multi-barrier pouch, prelabeled (for FTA Mini cards)
- Ziplock storage bag, prelabeled (for Protein Saver cards)
- Desiccant packs

- Computer with bar code scanner.

The following form is required to receipt and store infant blood spot cards:

- Completed Biospecimen Transmittal Form–Birth Specimens.

Receipt and storage data will be documented in BEST. If BEST is not available, then the hard copy backup Birth Biospecimen Receipt Form must be used to document receipt and storage data (see Appendices 1-C and 1-D in this part and volume for form and field-by-field instructions). In this case, when a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store each blood spot card. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST. Instructions for entering data from backup receipt forms into BEST can be found in the document *Guide to BEST Data Entry from Backup Biospecimen Forms* (located on the NCS Collaboration Portal).

9.1.2 Procedures for Receipt and Storage of Infant Blood Spot Cards

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following basic procedures are for the receipt and storage of infant blood spot cards. Refer to the BEST User's Guide for detailed instructions on how to complete the biospecimen receipt and storage process using BEST.

If an infant blood spot card is labeled with the mother's or child's name, remove any information that can personally identify a study participant before you store the specimen and ship it to the NCS repository. Specimens should be labeled with only the specimen identification number (ID) label from the collection kit and should never identify a participant by name.

1. Put on a lab coat and gloves. Always wear powder-free gloves when handling blood spot cards.
2. Log in to BEST.

3. If you have not already done so, wand the child subject label on the Biospecimen Transmittal Form–Birth Specimens by using the bar code scanner. Once you have accessed and confirmed the correct assignment, follow the steps outlined in the BEST User's Guide to complete the following activities in BEST:

   – Record and update visit parameters

   – Check out storage units

   – Receipt specimens

   – Assign specimens to specific storage units

4. Remove the blood spot cards from the insulated transport bag or from the envelope if mailed from a hospital.

5. After the FTA Mini card has been receipted in BEST:

   – Place the FTA Mini card inside the assigned multi-barrier pouch.

   – Ensure there is a desiccant pack inside the pouch.

   – Store the pouch at ambient temperature until the next ambient monthly shipment to the repository is prepared. For shipping procedures for ambient specimens, see Chapter 4 of Part 5 in this volume.

6. After the Protein Saver card has been receipted in BEST:

   – Place the Protein Saver card inside the assigned Ziplock storage bag.

   – Ensure there is a desiccant pack inside the bag and seal the bag.

   – Place the storage bag in the -30 °C freezer.

   – The storage bag should remain frozen until the shipment to the repository is prepared. For shipping procedures for frozen specimens, see Chapter 3 of Part 5 in this volume.

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Meconium Receipt and Storage Procedures

10.1 Meconium

This section describes the procedures for receipt and storage of meconium specimens at the Specimen Processing and Shipping Center (SPSC).

Meconium specimens will be transported at refrigerated temperature to the SPSC. Specimens may arrive at the SPSC in one of two ways, depending on if the meconium was transferred from the diapers to the collection vial at the birthing site. The SPSC may receive either (1) up to five diapers containing meconium or (2) a meconium collection vial. If meconium diapers are received at the SPSC, the meconium must be transferred to the collection vial prior to receipt in the Biological and Environmental Sample Tracking system (BEST). Only the collection vial will be electronically receipted and stored at -30° C until being shipped weekly to the central National Children's Study (NCS) repository (see Part 5 of this volume for biospecimen shipping procedures). Each meconium specimen will be stored in a pressure bag together with a frozen 3mL lavender blood tube collected from the mother. The pressure bag used to store the specimens in the freezer then will be used to ship the specimens.

Receipt and storage data will be documented using BEST. For detailed BEST user information, please refer to the BEST User's Guide.

10.1.1 Equipment, Supplies, and Forms

The following equipment and supplies are needed to receipt and store meconium specimens at the SPSC:

- Laboratory coat
- Gloves
- Wooden tongue depressors

- Extra plastic biohazard transport bags (for collection vial)
- 10 percent bleach solution
- Paper towels
- Biohazard waste container
- Small pressure bag, prelabeled
- Computer with bar code scanner.

The following form is required to receipt and store meconium specimens:

- Completed Biospecimen Transmittal Form–Birth Specimens.

