National Institute of Environmental Health Sciences

SOCIAL & SCIENTIFIC SYSTEMS, INC.
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Specimen Cold Chain SOP - Processing, Transportation & Storage Temperatures

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Process Owner Approval:	**Title:**	**Signature:**	**Date:**
Functional Area Approval:	**Title:**	**Signature:**	**Date:**

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the standard storage temperature for samples received in the SSS Core Laboratory as well as documenting our cold chain procedures to minimize temperature variability of the samples in our central processing laboratory.

2. SCOPE AND SAFETY PRECAUTIONS

This SOP applies to all SSS lab staff members who perform tasks related to specimen processing and shipping in the SSS Core Laboratory. Exercise Universal Precautions.

3. SAMPLE STORAGE TEMPERATURES

- Primary Storage – This is the standard and minimum storage temperature required to preserve this sample type.

Specimen Description	Temperature During Transport	Temperature During Processing	Primary Storage Temperature	Optimal Storage Temperature
Serum	+4°C	+4°C	-80°C	LN Vapor Phase
Plasma	+4°C	+4°C	-80°C	LN Vapor Phase
Packed Cell Volume	+4°C	+4°C	-80°C	LN Vapor Phase
Blood Clots	+4°C	+4°C	-80°C	LN Vapor Phase
Blood Cards	Ambient	Ambient	-20°C	-20°C
**Lymphocytes	Dry Ice	Ambient	-80°C	LN Vapor Phase

Whole Blood in Cryovials	Dry Ice	+4°C	-80°C	LN Vapor Phase
Whole Blood in Vacutainers	* Ambient or +4°C	+4°C	-20°C	-20°C
Urine	+4°C	+4°C	-80°C	-80°C
Dust/Dirt	Ambient	Ambient	-20°C	-20°C
Fecal Matter	+4°C	+4°C	-20°C	-20°C
Tissue Blocks	Ambient	Ambient	Ambient	Ambient
Slides	Ambient	Ambient	Ambient	Ambient
Breast Milk	+4°C	+4°C	-80°C	-80°C
Formula	+4°C	+4°C	-80°C	-80°C
Saliva (Oragene)	Ambient	Ambient	Ambient	-20°C
Saliva in Cryovials	+4°C	+4°C	-80°C	-80°C

- Optimal Storage – This is the temperature that will best preserve the viability of a sample if available. This is an optional storage temperature.

* The transport temperature of Vacutainers will vary depending on type of Vacutainer and what it is being used for.
**Whole Blood (e.g., ACD tube) collected for lymphocyte cryopreservation is transported and processed under ambient temperatures. Primary storage at SSS is -80C. Optimal long-term storage is LN Vapor Phase.

4. STORAGE TEMPERATURE DEVIATION PROCEDURE *NEW*

In the event that a storage temperature can't or hasn't been maintained please follow these procedures.

4.1.1 Temperature deviation during shipment

If a shipment temperature has deviated during shipment (i.e. shipment has warmed because all of the dry ice has sublimated due to a delayed shipment) document this discrepancy in the following manner

- Make a note on PHR-OPS-051.01 Shipment Receipt at CPL Form that the shipment arrived warm.
- If the shipment is being entered into a Study Management or Kit Receipt system, note the temperature deviation in the proper field.
- Notify the appropriate BSI personnel that there was a shipment discrepancy so that it can be recorded in BSI.

4.1.2 Temperature deviation due to freezer malfunction

If a freezer malfunction occurs and the temperature rises, move the samples to an alternate freezer and give a list of the affected boxes, and the temperature at the time of the move, to the appropriate BSI personnel so that the deviation can be noted in BSI. See PHR-OPS-001.xx Emergency Preparedness Plan for details.

4.1.3 Temperature deviation due to power outage

If a power outage occurs and the generator does not kick in to restore power to the freezers follow the procedures in PHR-OPS-001.xx Emergency Preparedness Plan. Write down the lowest temperature prior to power restoration or transfer to EPL so that it can be recorded in BSI.

5. USING THE CRYOCAGE TO MAINTAIN TEMPERATURE FOR -80°C SAMPLES ON THE BENCH *NEW*

If you need to work with samples in 5"x5" boxes that have been frozen at -80°C (i.e. sorting or labeling) always follow these steps.

- Place the CryoCage in the middle of an insulated tray.
- Surround the CryoCage with dry ice so that the dry ice is higher than the top of the box with the samples.
- Place the frozen box in the CryoCage and place dry ice in the top of the box so that it does not warm.
- If you are working with frozen straws use the CryoSleeve in the tall insulated bucket to hold the goblets.

NOTE: Samples should NEVER be placed on top of dry ice. The dry ice should always be higher than the sides of the box.

CryoCage

6. MAINTAINING THE TEMPERATURE OF STRAWS ON THE BENCH TOP

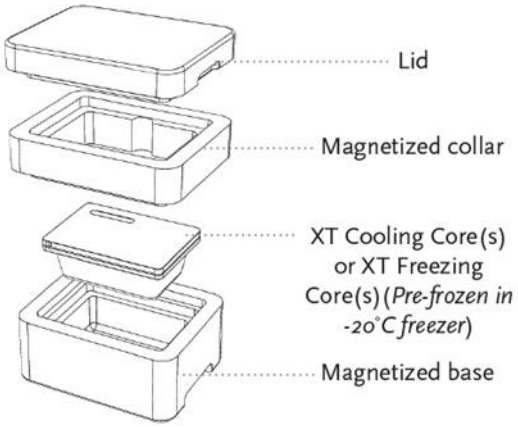
- Place the custom CryoSleeve cooling sleeve in the bottom of an insulated lab bucket with the holding bar at the bottom.
- Fill around the cooling sleeve with dry ice until it is level with the top of the cooling sleeve.
- Remove the top of the goblet and place it inside the cooling sleeve.
- Replace / add additional dry ice as needed during the day so that the level of dry ice is always level with the top of the cooling sleeve.

