

Semen Specimen Shipment Instructions

Notice to All Doctors and Staff

Receiving the tank



Please inspect the tank as soon as it arrives at your office.

Once a container seal has been compromised, the semen sample(s) shall be used for insemination, or otherwise discarded. (See the **Reporting Requirements** subsection below.)

Please save the box for your return shipment.

Using the specimens



This semen sample is to be used only by the intended recipient recorded when the semen order was placed.



The insemination should only be performed by a licensed physician or a qualified medical professional.

Opening the tank

The tank should only be opened by qualified medical personnel.

Please wear gloves and protective eye wear when opening the tank and handling the semen specimens.

Carefully remove the lid of the tank by vertically raising the lid.



Do not twist the lid of the tank.

Lift the inner metal open canister by the handle and carefully remove the cane with the specimen(s) from the canister.

Verifying specimens

Compare the specimen identification tag attached to each specimen cane to the insemination units to verify the canister/specimen number is the same.

Replacing the tank lid

Align the handle of the inner metal canister with the groove in the cork portion of the lid and gently push the top down into the tank.

Storing the specimens

If you have an office holding tank, the units should be transferred as soon as possible, preferably on the day of arrival in your office.

According to American Association of Tissue Banks (AATB) standards, it is the responsibility of the end-user clinician to maintain the semen specimen in appropriate storage conditions prior to insemination and to maintain recipient records for the purpose of tracing post-insemination.

Shipping details	<p>IDANT Laboratories ships semen specimens in “dry” shippers.</p> <p>The specimens, in Tank # _____, will remain frozen for _____ days upon receipt of the tank.</p> <p>The tank must be returned to IDANT Laboratories within two (2) weeks of receipt of the shipping tank. (See the <i>Instructions for Returning the Shipping Container</i> section below.)</p>
Client-depositor / donor records	<p>Semen analysis report(s) are enclosed.</p> <p>Medical records, processing details, and laboratory testing is available to the end-user physician upon a written request.</p>
Reporting requirements	<ol style="list-style-type: none"> 1 Problems regarding shipping or semen quality must be reported within 24 hours after receiving the tank, or replacement of sperm or credit will not be given. 2 Adverse outcomes potentially attributable to the semen sample must be reported promptly to IDANT Laboratories. 3 As part of IDANT Laboratories’ on-going efforts to maintain a high standard of quality control, regulatory agencies require all physicians to report conceptions and full-term pregnancies resulting from the use of our donor semen.

Specimen Information

Specimen requirements	<p>The following requirements pertain to anonymous donors.</p> <p>Volume: 0.5 cc Post-thaw motility: ≥ 40% Sperm concentration (ICI): ≥ 12.5% M/unit Sperm concentration (IUI): ≥ 5 M/unit Percent normal morphology: ≥ 14% by Krueger’s Strict Criteria</p> <p>Refer to the semen analysis report for the actual sperm concentration and percent motility values of the semen specimen(s) you have just received.</p> <p>Please note that there are no specimen requirements for directed donors and client-depositors.</p>
Specimen composition	<p>IUI units are processed with human tubal fluid media that has been prepared in accordance with in vitro diagnostic guidelines and the Current Good Manufacturing Practices (CGMPs).</p> <p>Insemination units are cryopreserved with 10%v/v glycerol or a cryopreserved media composed of 12%v/v glycerol, egg yolk, and buffer.</p>

Returning Unused Semen

Donor unit return / on hold policy

Semen specimens may be returned provided that (1) IDANT Laboratories is notified immediately, (2) there is no evidence of contamination or tampering of the straws upon inspection, and (3) the storage temperature is maintained.

Client-depositor cryopreserved semen may be returned to their original storage location provided the above requirements are met.

Cryopreserved donor semen, once released to a physician or clinic, can be returned provided that the above requirements have been met, but subsequently **ONLY** by the same physician or clinic for the recipient originally intended.

Anonymous semen donors may return unused semen specimens provided that (1) the recipient is willing to pay storage fees until those specimens are used, and (2) the unused specimens are used only by the same facility and with the same recipient.

Returned cryopreserved donor semen is placed in **On Hold** storage.

Returning units



Units cannot be removed from liquid nitrogen and then refrozen.

If you wish to return cryopreserved unit(s) to be used by your patient you must: (1) call and notify IDANT Laboratories that the unit(s) are being returned, and (2) complete and sign the Semen Return Request form and return it to IDANT Laboratories along with the units within the tank return deadline.

If the unit(s) are received in satisfactory condition, IDANT Laboratories will return them to the storage tank for your patient. If unit(s) are found to be in an unsatisfactory condition, your office will be notified.

Reordering units on hold

It is the responsibility of the physician and/or staff to notify IDANT Laboratories when units placed on hold are needed. Thus, when you order for a patient with units on hold, you must request that the on hold units be sent.


Charges for unreturned units

A service fee of \$30.00 is charged for unreturned unit(s). In addition, the clinic or the recipient is responsible to make a payment on the bill of the original shipment. (Once unit(s) are shipped from IDANT Laboratories, they become the property of the recipient and cannot be returned to be redistributed, and no refund can be made.)

The physician, clinic, or the recipient will not be charged for on hold unit(s) when reordered. (Only the shipping fees will apply.)

Returning the Shipping Tank

-
- To patients**
- 1 The tank must be returned within two (2) weeks of receipt. There will be a \$25.00 charge on your account per day for any tank kept longer than two weeks of receipt.
 - 2 If you are located within the New York Metropolitan area, you may call IDANT Laboratories at **212-330-8550** to have the tank picked up by one of our couriers.
 - 3 Please contact IDANT Laboratories before returning units to be placed back in storage. These units must be shipped in liquid nitrogen.

-
- Shipments outside of the New York Metropolitan area**
- 1 The tank must be returned within two (2) weeks of receipt. There will be a \$25.00 charge on your account per day for any tank kept longer than two weeks of receipt.
 - 2 If you paid for a **round-trip** delivery, you will find enclosed with the package inserts a pre-addressed air waybill. Please complete the sender information on this waybill.
 - 3 Place the dry tank in the shipping box, seal the box with packing tape, and place the return bill (if available) in the plastic pouch on the outside of the box.
-  If there is still liquid nitrogen in the tank after the units are removed, keep the tank open so that the nitrogen may evaporate.
- 4 IDANT Laboratories has enclosed a label to be posted on the outside of the shipping box so that the courier is aware that the box is a “dry shipper.”
 - 5 Please contact IDANT Laboratories before returning units to be put on hold. On-hold units must be shipped in liquid nitrogen as a “dangerous goods” package. Make four (4) copies of the air bill fax to send with the shipment.

International shipments Please refer to the courier information below for the return of the shipping tank. If you have any questions, please do not hesitate to contact IDANT Laboratories at 212-330-8550.

International Courier: _____

Street Address: _____

Contact Person: _____

Telephone Number: () - _____