

CSC

(Choline Substituted Cryopreservation)

Freezing Medium

Product No.

ART-8017



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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.

This product contains 12 mg/mL human
serum albumin.

Product Description	REF Number	Kit Size
CSC Freezing Medium Kit	ART-8017	Sufficient for one (1) freezing procedures

INTENDED USE

This product is intended for use in freezing
embryos. The kit is designed to be used in
conjunction with the SAGE CSC Thaw Kit
(ART-8018).

PRODUCT DESCRIPTION

CSC Freezing Medium will allow for the
efficient freezing of zygotes and cleavage
stage embryos. The components and
recommended procedures are the preferred
method for improved embryo survivability.

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

MATERIALS PROVIDED IN CSC FREEZING MEDIUM

1 x 10 mL vial of CSC Freezing Medium
(REF # ART-8017-A)

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.

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

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.

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

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).

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 CRYOPRESERVATION OF EMBRYOS

1. Pre-procedure Set-up: Remove bottle of CSC Freezing Medium (REF #ART-8017) from storage at 2-8 °C and warm to room temperature (22-24 °C). Set up one or more dishes, depending on the expected number of embryos to be cryopreserved, containing 1-2 mL of the CSC Freezing Medium covered with Sterile Oil for Tissue Culture (REF # ART-4008).

Note: Up to 8 embryos can be treated with 1 mL of CSC Freezing Medium and a similar number of embryos can be frozen in one vial or straw containing CSC Freezing Medium.

2. Transfer the embryos to 1-2 mL of CSC Freezing Medium (REF # ART-8017) for 20 minutes at room temperature (22-24 °C). It is recommended that the media be covered with Sterile Oil for Tissue Culture (REF # ART-4008) during use to minimize evaporation of water and a subsequent change in osmolality of the media.

3. Load up to 8 but normally 1 to 3 embryos into a cryocontainer (vial or straw) containing approximately 0.25 to 1.0 mL of CSC Freezing Medium, depending upon size of cryocontainer.

COOLING PROTOCOL

1. The cryocontainer is cooled from room temperature to -7 °C at 2 °C/min.
2. They are held at this temperature for 5 minutes, manually seeded and held at the same temperature for an additional 10 minutes.
3. They are then cooled at 0.3 °C/min to -35 °C and then transferred to a storage tank of liquid nitrogen.

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.

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

RELATED PRODUCTS

ART-4008P Oil for Tissue Culture
ART-8018 Thawing Medium Kit

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