Arctic™ Sperm Cryopreservation Medium

Catalog # 90170                                      12 x 5 mL

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Fax: 1 949 261 6522 • www.irvinesci.com

Glossary of Symbols*:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>Catalog Number</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td>STERILE A</td>
<td>Sterilized using aseptic processing techniques (filtration)</td>
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<tr>
<td>!</td>
<td>Caution, consult accompanying documents</td>
</tr>
<tr>
<td>2°C</td>
<td>Storage Temperature</td>
</tr>
<tr>
<td>Rx Only</td>
<td>Caution, Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.</td>
</tr>
</tbody>
</table>

*Symbol Reference - EN ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labeling.

Do not resterilize
Do not use if package is damaged

Do not re-use
Do not re-use
INDICATIONS FOR USE
Arctic™ Sperm Cryopreservation Medium is intended for use in assisted reproductive procedures involving the cryopreservation and storage of human sperm.

PRODUCT DESCRIPTION
Arctic Sperm Cryopreservation Medium is a dual buffered solution containing HEPES and MOPS that provides a secure environment to maintain physiological pH while handling sperm pre- and post-thaw. The formulation contains vitamins and amino acids to help with post-thaw sperm recovery. Arctic Sperm Cryopreservation Medium has a high glycerol concentration that uses less medium per application, requiring only a 1:3 ratio of medium to semen.

PROTEIN SUPPLEMENTATION
Arctic Sperm Cryopreservation Medium contains 20 mg/mL Human Serum Albumin (HSA). No protein supplementation is required prior to use.

QUALITY ASSURANCE
Arctic Sperm Cryopreservation Medium is membrane filtered and aseptically processed according to manufacturing procedures which have been validated to meet a sterility assurance level (SAL) of 10^-3.

Each lot of Arctic Sperm Cryopreservation Medium is tested for:
- Endotoxin by Limulus Amebocyte Lysate (LAL) methodology
- Sterility by the current USP Sterility Test <71>
- Sperm Cryosurvival Assay (Success of this test is based on ≥80% of control motility at post thaw, post gradient separation, and two hours post thaw)
- Albumin Recovery Assay

All results are reported on a lot specific Certificate of Analysis which is available upon request.

COMPOSITION:

<table>
<thead>
<tr>
<th>Salts &amp; Ions</th>
<th>Amino Acids</th>
<th>Proteins</th>
<th>Surfactants</th>
<th>Energy Substrates</th>
<th>Cytoskeletal Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium Chloride</td>
<td>Glycine</td>
<td>Human Serum Albumin</td>
<td>Copolymer Surfactant</td>
<td>Sodium Pyruvate</td>
<td>Kolliphor P 188</td>
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<tr>
<td>Calcium Lactate</td>
<td>Hypotaurine</td>
<td></td>
<td></td>
<td>Glucose</td>
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<tr>
<td>Magnesium Chloride</td>
<td>Adenosine</td>
<td></td>
<td></td>
<td>L-Alanyl-L-Glutamine</td>
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<tr>
<td>Calcium Chloride</td>
<td>L-Lactate</td>
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<tr>
<td>Buffers</td>
<td>Cryoprotectants</td>
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<tr>
<td>HEPES</td>
<td>Glycerol</td>
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<tr>
<td>MOPS</td>
<td>Sucrose</td>
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<tr>
<td>Potassium Bicarbonate</td>
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<td>Vitamins</td>
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<td>Ascorbic Acid</td>
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<td>Inositol</td>
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<tr>
<td>Protein Source</td>
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<tr>
<td>Human Serum Albumin</td>
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</tbody>
</table>

DIRECTIONS FOR USE

1. Semen is collected by masturbation following 2-3 days of abstinence.

2. One vial of Arctic Sperm Cryopreservation Medium is brought to room temperature or 37°C. If antibiotics are desired, they may be added at this step.

