Fairfax Cryobank

Instructions for Specimen Identification, Thawing and Specimen Quality Standard

This shipper contains frozen human semen as Donated Human Tissue (for Anonymous/ID Option or Directed Donors) or Human Transplant Tissue (Client Depositors) for assisted reproductive techniques. See the enclosed Summary of Records (SOR) for testing information. The enclosed paperwork with the shipment also contains information regarding the extender, wash media (if applicable) and any antibiotics.

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 immediately, 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 Fairfax Cryobank at 1-800-338-8407 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 safety note for glass vials: Always handle glass vials wrapped in a paper towel. To open, snap off the top, using thumb and forefinger. A file may be used to score the separation between top and bottom. Safety glasses are highly recommended when opening glass vials to protect against glass shards.

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 transplant tissue and recording insemination outcomes. The dosage is one vial or one straw 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 adverse reactions or outcomes such as cramping, nausea, or 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 Fairfax Cryobank (1-800-338-8407).** 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 packing slip. Individual specimens are packaged in 1 ml cryovials, straws, or glass vials which will contain the semen, and cryoprotectant buffer. Some vials may contain antibiotics and/ or egg yolk. See the packing slip label information for information specific to each cryovial.

Each cryovial is labeled with the donor ID number (or client account number), date frozen, vial number (if applicable), and processing lab label. For **Fairfax Cryobank brand**, all **unwashed ICI** ready donor specimens contain red coded caps, all **prewashed IUI** ready donor specimens contain orange or blue coded caps, all **IVF** donor specimens contain white coded caps, and all client depositor specimens contain green coded caps. For **Cryogenic Laboratories, Inc. brand**, all unwashed **ICI** ready donor specimens contain gray coded caps, all prewashed **IUI** ready donor specimens contain red coded caps, all **IVF** donor specimens contain white coded caps unless otherwise denoted on the enclose packaging information. Client depositor specimens also include the client's name or initials. Specimens are contained in cryovials on aluminum canes labeled with the client's name and donor ID number or client depositor's name and ID number. If the client name is not available the doctor's name will be used. Each cane is inside a cane sleeve in a single canister found in the liquid nitrogen shipper. Each cane will contain only the specimens for a single donor or client depositor. 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 Fairfax Cryobank @ 1-800-338-8407.

Removing Units from the Shipper:
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 cutting the zip tie and then pulling the plug straight up (do not twist).

2. Lift the canister so that the tops of the canes are visible for identification. Gently remove the cane containing the frozen samples from the cane sleeve, making sure not to remove the cane sleeve from the canister as you pull out the cane containing the vials. Once removed from the cane sleeve promptly place the cane back into the canister. The vials can then the checked against the packing slip to confirm that you have received the correct donor, specimen date, vial number, and number of vials. Do not lift the top of the canes above the top of the liquid nitrogen container opening for longer than a few seconds as this may result in initiating the thawing of the sample.

3. After verification that the vials received match the information on the packing slip, 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. If additional vials remain on the cane, or you wish to transfer the cane to a storage tank in your laboratory, place the cane containing the samples back into the cane sleeve and then transfer the cane in the sleeve to your storage tank.

4. Once exposed, use forceps to grasp the cryovial and remove it from the aluminum cane holder. Replace the cane containing additional vials back into the canister as quickly as possible. Then lift the cane and insert into the cane sleeve as quickly as possible. Once inserted, be sure the canister is all the way to the bottom of the nitrogen container and replace the container top securely.

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

6. 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, before removing semen from the cryovial. The specimen should be used within 2 hours of thaw.

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 cover slip, and place on 36 º C slide warmer, and allow to equilibrate for 5 minutes. Determine total motility and follow individual lab protocol using the preferred counting chamber to determine total concentration. To obtain a total motile cell count/concentration, a concentration per milliliter (mL), percentage of motility and volume in milliliters (mL) must be determined.

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 for 15 minutes or until completely thawed. Remove from the incubator promptly after thawing.

Alternate 2 – thaw at Room Temperature on a countertop for 15-20 minutes or until completely thawed.

Thaw Procedure "O" For samples that were frozen by a facility other than Fairfax Cryobank, Inc.

1. If your specimen is in a straw:
    a. Stand the straw vertically on a tabletop at room temperature for 10 minutes to 15 minutes or until thawed.
    b. Once the specimen has thawed completely, wipe any condensation from the outside of the straw.
    c. Straws are opened by cutting one end, then invert the straw so the open end is in a sterile container, then cut the other end to let gravity drain the contents of the straw into the sterile container.
    d. Gently, but thoroughly, mix each specimen in its respective sterile container by pipetting up and down using a 200 ul pipet tip. The specimen should be used within 2 hours of thaw.
    e. 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 cover slip, and place on 36 º C slide warmer, and allow to equilibrate for 5 minutes before analysis.
    f. Verify the specimen identification prior to insemination.

2. If your sample is in a vial, straw, or glass ampoule, or was frozen by a facility other than Fairfax Cryobank, Inc.
    a. Please see the original processing paperwork enclosed for thaw instructions from the laboratory that froze the sample(s).
    b. Verify the specimen identification prior to insemination.

Specimen Quality Standard

Terms and conditions of the Fairfax Cryobank, Inc. (hereafter referred to as "Cryobank") Anonymous and ID Option specimen quality standard:

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 1-800-338-8407 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. Notification is to be made by calling 1-800-338-8407 to file a complaint over the phone with our Client Services department and receive the necessary Specimen Complaint Form or by downloading the Specimen Complaint Form directly from our website at: http://fairfaxcryobank.com/medicalprofessionals.shtml.

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

h. If pregnancy or fertilization 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.