



SAR HEALTHLINE (P) LTD

Quinn's Advantage™ Thaw kit

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

Product Description	Catalogue Code	Unit Size
Quinn's Advantage™ Thaw kit	ART-8016	3 x 12mL

INTENDED USE

Quinn's Advantage™ Thaw Kit was developed for thawing frozen blastocysts or frozen embryos.

DESCRIPTION

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

MATERIALS PROVIDED IN THE THAWKIT

1. 1 12mL vial of 0.5M Sucrose Thawing Medium with 12mg/mL Human Serum Albumin
2. 1 12mL vials of 0.2M Sucrose Thawing 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 EMBRYOS / 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 cryopreservatives, controlling the rate of freezing and thawing, and carefully diluting the cryopreservative from the embryo after thawing, methods have been developed that allow 80% or more of frozenthawed embryos to survive and be replaced into the reproductive tract of the woman who produced the oocytes or a genetically nonrelated recipient.

THAWING PROTOCOL

If the straws have been transferred to liquid nitrogen after being slow cooled to between -30°C and -37°C, they should be thawed rapidly (at least 275°C/min) so that intracellular ice is swiftly dispersed. This will help revert cellular damage by the ice crystals. The easiest way to achieve this is to initially hold the straw in air for 30 to 40 seconds and then immerse it in a water bath at 30°C to 35°C until the ice has fully melted. This method allows for any liquid nitrogen that may have entered the straw through an imperfectly sealed plug to be blown off before the straw is placed in a water bath. Little loss of straws or their contents occurs with this technique.

Thaw only one cryocontainer at a time. Transfer the liquid contents of the thawed solution to a dry dish and quickly locate the embryos. Pick the embryos up in a minimal amount of solution and transfer them first to 3mL of 0.5M Sucrose Thawing Medium at 37°C for 10 minutes, followed by 3mL of 0.2M Sucrose Thawing Medium at 37°C for 10 minutes, using a new transfer pipette for each procedure to minimize the carry-over of

cryoprotectant from one solution to the next. It is 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. The embryos are then washed through 7 drops of Freeze/Thaw Diluent Solution at 37°C. This can be achieved by placing 7 drops, each of 100 μ l, under Sterile Oil for Tissue Culture in a large culture dish. The embryos are placed in each drop and thoroughly washed by pipetting up and down several times over a period of about 1 minute before being transferred to the next drop. A new transfer pipette should be used after the first drop but the same pipette can be used for subsequent transfers. After the sixth washing drop, the embryos can be transferred to the seventh drop and held for up to 30 minutes at 37°C before transfer, or placed into culture.

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

STORAGE INSTRUCTIONS AND STABILITY

Store unopened containers refrigerated at 2-8°C. Warm to incubator(37°C)temperature 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 (HBsAG) 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 Creutzfeldt 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.