Receipt and storage data will be documented in BEST. If BEST is not available, then the hard copy backup Birth Biospecimen Receipt Form must be used to document receipt and storage data (see Appendices 1-C and 1-D in this part and volume for form and field-by-field instructions). In this case, when a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store the vial. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST. Instructions for entering data from backup receipt forms into BEST can be found in the document *Guide to BEST Data Entry from Backup Biospecimen Forms* (located on the NCS Collaboration Portal).

10.1.2 Procedures for Receipt and Storage of Meconium Specimens

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following basic procedures are for the receipt and storage of meconium specimens. Refer to the BEST User's Guide for detailed instructions on how to complete the biospecimen receipt and storage process using BEST.

If the meconium vial is labeled with the mother's or child's name, remove any information that can personally identify a study participant before you store the specimen and ship it to the NCS repository. Specimens should only be labeled with the specimen identification number (ID) label from the collection kit and should never identify a participant by name.

1. Put on a lab coat and gloves.

2. Log in to BEST.

3. If you have not already done so, wand the child subject label on the Biospecimen Transmittal Form–Birth Specimens by using the bar code scanner. Once you have accessed and confirmed the correct assignment, follow the steps outlined in the BEST User's Guide to complete the following activities in BEST:

   – Record and update visit parameters

   – Check out storage units

   – Receipt specimens

   – Assign specimens to specific storage units.

4. Remove the meconium diapers or the biohazard bag containing the meconium vial from the biospecimen transport cooler. If a vial was collected, do not remove the vial from the plastic biohazard transport bag. If diapers were collected, the empty prelabeled Para-pak vial from the collection kit should have been picked up by the data collector from the birthing site.

5. If meconium diapers are received, transfer the meconium from the diapers to the prelabeled Para-pak collection vial as follows:

   – Confirm that the kit ID on the meconium vial matches the kit ID (DC label) on the transmittal form.

   – Use the wood tongue depressors or the scoop attached to the collection vial to scrape the meconium from the diapers to the collection vial up to the fill line indicated on the vial (about two-thirds full). Do not transfer any more meconium than is necessary to fill the vial to the fill line.

   – Dispose of the wooden tongue depressors and diapers in the biohazard waste container.

   – Place the meconium collection vial into a biohazard transport bag and seal the bag.

   – Clean all surface areas thoroughly with 10 percent bleach solution and put used paper towels and other contaminated materials in the biohazard waste container.

6. After the meconium specimen has been receipted in BEST, place the meconium specimen in the assigned pressure bag, keeping the vial in the biohazard transport bag. Do not seal the pressure bag until the time the shipment is prepared.

7. Store the pressure bag in the freezer storage bin. If the pressure bag contains a frozen blood tube, the pressure bag should be stored *on its side*.

8. For storage units with blood tubes, the pressure bag should be stored on its side until the 3mL lavender tube is frozen to reduce the possibility of tube breakage. Once the 3mL lavender tube is frozen, the pressure bag may be placed in an upright position and should be kept frozen until the shipment to the repository is prepared. For shipping procedures for frozen specimens, see Chapter 3 of Part 5 in this volume.

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Breast Milk and Infant Formula Receipt and Storage Procedures

11.1 Breast Milk and Infant Formula

This chapter describes the procedures for receipt and storage of breast milk and infant formula samples at the Specimen Processing and Shipping Center (SPSC).

Breast milk and infant formula samples will be transported on dry ice to the SPSC, where they will be electronically receipted and stored at -30° C until they are shipped weekly to the central National Children's Study (NCS) repository (see Part 5 of this volume for biospecimen shipping procedures). Each breast milk or formula sample will be stored in a pressure bag and may be stored together with breast milk or formula samples from other participants. The pressure bag used to store the samples in the freezer will then be used to ship the samples.

Receipt and storage data will be documented using the Biological and Environmental Sample Tracking system (BEST). For detailed BEST user information, please refer to the BEST User's Guide.

11.1.1 Equipment, Supplies, and Forms

The following equipment and supplies are needed to receipt and store breast milk and infant formula samples at the SPSC:

- Laboratory coat
- Gloves
- Small pressure bag, prelabeled
- Computer with bar code scanner.

The following form is required to receipt and store breast milk and infant formula samples:

- Completed Biospecimen Transmittal Form.