3. Allow sample to liquefy at room temperature or 37°C for 15-30 minutes. Measure the volume of the ejaculate.

   **Note:** If performing density gradient separation prior to cryopreservation, then please refer to the product insert for Isolate (Catalog # 99264) available at www.irvinesci.com or your own laboratory specific protocols and procedures.

4. The liquefied semen sample or processed sample is transferred to a sterile 15mL conical centrifuge tube. Add an appropriate volume of Arctic Sperm Cryopreservation Medium drop-wise, slowly, until a 3:1 ratio of semen sample to medium is achieved. For example, for each 1 mL of semen, add 0.33 mL of medium.

   **TIP:** To prevent osmotic shock, use of a 1cc sterile pipette is recommended to reduce the size of the drop, especially if semen volume is low (up to 1 mL).

5. Transfer the final mixture into the patient labeled storage vessel of your choice (cryostraws or cryovials) according to the manufacturer’s filling protocol. To allow for water expansion, avoid overfilling the container(s). Seal the device according to the manufacturer’s recommended protocol and start the freezing process.

   **TIP:** For cryostraws, put the cryostraw in a horizontal position to reach a homogeneous distribution of LN vapor temperature. For cryovials, put the cryostraw in a horizontal position to reach a homogeneous distribution of LN vapor temperature along the cryostraw and to avoid unequal spermatid sedimentation due to potential spermatid sedimentation in cryostraw.

6. The freezing process from room temperature (20-25°C) to -80°C.

   **Note:** If using a programmable freezer, mimic the freezing procedure below.

   a. Load the cryostraws/cryovials to the cryocane (wand), immerse into a beaker of water at ambient temperature, and place in the refrigerator (0-5°C) for 90 minutes.
   b. Place cryostraw or liquid nitrogen vapor for 30 minutes by either suspending them in the liquid nitrogen storage tank above the liquid level or placing them in the vapor phase in a small temporary liquid nitrogen dewar.
   c. Plunge the cryocane into the liquid nitrogen tank for storage at -196°C.

7. To thaw, carefully remove the cryostraws/cryovials from liquid nitrogen storage and let stand for 5 minutes at room temperature.

   a. Place the cryostraws/cryovials into a waterbath at 37°C for 10 minutes.
   b. Gently mix the contents by pipette action.
   c. Process sperm according to own laboratory procedures.

STORAGE INSTRUCTIONS AND STABILITY
Store the unopened bottles refrigerated at 2° to 8°C.

When stored as directed, Arctic Sperm Cryopreservation Medium is stable until the expiration date shown on bottle label.

PRECAUTIONS AND WARNINGS
This device is intended to be used by staff trained in assisted reproductive procedures. These procedures include the intended application for which this device is intended.

The user facility of this device is responsible for maintaining traceability of the product and must comply with national regulations regarding traceability, where applicable.

Do not use any bottle of medium which shows evidence of particulate matter, cloudiness or is not clear and colorless.

To avoid problems with contamination, handle using aseptic techniques and discard any excess medium that remains in the bottle or vial after the procedure is completed.

Information on known characteristics and technical factors that could pose a risk if the product were to be re-used have not been identified therefore the product is not to be used after the initial opening of the container.

For additional details on the use of these products, each laboratory should consult its own laboratory procedures and protocols which have been specifically developed and optimized for your individual medical program.

The medium does not contain antibiotics. For procedures requiring antibiotics, these may be optionally added to the medium prior to use. In all cases, antibiotic usage should be determined by appropriate medical personnel to ensure that the patient is not sensitized to these antibiotics.

US: This product contains Human Serum Albumin (HSA). Human source material used in the manufacture of this product has been tested by FDA-licensed kits and found to be non-reactive to the antibodies to Hepatitis C (HCV), and antibodies to Human Immunodeficiency Virus (HIV). However, no test method offers complete assurance that products derived from human sources are noninfectious. Handle all human source material as if it were capable of transmitting infection, using universal pre-cautions. Donors of the source material have also been screened for Creutzfeldt-Jakob disease (CJD).

Regarding traceability, where applicable.

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