



Blastocyst

Blastocyst Vitrification Kit K-SIBV-5000

Intended Use

Blastocyst Vitrification Kit is intended for the vitrification and containment of Human blastocysts for A.R.T. procedures. This kit is designed for use with Blastocyst Warming Kit (K-SIBW-5000).

General Information

Blastocyst Vitrification Kit consists of three HEPES buffered media designed for sequential use. Vitrification solutions are supplemented with Human serum albumin (up to 20.0mg/mL) and gentamycin (0.01mg/mL).

WARNING: Blastocyst Vitrification Kit is not ready for use. It requires the combination of vitrification solutions by the end user prior to use.

Vitrification Solution 4 is Dimethyl sulphoxide (DMSO). A material Safety Data Sheet (MSDS) is available upon request.

Product Description

The three media are all based upon the formulation of Cryobase buffer, a 10 mM HEPES buffered media containing 20.0 mg/mL HSA, 0.01 mg/mL gentamycin. Solution 1 contains Cryobase buffer only. Solution 2 is used for preparation for vitrification and contains Cryobase buffer with 8 % ethylene glycol and 8 % DMSO. Solution 3 is used during cyrostorage and contains Cryobase buffer with 0.68 M trehalose, 16 % ethylene glycol and 16 % DMSO. Solution 4 is a glass ampoule of DMSO.

Storage and Stability

Blastocyst Vitrification Kit must be stored in original unopened container, refrigerated at 2-8 °C. When stored as directed, Blastocyst Vitrification Kit is stable until the expiration date shown on the kit box. This product cannot be re-sterilized after opening. Discard after use.

Directions for Use

The following is a general procedure for using Blastocyst Vitrification Kit.

Each laboratory should establish procedures and protocols that are optimized for the individual medical facility.

For more information on the recommended use of Blastocyst Vitrification Kit, please see the Cook Medical Embryo Culture - Suggested Laboratory Protocols. The manual is available upon request from Cook Medical.

Preparation

- Aseptic technique should be used.
- DMSO is a frozen solid at 2-8°C. Before use equilibrate Vitrification Solution 4 (DMSO) to room temperature prior to use.
- Snap the neck off the ampoule of Vitrification Solution 4 (DMSO) and add 400 µL to 4.6 mL of Vitrification Solution 2 and mix well.
- Add 1 mL of Vitrification Solution 4 (DMSO) to 5.25 mL of Vitrification Solution 3 and mix well.
- Prepare the vitrification solutions in a 4 well dish by adding 800 µL of Vitrification Solution 1 into well 1 and 2, 800 µL of the prepared Vitrification Solution 2 into well 3, and 800 µL of the prepared Vitrification Solution 3 into well 4.
- Equilibrate the three Vitrification Solutions to 37 °C prior to use.

Method

- Place the embryo(s) to be cryopreserved into well 1, maximum of three embryos.
- Move the specific embryo to be vitrified into well 2. Have the allocated vitrification device ready.
- Set a timer for three minutes but do not start the timer.
- Move the embryo to well 3 for two minutes, start the timer.
- With one minute remaining on the timer move the embryo to well 4. Complete the next step within 20 - 30 seconds.
- Using a positive displacement pipette, aspirate 1.5 µL of solution, then the embryo and the remaining volume of vitrification solution 3 into the pipette. Avoid bubbles.
- Expel the droplet containing the embryo onto vitrification device and vitrify immediately according to laboratory approved methods.

Specifications and Quality Assurance

This product is supplied 'STERILE'. Blastocyst Vitrification Kit is sterilized by terminal filtration to give a sterility assurance level (SAL) of 10⁻³.

Each lot of Vitrification Kit is tested for:

- Endotoxin by LAL
- Biocompatibility by MEA
- Osmolality and pH
- Bioburden
- Sterility

All results are provided on lot specific Certificate of Analysis, available upon request.

Precautions

All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HBc, HCV and non-reactive for HbsAg, HCV RNA and HIV-1 RNA and syphilis. Donors of the source material have been screened for CJD.

No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

Data collected to date has shown acceptable performance and safety of IVF for the treatment of sub-fertile patients. However, the long-term risk of these products and treatments is currently unknown. Therefore, any IVF procedure must occur in the context of appropriately informed patient consent.

Federal (USA) law restricts this device to sale by or on the order of a physician.

Contraindications

Blastocyst Vitrification Kit contains gentamycin. Gentamycin or similar antibiotics should not be used on a patient that has a known allergy to gentamycin.

DO NOT USE PRODUCT IF:

- Packaging appears damaged or the seal is broken.
- Solution appears turbid.
- Expiry date has been exceeded.



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