

CSC (Choline Substituted Cryopreservation) Thawing Medium

Product No.

ART-8018



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Symbols:

Catalog Number	
Batch Number	
Use By (year, month, day)	
Do Not Reuse	
Temperature Limitation	
Aseptic Technique Sterilization Membrane Filtered (SAL 10 ⁻³)	
ATTENTION: See instructions for use	
Manufacturer	
U.S. Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner)	Rx Only

For laboratory procedures only; other uses must be qualified by the end user.

Product Description	REF Number	Kit Size
CSC Thawing Medium Kit	ART-8018	Sufficient for four (4) thawing procedures

INTENDED USE

This product is intended for thawing of embryos frozen with ART-8017, CSC Freezing Medium. This kit is designed to be used in conjunction with the SAGE CSC Freezing Medium Kit (ART-8017).

PRODUCT DESCRIPTION

The components of this kit will allow for the efficient thawing of zygotes and cleavage stage embryos. The components and recommended procedures are the preferred method for improved embryo survivability.

On average, preliminary results obtained so far indicate that one may expect 76% of frozen thawed embryos to survive (data on file).

This product contains 10 mg/L of gentamicin, an aminoglycoside antibiotic.

MATERIALS PROVIDED IN THE THAWING KIT

- A: 4 x 2 mL vials of CSC Thawing Medium 0.5 M Sucrose (REF # ART-8018-A)
- B: 4 x 2 mL vials of CSC Thawing Medium 0.2 M Sucrose (REF # ART-8018-B)
- C: 4 x 4 mL vials of CSC Washing Medium HEPES Buffered HTF (REF # ART-8018-C)

PRECAUTIONS AND WARNINGS

Do not use medium that shows evidence of particulate matter, cloudiness, or is not rose colored.

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

The 0.5 M Sucrose CSC Thawing Medium (ART-8018-A) component in this kit contains 12 mg/mL human serum albumin.

The 0.2 M Sucrose CSC Thawing Medium (ART-8018-B) component in this kit contains 12 mg/mL human serum albumin.

The CSC Washing Medium with HEPES (ART-8018-C) component in this kit contains 12 mg/mL human serum albumin.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when testing for antibodies to HIV-1/ HIV-2, HCV and non-reactive for HBsAg, HCV RNA and HIV-1 RNA. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents. Donors of the source material have been screened for Creutzfeldt-Jacobs disease (CJD). Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of CJD is also considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin. Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for

specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of proven virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes.

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

Reproductive media products are intended for single use only. Re-use of reproductive media may result in using a product past its labeled expiration date or increase the risk of microbial contamination in a subsequent procedure if the practitioner fails to utilize adequate aseptic techniques.

Use of expired or microbial contaminated product may result in suboptimal conditions to promote fertilization and/or embryo quality during in-vitro culture. These conditions may result in the failure of the embryo to develop properly or to implant, potentially leading to a failed assisted reproductive procedure.

Note: Embryo is considered a general term. More precisely, SAGE considers the period of time initiating when a single diploid cell results from the fusion of male and female genome resulting in zygote formation with subsequent development from repeated mitotic divisions forming a solid mass or morula (typically day 4-5) and after which a fluid-filled cavity

develops resulting in blastocyst formation (typically day 5-6) ending with embryo implantation that begins the end of the first week and is completed by the end of the second week post conception.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

This product contains the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

QUALITY ASSURANCE

One-cell MEA tested and passed with 80% or greater blastocyst. USP Endotoxin tested and passed with <1 EU/mL.

A Certificate of Analysis is available for this product.

DIRECTIONS FOR USE FOR THAWING OF EMBRYOS

1. Pre-procedure Set-up: Remove one bottle each of CSC Thawing Medium 0.5 M Sucrose (REF # ART-8018-A), CSC Thawing Medium 0.2 M Sucrose (REF # ART-8018-B), and CSC Washing Medium HEPES Buffered HTF (REF # ART- 8018-C) from storage at 2–8 °C and warm to room temperature (22-24 °C).
2. For each thawing procedure, set up four dishes. The first dish contains 2 mL of the CSC Thawing Medium 0.5 M Sucrose, the second dish contains 2 mL of the CSC Thawing Medium 0.2 M Sucrose, and the 3rd and 4th dish both contain 2 mL of the CSC Washing Medium. The contents of each dish is covered with Sterile Oil for Tissue Culture (REF # ART-4008).

THAWING PROTOCOL

1. If embryos were frozen in straws, they should be thawed rapidly (at least 275 °C/ min). Initially hold the straw in air for 30 to 40 seconds and then immerse it in a water bath at 30-35 °C until the ice has fully melted. Vials are thawed by immersion in a 32 °C water bath until all ice crystals have disappeared. Thaw only one cryocontainer at a time.
2. Transfer the liquid contents of the thawed medium to a dry dish and quickly locate the embryos. Pick the embryos up in a minimal amount of medium and transfer them first to 2 mL of CSC Thawing Medium 0.5 M Sucrose (REF # ART-8018-A) at ambient temperature (22-24 °C) for 10 minutes.
3. Then, using a fine-bore pipette, transfer the embryos from the CSC Thawing Medium 0.5 M Sucrose to 2 mL of CSC Thawing Medium 0.2 M Sucrose (REF # ART-8018-B) at ambient temperature for 10 minutes, using a new transfer pipette for each procedure to minimize the carry-over of cryoprotectant from one solution to the next.
4. The embryos are then washed through two dishes containing 2 mL of CSC Washing Medium (REF # ART-8018-C) at 37 °C, holding in each solution for 5 minutes. The embryos are thoroughly washed by pipetting up and down several times over a period of about 1 minute in each solution. A new transfer pipette should be used for the first wash solution but the same pipette can be used for subsequent transfers.
5. The embryos are then transferred or placed into culture.

Each laboratory should make its own determination of the particular details to use for each particular procedure.

Information on specific aspects of IVF, embryo culture, and cryopreservation is available in our

Product Catalog.

STORAGE INSTRUCTIONS AND STABILITY

Store unopened containers refrigerated at 2-8 °C. Warm to room temperature (22-24 °C) or incubator (37 °C) temperature, as appropriate, prior to use. Do not freeze or expose to temperatures greater than 39 °C. The product is stable in unopened containers until the expiration date shown on the label.

- A. Remove desired volume of product using aseptic procedures. One vial contains adequate volume of medium for one thawing procedure.
- B. Once removed, do not return any volume of product to the original container. Discard remaining product.
- C. Do not use if the product becomes discolored, cloudy, turbid, or shows any evidence of microbial contamination.

RELATED PRODUCTS

ART-8017 CSC Freezing Medium Kit
ART-4008P Oil for Tissue Culture

SAGE In Vitro Fertilization™ has a full line of products for the Reproductive Medicine Specialist. Please call or write for specific information or to receive a copy of our current catalog. For technical questions, or to reach our Customer Service Department, call the SAGE Support Line.

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Call the SAGE SUPPORT LINE:

In the U.S.: (800) 243-2974

International: (203) 601-9818