Receipt and storage data will be documented in BEST. If BEST is not available, then the hard copy backup Biospecimen Receipt Form must be used to document receipt and storage data (see the appendices in Chapter 3 of Part 1 for forms and field-by-field instructions). In this case, when a storage unit assignment cannot be made by BEST, an available prelabeled storage unit should be selected to store the sample. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST. Instructions for entering data from backup receipt forms into BEST can be found in the document *Guide to BEST Data Entry from Backup Biospecimen Forms* (located on the NCS Collaboration Portal).

11.1.2 Procedures for Receipt and Storage of Breast Milk and Infant Formula

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following basic procedures are for the receipt and storage of breast milk and infant formula samples. Refer to the BEST User's Guide for detailed instructions on how to complete the biospecimen receipt and storage procedures using BEST.

1. Put on a lab coat and gloves.
2. Log in to BEST.
3. If you have not already done so, wand the mother's subject label on the Biospecimen Transmittal Form by using the bar code scanner. Once you have accessed and confirmed the correct assignment, follow the steps outlined in the BEST User's Guide to complete the following activities in BEST:
   - Record and update visit parameters
   - Check out storage units
   - Receipt specimens

– Assign specimens to specific storage units.

4. Be sure to wear the dry ice glove when removing the biohazard bag containing the breast milk or infant formula sample from the dry ice chamber of the biospecimen transport cooler.

5. After the sample has been receipted in BEST, place the sample in the assigned pressure bag, keeping the collection container in the biohazard transport bag. Do not seal the pressure bag until the time the shipment is prepared.

6. Store the pressure bag in the freezer storage bin.

7. The pressure bag should be kept frozen and unsealed until the shipment to the repository is prepared. For shipping procedures for frozen specimens, see Chapter 3 of Part 5 in this volume.

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Part 3

Addendum 3-A

Group 2 Version of
Chapter 2, Part 3
Urine Receipt and Storage Procedures

Updated Chapter

—Part 3—
Chapter
2

Urine Receipt and Storage Procedures

2.1 Adult and Infant Urine

This section describes the procedures for receipt and storage of adult and infant urine specimens at the Specimen Processing and Shipping Center (SPSC).

Urine specimens will be transported to the SPSC, where they will be electronically receipted and stored at -30° C until they are shipped weekly to the central NCS repository (see Part 5 of this volume for biospecimen shipping procedures). With the exception of pregnancy urine and infant urine specimens, each urine specimen will be stored in a pressure bag together with frozen vaginal swabs (for mother visits) and frozen blood specimens collected from the same study participant at one study visit (i.e., the Frozen Mixed storage unit). Pregnancy urine and infant urine specimens will be stored together in the Frozen Urine storage unit and up to two specimens may be stored in the same storage unit. The pressure bags used to store specimens in the freezer then will be used to ship the specimens.

Adult urine receipt and storage procedures are the same for all study events with the exception of the T3 mother study event (for Group 2 Vanguard Centers only). For the T3 mother study event, a different version of the adult urine collection kit is used to collect the urine (the Adult Urine 2 Cup Collection Kit). Urine is transferred to a second collection container at the time of collection so that one collection container is transported frozen and the other at refrigerated temperature to the SPSC. The refrigerated urine specimen will be aliquoted and combined with a preservative before being stored frozen at the SPSC. Receipt, processing, and storage procedures are described separately for the T3 study event in the sections that follow.

Receipt and storage data will be documented using the Biological and Environmental Sample Tracking system (BEST). For detailed BEST user information, please refer to the BEST User's Guide.

2.1.1 Equipment, Supplies, and Forms

2.1.1.1 P1 Mother, T1 Mother, T1 Father, 6 Month

The following equipment and supplies are required to receipt and store urine specimens at the SPSC that were collected at the P1 mother, T1 mother, T1 father, and 6-Month data collection activities, including pregnancy urine and infant urine specimens:

- Laboratory coat
- Gloves
- Dry ice glove
- Small pressure bag, prelabeled
- Computer with bar code scanner.

The following form is required to receipt and store urine specimens:

- Completed Biospecimen Transmittal Form.

Receipt and storage data will be documented in BEST. If BEST is not available, then the appropriate hard copy backup Biospecimen Receipt Form must be used to document receipt and storage data (see the appendices at the end of this chapter for forms and field-by-field instructions for each study event). In this case, because a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store each specimen. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST. Instructions for entering data from backup receipt forms into BEST can be found in the document *Guide to BEST Data Entry from Backup Biospecimen Forms* (located on the NCS Collaboration Portal).

