

Gamete

Oocyte Freeze K-OCF-5000

Intended Use

Oocyte Freeze is intended to be used during freezing of oocytes.

General Information

This kit is designed for use with Oocyte Thaw (K-OCT-5000).

Oocyte Freeze is supplemented with Human serum albumin (up to 12mg/mL) and gentamycin (0.01mg/mL).

Ready to use after equilibration to 37 °C.

Storage and Stability

Oocyte Freeze must be stored in original unopened container, refrigerated at 2-8 °C.

When stored as directed Oocyte Freeze is stable until the expiration date shown on the vial label.

This product cannot be re-sterilized after opening.

Discard after use.

Directions for Use

The following is a general procedure for using Oocyte Freeze.

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

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

- Aseptic technique should be used.
- All oocytes must be complete denuded of cumulus and coronal cells prior to cryopreservation.
- Dispense 0.4 mL of Freeze Solution 1 into well 1 of a 4 well dish.
- Dispense 0.4 mL of Freeze Solutions 2 and 3 into wells 2 and 3 respectively and allow solutions to equilibrate to room temperature prior to use.
- All dehydration steps must be performed at room temperature.
- Transfer oocyte(s) to well 1, containing Freeze Solution 1 for 7 minutes, 30 seconds.
- Transfer oocyte(s) with a minimum volume of Freeze Solution 1 into well 2 containing Freeze Solution 2 for 7 minutes 30 seconds.
- Transfer oocyte(s) with a minimum volume of Freeze Solution 2 into well 3 containing Freeze Solution 3 for 5 minutes.
- Using Freeze Solution 3 in well 3 as the loading solution, load the oocytes into the labeled straw in accordance with the manufacturer.
- Place the straws in the freezing machine and initiate the freeze program suitable for oocyte cryopreservation.
- Store cryopreserved embryo in liquid nitrogen.

Specifications and Quality Assurance

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

Each lot of Oocyte Freeze is tested for:

- Endotoxin by LAL
- Biocompatibility by MEA
- 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 and 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

Oocyte Freeze 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.