CryoSleeve

CryoSleeve Surrounded by Dry Ice

7. MAINTAINING THE TEMPERATURE OF VACUTAINERS AND CRYOVIALS ON THE BENCH TOP

The purpose of this standard operating procedure (SOP) is to describe how to use the CoolBox™ System to regulate sample temperature on the benchtop in the SSS Core Laboratory.



7.1 Maintaining the Temperature of Vacutainers on the Bench Top

- Place the XT Cooling Core and the CoolRack® LV in the refrigerator overnight.
- Remove the XT Cooling Cores from the refrigerator and place it on the benchtop for 15-20 minutes until the temperature indicator reads 1°C. Place in the base of the CoolBox™ 2XT
- Secure collar on base.

- When the temperature strip on the XT cooling cores registers 1°C place the CoolRack® LV sample modules on top.
- Load the Vacutainers.

7.2 Maintaining the Temperature of Cryovials on the Bench Top During Processing

- Place the XT Cooling Core and the CoolRack® XT in the refrigerator overnight.
- Remove the XT Cooling Cores from the refrigerator and place it on the benchtop for 15-20 minutes until the temperature indicator reads 1°C. Place in the base of the CoolBox™ 2XT
- Secure collar on base.
- When the temperature strip on the XT cooling cores registers 1°C place the CoolRack® XT sample modules on top.
- Load the labeled cryovials.

7.3 Benchtop Freezing of Cryovials

- Place the XT Cooling Cores in a -80°C Freezer for at least 1 hour.
- Place 1.5 inches of dry ice in an insulated tray.
- Remove the XT Cooling Cores from the -80°C freezer and place on top of the dry ice in the insulated tray.
- Secure collar on base.
- Load the labeled and filled cryovials as they are processed.

7.4 Caution

- Lift CoolBox 2XT from the bottom using handholds on the sides.
- Always use two hands when carrying or lifting the CoolBox™ 2XT.
- Avoid touching the top metal surface of the XT Cooling Core and XT Freezing Core when removing from freezer.

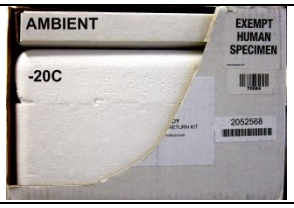
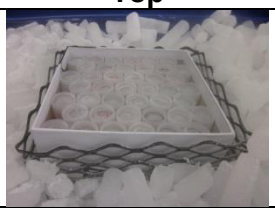
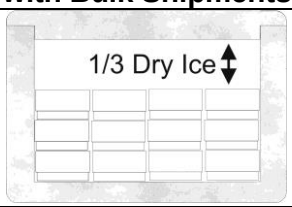
7.5 Cleaning

All components can be cleaned with aqueous detergents, alcohol, and 10% bleach.

8. SAMPLE INTEGRITY THROUGHOUT THE COLD CHAIN

Biological sample cold chain management is a system for storing and transporting blood, urine and human tissues, within the correct temperature range and conditions, from the point of collection from study participants (or environmental samples) to the final analysis of the sample. Deviations from specified temperature ranges and conditions during storage and transportation can seriously affect the viability of the constituents of biological and environmental samples, thus leading to inaccurate assays and analysis.

SSS has established a reliable cold chain sample management system that insures that all blood, urine and human tissue products are maintained at the correct temperatures during processing, preventing temperature excursions and unintended freeze thaw cycles.

Home Sample Collection Kit	Maintaining +4C at the Bench Top	Maintaining -20°C & -80°C at the Bench Top	Maintaining Temperature with Bulk Shipments
			
Specimens collected at participants homes are transported using custom designed shippers. The shipper contains both an ambient section and a -20°C section. A frozen phase change cold pack is used to maintain the temperature in the -20°C section.	Off-the-Shelf CoolRack® tube modules, from Biocision®, provide consistent temperature to all samples (+/- 0.1°C), ensuring that refrigerated samples maintain the proper temperature throughout all bench top procedures for up to 10 hours.	SSS Proprietary SSS's proprietary Cryo-Sleeves and CryoCages ensure that frozen samples stay frozen by providing a barrier where dry ice can be placed at the correct height to minimize temperature fluctuations while making it easy to swap out frozen boxes and goblets without having to reload the dry ice tray. Techs place the cryo cage in the middle of an insulated tray and surround it with dry ice so that the ice is higher than the box. They also place dry ice in the cover of the box so that it does not warm up.	Shipments are packed in IATA compliant Styrofoam shippers with sides at least 2" thick with high density foam ≥ 1.5 PCF that can maintain temp for at least 48 hours. -80°C shipments are packed with at least 1/3 of the shipper's volume filled with dry ice. -20°C Shipments are packed with frozen phase change blocks (cold packs) so that the blocks surround the samples.