2.1.1.2 T3 Mother (Group 2 Vanguard Centers only)

The following equipment and supplies are required to receipt, process, and store urine specimens at the SPSC for the T3 mother data collection visit only:

- Laboratory coat

- Gloves
- Face shield or goggles
- Dry ice glove
- 2-mL vial, prescreened (for aliquot 4266)
- 2-mL vial, prescreened, prefilled with 20µL sulfamic acid preservative (for aliquot 4265; see Appendix 2-A for the Material Safety Data Sheet)
- Sterile disposable plastic transfer pipettes, prescreened
- Small pressure bag, prelabeled
- Computer with bar code scanner.

Note that the 2-mL vials provided by NCS for aliquoting and storing the urine are prescreened for specific contaminants. Study Centers must use the vials provided by NCS and may not substitute these supplies.

The following form is required to receipt and store urine specimens:

- Completed Biospecimen Transmittal Form.

Receipt and storage data will be documented in BEST. If BEST is not available, then the appropriate hard copy backup Non-Blood Biospecimen Receipt Form must be used to document receipt and storage data (see Appendices 1-A and 1-B in Part 3 for form and field-by-field instructions for each study event). In this case, because a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store each specimen. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST.

2.1.2 Procedures for Receipt and Storage of Adult and Infant Urine Specimens

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

2.1.2.1 P1 Mother, T1 Mother, T1 Father, 6 Month

The following basic procedures are for the receipt and storage of urine specimens collected at the P1 mother, T1 mother, T1 father, and 6-Month data collection activities, including pregnancy urine and infant urine specimens. Refer to the BEST User's Guide for detailed instructions on how to complete the biospecimen receipt and storage process using BEST.

1. Put on a lab coat and gloves.
2. Log in to BEST.
3. If you have not already done so, wand in the subject label on the Biospecimen Transmittal Form by using the bar code scanner. Once you have accessed and confirmed the correct assignment, follow the steps outlined in the BEST User's Guide to complete the following activities in BEST:
    - Record and update visit parameters
    - Check out storage units
    - Receipt specimens
    - Assign specimens to specific storage units.
4. Be sure to wear the dry ice gloves when removing the urine collection container from the dry ice chamber of the biospecimen transport cooler.
5. After the urine specimen has been receipted in BEST, place the urine specimen in the assigned pressure bag, keeping the container within the biohazard transport bag. Do not seal the pressure bag until the time the shipment is prepared.
6. Store the pressure bag in the freezer storage bin. If the pressure bag contains a frozen blood tube (i.e., a Frozen Mixed storage unit), the pressure bag should be stored *on its side*.
7. For storage units with blood tubes, the pressure bag should be stored on its side until the 3-ml lavender tube or PAXgene tube is frozen to reduce the possibility of tube breakage. Once the blood tube is frozen, the pressure bag may be placed in an upright position and should be kept frozen until the shipment to the repository is prepared. For shipping procedures for frozen specimens, see Chapter 3 of Part 5 in this volume.

2.1.2.2 T3 Mother (Group 2 Vanguard Centers Only)

The following procedures are for the receipt, processing, and storage of adult urine specimens for the T3 mother data collection visit only. Refer to the BEST User's Guide for more detailed instructions on how to use BEST to implement these procedures.

1. Put on a lab coat, gloves, and face shield or goggles.

2. Log into BEST.

3. If you have not already done so, wand in the subject label on the Biospecimen Transmittal Form by using the bar code scanner. Once you have accessed and confirmed the correct assignment, record the visit parameters in BEST and update any parameters if needed.

4. Remove the UR03 urine collection container from the refrigerated chamber of the biospecimen transport cooler and remove the container from the biohazard transport bag.

5. Wand in the bar code label on the UR03 urine collection container to record the date and time of receipt at the SPSC.

6. Record any problems observed with the specimen upon receipt by clicking the "⊕" next to the item and entering a comment.

7. Remove the adhesive labels from the biohazard transport bag and confirm that the kit identification number (ID) on the aliquot labels matches the kit ID on the UR03 urine collection container. If the aliquot labels are not available, manually label the aliquot vials with the appropriate item ID. The item ID consists of the nine-digit kit ID and the four-digit extension (e.g., 4265).

