

Quinn's Advantage™ Blastocyst Freeze kit

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

Product Description	Catalogue Code	Unit Size
Quinn's Advantage™ Blastocyst Freeze kit	RM-ART-8015	3 x 12mL

INTENDED USE

Quinn's Advantage™ Blastocyst Freeze Kit was developed for use in freezing blastocysts.

DESCRIPTION

The components of this kit will allow for the efficient freezing of blastocyst stage embryos. The components and recommended procedures are the preferred method for improved blastocyst survivability.

MATERIALS PROVIDED IN THE EMBRYO FREEZE KIT

1. 1 12mL vial of 5% Glycerol Freezing Medium with 12mg/mL Human Serum Albumin
2. 1 12mL vials of 9% Glycerol with 0.2M Sucrose Freezing Medium with 12mg/mL Human Serum Albumin
3. 1 12mL vial of Freeze/Thaw Diluent Solution with 12mg/mL Human Serum Albumin

RECOMMENDED PROCEDURES FOR CRYOPRESERVATION OF BLASTOCYSTS

Controlled hyperstimulation of women undergoing IVF or GIFT produces, on average, 10 to 12 mature oocytes for insemination. It is prudent to replace only a limited number of the resulting embryos, as multiple pregnancies can arise if too many embryos are replaced. Therefore, the majority of patients will have supernumerary embryos. These embryos can be cryopreserved and stored for later use, thus avoiding the necessity of the couple to undertake another stimulated cycle to recover more oocytes for IVF.

The major cause of cell damage during cryopreservation is the formation of intracellular ice during freezing and thawing. By using cryoprotectants, controlling the rate of freezing and thawing, and carefully diluting the cryoprotective from the embryo after thawing, methods have been developed that allow 80% or more of frozen-thawed embryos to survive and be replaced into the reproductive tract of the woman who produced the oocytes or a genetically non-related recipient.

Place fully expanded blastocysts into 1.0mL of Freeze/Thaw Diluent solution at 37°C for 5 minutes. Transfer to 1.0mL of the 5% Glycerol Freezing Medium at 37°C for 10 minutes. Transfer to 1.0mL of the 9% Glycerol + 0.2M Sucrose Freezing Medium at 37°C and load into straws* containing the same solution; hold at 37°C in the 9% Glycerol+0.2M Sucrose Freezing Medium for a total of 10 minutes before cooling is initiated.

* Vials, eg 1.2mL plastic cryovials, can also be used and have been found to be preferable by some laboratories.

It is important to make sure that the embryos are well mixed with the cryoprotectant solutions. This can be accomplished by pipetting the embryos up and down in the solution several times after adding them to the cryoprotectant solution. It is also recommended that the media be covered with Sterile Oil for Tissue Culture during use to minimize evaporation of water and a subsequent change in osmolality of the solutions.

COOLING PROTOCOL

Embryos are usually frozen in straws, but 1.2mL vials can be used as an alternative. The embryos are taken from a starting temperature of 37°C to -6°C at 2°C/min. They are then seeded manually and held at -6°C for a total of 10 to 15 minutes before being cooled at about 0.3°C/min to around -35°C. They are then transferred to a storage tank of liquid nitrogen.

Each laboratory should make its own determination of which medium to use for each particular procedure.

STORAGE INSTRUCTIONS AND STABILITY

Store unopened containers at 2-8°C. Bring to 37°C prior to use. Do not freeze or expose to temperatures greater than 39°C. The product is stable until the expiration date shown on the label or within 30 days of the Date of First Use provided that proper aseptic procedures have been observed by the user:

- A. Remove desired volume of product using aseptic procedures
- B. Once product has been removed from the original container, reseal the container to ensure a tight seal. Write the date the product was first opened on the product label. Do not use product longer than 30 days after opening the container.
- C. Once removed, do not return any volume of product to the original container.
- D. Once the product has been opened, store the sealed container at 2-8°C
- E. Do not use if the product becomes discoloured, cloudy, turbid, or shows any evidence of microbial contamination.

One-cell MEA tested and passed with 80% or greater blastocyst. USP Endotoxin gel clot tested and passed with <1 EU/ml. A Certificate of Analysis is available for this product.



PRECAUTIONS AND WARNINGS

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

To avoid problems with contamination, practice aseptic technique and discard minimal amounts of excess medium remaining in the bottle.

This product contains albumin, a derivative of human blood. All donors used in its manufacture were individually tested and found to be nonreactive for hepatitis B surface antigen (HB_sAG) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV) by approved testing methods. Donors of the source material have been screened for Creutzfeld Jakob 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.

RELATED PRODUCTS

SAGE Assisted Reproduction Products™ has a full line of products for the Reproductive Medicine Specialist. Please call or write for specific information, technical questions, customer support, or to receive a copy of our current price list. Your UK distributor for SAGE products is:

Rochford Medical Ltd, PO Box 1311, Oxford OX4 4WE Tel: 01865 772420 Fax: 01865 715598

Patrick Quinn, PhD, HCLD, SAGE Assisted Reproduction Products™.