



Fertilization

Hyaluronidase K-SIHY-1-5

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. It is supplemented with Human serum albumin (5mg/mL) and gentamycin (0.01mg/mL).

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

Storage and Stability

Hyaluronidase must be stored in original unopened container, frozen at -20 °C.

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.

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

- 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
- 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.

DO NOT USE PRODUCT IF:

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