0217-08

Sperm Freezing Medium

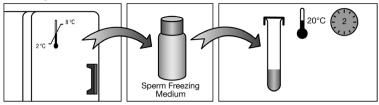
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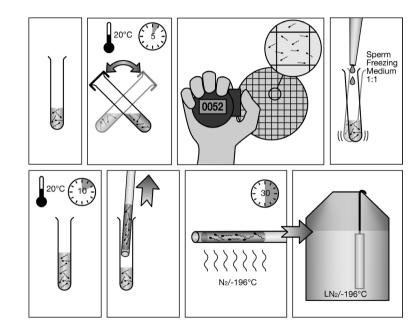
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OCSIO MEDICULT MEDIA

Freezing





Sperm Freezing Medium

Intended use

Sperm Freezing Medium is for the cryopreservation of human spermatozoa.

Composition

Synthetic Serum Replacement (SSR®)* (USA: ART Supplement) * Contains Recombinant Human Insulin Human Serum Albumin (HAS) Glycerol Sucrose Glucose Sodium lactate Physiological salts Sodium bicarbonate HEPES Gentamicin sulphate 10µg/mL

Quality control testing

Sterility tested (Ph.Eur., USP) pH tested (Ph.Eur., USP) Endotoxin tested ≤ 0.1 EU/mL (Ph.Eur., USP) Not Mouse Embryo Assay (MEA) tested Sperm Survival tested

Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.origio.com.

Storage instructions and stability

Store in original container at 2-8°C,

protected from light.

Do not freeze prior to use.

Discard excess (unused) media following warming.

The product is to be used within 7 days after opening.

When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.

Precautions and warnings

Do not use the product if:

- 1. Product packaging appears damaged or if the seal is broken.
- 2. Expiry date has been exceeded.

Caution: All blood products should be treated as potentially infectious. Source material used to manufacture this product were tested and found non-reactive for HbsAg and negative for Anti-HIV-1/-2, HIV-1, HBV, and HCV. Furthermore source material have been tested for parvovirus B19 and found to be non-elevated. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

Caution: US federal law restricts this device to sale by or on the order of a physician (Rx only).

Note:

Concentrating the sperm prior to freezing can enhance post-thaw recovery of semen samples with low sperm counts. A final concentration of minimum 10 million/mL is recommended.

Instructions for use Freezing:

- After liquefaction, measure the total volume of the ejaculate and carry out semen analysis as required.
- Ensure that both semen sample and Sperm Freezing Medium are at room temperature before diluting the semen 1:1 (v/v) with the Sperm Freezing Medium. The medium should be added drop by drop onto the semen and the solution carefully mixed after each addition.
- 3. The mixture is left at room temperature for a minimum of ten minutes.
- 4. Load the diluted semen into straws or cryo-tubes and seal according to the manufacturers recommendations. It is very important to leave some air space in the lower part of the straw for sealing as well as to allow expansion of the solution during freezing.
- 5. Suspend the straws horizontally for 30 minutes, just above the surface of the liquid nitrogen. Cryo-tubes should be attached to a cane and then suspended above the surface of the liquid nitrogen for the same period of time.
- Finally, transfer the straws or cryo-tubes into the liquid nitrogen and store at -196°C.

Thawing:

- 1. Warm straws at room temperature for 5 minutes.
- Open the straws or cryo-tubes according to the manufacturer's instructions and remove the thawed semen.
 Immediately prepare sperm by the density gradient or the swim-up procedure.