

Embryo Culture – Fertilization

Instructions for Use

FERTILIZATION

HYALURONIDASE K-SIHY-1-5

GENERAL PROCEDURE

The following is a general procedure for using Cook IVF Media products. Each laboratory should establish procedures and protocols that are optimized for the individual medical facility.

INTENDED USE

Hyaluronidase is used to remove the cumulus cell complex surrounding the oocyte prior to ICSI.

GENERAL INFORMATION

Hyaluronidase is a bicarbonate buffered enzyme preparation containing 80 IU/ml hyaluronidase of ovine origin. It is supplemented with Human serum albumin (5 mg/mL) and gentamicin (0.01 mg/mL).

Ready to use after equilibration to 37°C and 6% CO₂.

STORAGE AND STABILITY

Hyaluronidase must be stored in original unopened container, refrigerated at 2-8°C. Do not freeze.

When stored as directed Hyaluronidase 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 Hyaluronidase.

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

- Aseptic technique should be used.
- The oocyte cumulus complexes should be placed into the Hyaluronidase for NO LONGER than one minute.
- Warm the Hyaluronidase to 37°C and equilibrate in a 6% CO₂ incubator for a minimum of 4 hours prior to use.
- Ensure Culture Oil (K-SICO) is used to avoid evaporation.
- Place the Hyaluronidase in one well of a 4-well dish, and aliquots of either Cleavage Medium (K-SICM) or Gamete Buffer (K-SIGB) in the other three wells.
- Use these three wells for washing the oocytes following the Hyaluronidase treatment.

SPECIFICATIONS AND QUALITY ASSURANCE

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

Each lot of Hyaluronidase is tested for:

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

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

PRECAUTIONS

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.

It is strongly recommended that every time Cook IVF Media is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

CONTRAINDICATIONS

This product contains gentamicin. Gentamicin should not be used on a patient that has a known allergy to gentamicin or similar antibiotics.

OVINE SOURCED HYALURONIDASE

The hyaluronidase used in this product is sourced from ovine testis. According to the WHO Guidelines on Tissue Infectivity distribution in Transmissible Spongiform Encephalopathies (2006) and according to EC Directive 2004/C24/03 *“Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMA/410/01/Rev2) ovine testis material is classified as Category C – Tissues with no detected infectivity”*. In addition, the raw material used in the manufacture of this product is EDQM certified TSE free.

DO NOT USE PRODUCT IF:

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



MANUFACTURER

WILLIAM A. COOK AUSTRALIA PTY. LTD.
95 Brandl Street, Brisbane Technology Park
Eight Mile Plains, Brisbane, QLD 4113 AUSTRALIA

www.cookmedical.com

© COOK 2012

EC REPRESENTATIVE



COOK IRELAND LTD.
O'Halloran Road, National Technology Park
Limerick, IRELAND

IFU-SIHY_EN/1