Fairfax Cryobank

**CAN-AM Cryoservices Instructions for Semen Identification, Thawing and Specimen Quality Standard**

This shipper contains semen as Donated Human Tissue (for Non-ID/ID Option Donors) for assisted reproductive techniques. See the enclosed Summary of Records (SOR) for testing information.

**Storage:**
Specimens may be held in the shipper for a limited amount of time, please see the shipping documents for information specific to the type of shipper you have received. If the specimens are not to be used imminently, they must be stored in an appropriately designed liquid nitrogen Dewar. Exposure to temperatures warmer than -130 °C will be detrimental to sperm integrity and viability. Do not thaw and refreeze the specimens, as they are highly sensitive to temperature changes. The semen may not be sterilized.

**Safety information:**
Liquid nitrogen is non-toxic, non-flammable, non-carcinogenic and chemically inert. The temperature of the cryogenic liquid is -196°C (-321°F). Contact with liquid nitrogen can cause tissue freezing or frostbite on dermal contact or if splashed into the eyes. Nitrogen is defined as a simple asphyxiant, use only in well-ventilated areas. Prompt medical attention is mandatory in all cases of overexposure to nitrogen. In case of emergency resulting from the handling of liquid nitrogen shipping container or specimen containers frozen in liquid nitrogen, call your local emergency service provider. Contact CAN-AM Cryoservices at 1-888-245-3471 with any questions regarding proper handling of shipping containers. Use of cryogloves to handle the nitrogen cooled canes and cryovials is recommended. Use of safety glasses is also recommended.

**Special Note:**
The cryopreserved semen contained in our shipper is intended for use by the requesting physician and his/her staff. The specific specimen identified on the Packing Slip is to be used only for the indicated client (recipient). The physician/clinician is responsible for maintaining the cryopreserved semen specimen in the proper storage conditions until the specimen is thawed and prepared for insemination. The physician/clinician is responsible for maintaining recipient records for the purpose of tracking the semen and recording insemination outcomes. The dosage is one vial per insemination (unless noted). Additional doses of the same donor may be used according to the physician's advice. Although every reasonable precaution has been implemented, the insemination procedure may produce unwanted but potential reactions or outcomes such as cramping, nausea, and vomiting. Communicable diseases, such as STDs and genetic anomalies may potentially be attributed to the cryopreserved semen used during the insemination. **ALL ADVERSE REACTIONS/OUTCOMES MUST BE REPORTED PROMPTLY TO** CAN-AM Cryoservices (1-888-245-3471). Safety Regulations require the report of Adverse Reactions, Errors and Accidents by Health Professionals directly to Primary Establishments (Fairfax), in writing. Once a container seal has been compromised (or semen thawed), the semen shall either be inseminated or used in an ART procedure or discarded.

**Specimen Identification:**
The post thaw analysis and identification label for each specimen is listed on the SOR. Individual specimens are packaged in 1 ml cryovials, which will contain the donor semen, and cryoprotectant buffer. Some vials may contain antibiotics and/or egg yolk, see the DB-001 T.001 Statement of Semen Processing, Compliance, and Distribution (Canada) for more information specific to each cryovial date.

Each cryovial is labeled with the donor ID number, vial number and date frozen.

Specimens are contained in cryovials on aluminum canes labeled with the donor ID number. Each cane is inside a single canister found in the liquid nitrogen shipper. Each cane will contain only the specimens for a single donor. The shipper contains an absorbent material that holds the liquid nitrogen to prevent spillage. You will not be able to see any liquid in the container. If you have any questions, please discuss with your Laboratory Director and/or call CAN-AM Cryoservices at 1-888-245-3471.

**Removing Units from the Shipper:**
Please read all enclosed paperwork included in the shipment prior to removal of the samples for thawing and use. Use of cryogloves to handle the nitrogen cooled canes and cryovials is recommended. Use of safety glasses is also recommended.

To remove a specimen from the nitrogen container, follow these steps:

1. Remove the lid of the liquid nitrogen container by pulling straight up (do not twist).

2. Lift the canister so that the tops of the canes are visible for identification. Do not lift the top of the canes above the top of the liquid nitrogen container opening; this may result in premature thawing.

3. After identification of the desired cane, grasp the cane by the top and lift above the opening of the container sufficiently to expose the uppermost cryovial. It is recommended to only expose the cryovial you wish to retrieve. Any cryovial(s) below the top one should not be lifted above the opening of the container.

4. Check the packing slip and compare it to the number of cryovials in the canister- some units may have fallen off the canes during shipping and are at the bottom of the canister.

5. Once exposed, use cooled forceps to grasp the cryovial and remove it from the aluminum cane holder. Replace the cane into the canister as quickly as possible, lower the canister to the bottom of the nitrogen container and replace the container top securely.

6. Wrap the vial in a paper towel for several seconds.

7. Follow the thaw procedure as listed below:

**THAW PROCEDURE "V"**

1. Always keep the vial in an upright orientation while thawing.

2. Place the frozen vial in a dry block at 37º Celsius for 10 minutes. Remove from the thaw block promptly after thawing.

3. Once the specimen has thawed completely, wipe any condensation from the outside of the cryovial and then unscrew the cryovial cap. Gently, but thoroughly, mix each specimen in its respective cryovial using a vortex or by pipetting up and down using a 200 ul pipet tip or sterile 1 ml pipette, before removing semen from the cryovial. Prompt use of the specimen is recommended for best results.