8. Label the empty 2-mL vial using the adhesive label from the kit that has the extension 4266. Aliquot 4266 does not require any preservative. *Be sure to use the empty 2-mL vial when preparing this aliquot.*

9. Label the 2-mL vial that is prefilled with 20µl sulfamic acid preservative using the adhesive label from the kit that has the extension 4265. Aliquot 4265 requires the preservative. *Be sure to use the 2-mL vial that contains the preservative when preparing this aliquot.*

10. Using a sterile prescreened transfer pipette, aliquot 2 mL of urine from the UR03 urine collection container into the empty vial labeled with the 4266 extension. Fill the vial to the fill line indicated on the vial and screw the cap on the vial tightly. *Be sure to use the empty 2-mL vial when preparing this aliquot.*

11. With the same transfer pipette, aliquot 2 mL of urine from the UR03 urine collection container into the vial that is prefilled with 20µl sulfamic acid preservative and is labeled with the 4265 extension. Fill the vial to the fill line indicated on the vial and screw the cap on the vial tightly. *Be sure to use the 2-mL vial that contains the preservative when preparing this aliquot.*

12. Place the two aliquot vials in the biohazard transport bag with the absorbent pad and seal the bag.

13. Put on the dry ice glove and remove the UR02 urine collection container from the dry ice chamber of the biospecimen transport cooler.

14. Wand in the bar code labels on the UR02 urine collection container, the 4265 aliquot vial, and the 4266 aliquot vial. This action automatically records the storage time. Do not remove the containers from the plastic biohazard transport bags.

15. Record any problems observed with the UR02 specimen or the aliquots by clicking the "⊕" next to the item and entering a comment.

16. BEST will assign a specific storage unit (i.e., pressure bag) to store the urine specimens, given that there are available storage units that have been prelabeled and created in BEST. If no storage unit is available, follow the instructions in the BEST User's Guide to create a new storage unit. Retrieve the pressure bag designated by BEST.

17. Place the urine specimens in the assigned pressure bag, keeping the containers within the biohazard transport bags. Do not seal the pressure bag until the time the shipment is prepared.

18. Store the pressure bag *on its side* in the freezer storage bin. Confirm the master storage unit location (i.e., upper or lower freezer compartment) in BEST. If the location is not accurate, update the storage location information.

19. The pressure bag should be stored on its side until the PAXgene tube is frozen to reduce the possibility of tube breakage. Once the blood tube is frozen, the pressure bag may be placed in an upright position and should be kept frozen until the shipment to the repository is prepared. For shipping procedures for frozen specimens, see Chapter 3 of Part 5 in this volume.

20. Dispose the empty UR03 urine collection container and any used transfer pipettes in the biohazard waste container and clean the work area.

Part 3

Appendix 2-A

Material Safety Data Sheet (MSDS) for Sulfamic Acid

Appendix 2-A.
Material Safety Data Sheet (MSDS) for Sulfamic Acid

CCI
COLUMBUS CHEMICAL INDUSTRIES INC.
P.O. BOX 8
COLUMBUS, WISCONSIN 53925-0008
(920) 623-2140
FAX (920) 623-2577

Material Safety Data Sheet
May be used to comply with OSHA's Hazard Communication Standard, 29 CFR 1910 1200. Standard must be consulted for specific requirements

U.S. Department of Labor
Occupational Safety and Health Administration
(Non-Mandatory Form)
Form Approved
OMB No. 1218-0072

IDENTITY *(as Used on Label and List)*
Sulfamic Acid

Note: *Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.*

Section I

Manufacturers /Distributor Address Number Street City State and Zip Code
Columbus Chemical Industries
N4335 Temkin Road
Columbus, Wisconsin 53925

Emergency Telephone Number
CHEMTREC 1 (800) 424-9300
Telephone Number for Information
1-920-623-2140
Date Prepared
04-27-2006
Signature of Preparer (optional)

Section II - Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	CAS #	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Sulfamic Acid	5329-14-6	Not Available	Not Available	Not Available	

*SYNONYMS: Amidosulfamic acid; Amidosulfonic acid; Aminosulfonic acid.

Section III - Physical/Chemical Characteristics

Boiling Point	Decomposes	Specific Gravity (H_2O = 1) @ 20 °C/68 °F	2.15
Vapor Pressure (mm Hg)	Not Available	Melting Point Decomposes @	200 °C (399 °F)
Vapor Density (AIR = 1)	Not Available	Evaporation Rate (Butyl Acetate = 1)	Not Available

Solubility in Water
22 g / 100 g @ 20 °C (68 °F); pH of 1% aqueous solution = 1.18
Appearance and Odor
Odorless, white, crystalline solid.

Section IV Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
Not flammable.		Not Applicable	Not Applicable

Extinguishing Media
Water spray, chemical foam or carbon dioxide.
Special Fire Fighting Procedures
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin or eyes. Use water spray to keep fire-exposed containers cool.
Unusual Fire and Explosion Hazards
Release of toxic gases under fire conditions. Aqueous solutions of sulfamic acid are strongly acidic.

Appendix 2-A.
Material Safety Data Sheet (MSDS) for Sulfamic Acid (continued)

Section V Reactivity Data

Stability	Unstable			Conditions to Avoid	Strong oxidizing reagents, metals,
	Stable	X			silver metal, excessive heat.

Incompatibility Materials to Avoid
Chlorine, hypochlorous acid, hypochlorites, cyanides, nitric acid, sulfides, fuming nitric acid.

Hazardous Decomposition or Byproducts
Sulfur dioxide, sulfur trioxide, ammonia.

Hazardous Polymerization			Conditions to Avoid
	May Occur		
	Will Not Occur		Not listed

Section VI Health Hazard Data

Routes of Entry	Inhalation ?	Skin ?	Ingestion ?
	Yes	Yes	Yes

Health Hazards *(Acute and Chronic)*
Irritating to the skin, eyes, mucous membranes and upper respiratory tract. SENSITIZER! Can cause blindness upon eye contact. May be harmful if swallowed. Inhalation may result in inflammation and edema of the larynx and bronchi. Repeated or prolonged inhalation of dust can produce respiratory irritation, lung damage, and chronic respiratory irritation.

Carcinogenicity	NTP	IARC Monographs	OSHA REGULATED?
	Not listed	Not listed	Not listed

Signs and Symtoms of Exposure.
Burning sensation, itchiness, redness, sneezing, coughing, wheezing, laryngitis, shortness of breath, headache, nausea, vomiting, choking, blisters, tissue destruction, bloody diarrhea, edema, bronchitis, unconsciousness, death.

Medical Conditions Generally Aggravated by Exposure Asthma, emphysema, other respiratory diseases.

Emergency and First Aid Procedures EYES/SKIN: Flush immediately with plenty of water for at least 15 minutes. Remove contaminated clothing. Remove contact lenses if possible. Call physician. INGESTION: Do not induce vomiting. Loosen tight clothing. If not breathing, give mouth-to-mouth resuscitation. Get medical attention. INHALATION: Move to fresh air. Give oxygen if breathing is difficult, artificial respiration if not breathing. Seek medical attention.

Section VII Precautions for Safe Handling and Use

Steps to be Taken in Case Material is Released or Spilled Evacuate unprotected personnel from area. Eliminate all ignition sources. Wear self-contained breathing apparatus rubber boots, heavy protective gloves and chemical safety goggles. Pick up and carefully place material into clean, dry container; cover and remove from area. Flush spill area with water.

Waste Disposal Method Dispose of material in accordance with all Federal, state, and local regulations.

Precautions to be Taken in Handling and Storing Do not get in eyes or on skin or clothing. Do not taste or swallow. Avoid breathing dust. Use only with adequate ventilation. Wash thoroughly after handling. Store in a cool, dry area. Keep container tightly closed. Do not store with cyanides, sulfides, chlorine, hypochlorous acid or hypochlorites.

Other Precautions Containers, even when empty, will retain residue. Always obey hazard warnings and handle empty containers as if they were full.

Section VII Control Measures

Respiratory Protection *(Specify Type)* NIOSH/MSHA-approved respirator with dust/mist cartridge.

Ventilation — **Local Exhaust** Required. **Special** Safety shower nearby.
Mechanical *(General)* Recommended. **Other** Eyewash station nearby.

Protective Gloves Chemical-resistant rubber gloves. **Eye Protection** Chemical Safety Goggles.

Other Protective Clothing or Equipment Boots; protective clothing; full-face respirator, if needed.

Work /Hygienic Practices Do **NOT** wear contact lenses. Wear appropriate personal protective equipment. Wash thoroughly after handling. Avoid breathing dust. Avoid contact with eyes, skin and clothing. Use only with adequate ventilation. Avoid prolonged or repeated exposure. SENSITIZER.