4. Perform a post-thaw evaluation at the time of thaw and before any additional processing. Place 10 µl of the recently mixed specimen on a microscope slide, cover with a 22 x 22 mm cover slip, place on 36º C slide warmer, and allow to equilibrate for 5 minutes. Determine total motility and follow individual lab protocol using the preferred counting chambers to determine total concentration.

5. Verify the specimen identification prior to insemination.

NOTE:
If your clinic does not have a dry block, the following alternates may be used. Please be aware that sub-optimal results may be achieved. **Use of a water bath is never acceptable.**

Alternate 1 – thaw in a 37º C incubator. Remove from the incubator promptly after thawing.
Alternate 2 – thaw at Room Temperature on a counter top for 15-20 minutes or until completely thawed.

**Fairfax Cryobank, Inc. hereafter known as "Cryobank" Specimen Quality Standards**

Terms and conditions of the Cryobank Anonymous and ID Option specimen quality standards are as follows:

| *Fairfax Cryobank, Inc. Brand Specimen Quality Standards* | | |
|---|---|---|
| **Specimen Prep Type** | **Minimum Total Motile Cells/ milliliter (TMC)*** | **Clinical Use** |
| IUI | 20 million/mL (10 million/vial) | Pre-washed vials, ready for intrauterine insemination |
| ICI | 20 million/mL (10 million/vial) | Ready for intracervical insemination OR can be washed for use as an IUI specimen |
| IVF | 5 million TMC/vial | Ready for intracervical insemination or can be washed for use as an IUI or IVF or IVF with ICSI |
| IUI ART | > 6 million/vial | Ready for IUI individually or combined, or can be washed post thaw and used for IVF with/without ICSI |
| ICI ART | > 6 million/vial | Ready for ICI individually or combined, or can be washed post thaw and used for IUI or IVF with/without ICSI |

| *Cryogenic Laboratories, Inc. (CLI) Brand Specimen Quality Standards* | | |
|---|---|---|
| **Specimen Prep Type** | **Total Motile Cells/vial (TMC)** | **Clinical Use** |
| IUI | 10 million/vial | Pre-washed vials, ready for intrauterine insemination |
| ICI | 18 million/vial | Ready for intracervical insemination OR can be washed for use as an IUI specimen |
| IVF | 5 million/vial | Ready for intracervical insemination or can be washed for use as an IUI or IVF or IVF with ICSI |
| IUI ART | > 6 million/vial | Ready for IUI individually or combined, or can be washed post thaw and used for IVF with/without ICSI |
| ICI ART | > 6 million/vial | Ready for ICI individually or combined, or can be washed post thaw and used for IUI or IVF with/without ICSI |

a. Sperm counts will vary 10-30% depending on the lab personnel and counting method. Laboratory variation is expected and taken into consideration when processing complaints. The possibility exists that sperm counts performed at other laboratories may be less than the stated specimen standards. Semen is not a homogenous or uniform mixture which adds to sample variability. A variation in count does not indicate the specimen is not suitable for insemination or that a pregnancy will not result if used for an insemination. Cryobank takes these variations into account when determining eligibility for refund or credit.

b. The physician/clinic must follow the Cryobank's printed thaw procedures enclosed in each shipment. Thaw procedures may vary among specimen types.

c. Our specimen quality standard applies at the time of thaw and *prior* to any post thaw processing. Sperm cells will be lost in the process of washing a specimen. A pre-processing count must be taken to determine if the specimen meets the Specimen Quality Standard. If the physician's office is not able to provide a pre-processing count and the specimen was washed and/or processed before use, you can expect the total motile cell (TMC) count to be less than the stated quality standard. We back our quality standard at the time of thaw only.

d. Specimens stored outside the Cryobank longer than 120 days are not eligible for refunds or credits. We do not have control over the storage and handling practices of outside laboratories or at other storage facilities.

e. Our shipping tanks will keep specimens frozen for 7 days. **Physicians or laboratory personnel who receive our tanks containing specimens should check the tank upon arrival to be sure that the specimens arrive frozen.** If you suspect that specimens have thawed, please call 1-888-245-3471 immediately and speak with a Client Services Representative. If the specimen arrives thawed, we will ship via FedEx Priority Overnight Service replacement specimens at no charge. If replacement specimens are shipped and not used, they can only be returned to the Cryobank for storage and are not eligible for any credit. If a replacement specimen is not available on your donor, a different donor you select of equal value may be substituted. If a specimen from a different donor is not an acceptable solution, you will be credited for the cost of the thawed specimens and the cost of shipping. Shipping tanks are available that will keep the specimens frozen for 14 days for an additional charge. Contact Client Services for details.

f. If a specimen's TMC tests below our quality standard *prior* to any additional processing, the physician/clinic must report specific specimen data and submit a complaint within 30 business days of thawing accompanied by the laboratory report documenting TMC as assessed by the treating physician/clinic. Complaints/laboratory report should be sent to the attention of the Laboratory Director at info@canamcryo.com or Fax to 1-888-625-8653. Any questions regarding the process of submitting a specimen quality complaint can be discussed with CAN-AM Cryoservices at 1-888-245-3471.

g. Shipping costs cannot be refunded unless specimens arrive thawed.

h. If pregnancy is achieved, the client is not eligible for any refund or credit, regardless of the total motile count (TMC) of the specimen prior to or after any processing.

i. The Cryobank's liability for any deficiency in specimen quality will be limited to supplying a replacement specimen or full or partial refund for the cost of the specimen only, excluding shipping fees, at the Cryobank's discretion. The Cryobank will in no event be liable for any consequential or incidental damages, including but not limited to any additional or associated expenses incurred by the patient during infertility treatment.

j. This specimen quality standard is void if ownership of specimens is transferred to a different owner prior to use.