



## Hyaluronidase, 80 U/mL in HEPES-HTF with 5 mg/mL HSA

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

Product Description	REF Number	Unit Size
Hyaluronidase, 80 U/mL in HEPES-HTF	ART-4007-A	6 x 1.0 mL

### INTENDED USE

Prior to intracytoplasmic sperm injection (ICSI), the cumulus cells have to be removed from the oocyte so that there is a clean surface on the zona pellucida to permit the easy handling of the oocyte with microtools for holding and injection. Brief exposure of the oocyte-cumulus masses to hyaluronidase solution digests the hyaluronic acid holding the cumulus cells together. The cumulus cells can then be more easily removed mechanically by pipetting the oocyte-cumulus mass through fine-bore pipettes slightly larger than the diameter of the oocyte.

### PRODUCT DESCRIPTION

Hyaluronidase is an enzyme found in high concentration in the acrosome of most mammalian spermatozoa. It randomly attacks the hexosaminidic linkage of hyaluronic acid, the glycosaminoglycan that makes up the extracellular matrix holding cumulus cells together.

This product contains 10 mg/L of gentamicin, an aminoglycoside antibiotic.

### PRECAUTIONS AND WARNINGS

Do not use medium that shows evidence of particulate matter or cloudiness, or is not rose-colored.

Hyaluronidase (Ref# 4007-A) contains 5 mg/mL of human serum albumin.

**Caution:** All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when testing for antibodies to HIV-1/HIV-2, HCV and non-reactive for HBsAg, HCV RNA and HIV-1 RNA. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents. Donors of the source material have been screened for Creutzfeldt-Jacobs 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.

**Note:** Embryo is considered a general term. More precisely, SAGE considers the period of time initiating when a single diploid cell results from the fusion of male and female genome resulting in zygote formation with subsequent development from repeated mitotic divisions forming a solid mass or morula (typically day 4-5) and after which a fluid-filled cavity develops resulting in blastocyst formation (typically day 5-6) ending with embryo implantation that begins the end of the first week and is completed by the end of the second week post conception.

**Caution:** U.S. Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

This product contains the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

### QUALITY ASSURANCE

One-cell MEA tested and passed with 80% or greater blastocyst. USP Endotoxin tested and passed with <1 EU/mL.

A Certificate of Analysis is available for this product.

### DIRECTIONS FOR USE

Oocyte-cumulus complexes (OCC) can be placed in a drop of hyaluronidase medium (100 µL) under oil (REF #4008). After 30 to 45 seconds, the OCCs are pipetted in and out of a fine-bore glass pipette to loosen the weakened cumulus mass and release the oocyte with attached corona radiata cells. The oocyte is then transferred to a 100-µL drop of Quinn's Advantage® Medium with HEPES (REF #1023/1024) containing 5 mg/mL HSA (REF #3001/3003) and the corona radiata cells removed by gentle pipetting using a narrow-bore glass pipette. The first pipette used to remove the oocyte with adhering corona radiata cells from the cumulus mass should have an inside diameter of 250 to 300 µm. The second pipette for the removal of the corona radiata cells should have a diameter of about 135 µm. The cumulus-free oocytes are further washed through a series (4-5) of 100-µL drops of Quinn's Advantage® Medium with HEPES (REF #1023/1024) containing 5 mg/mL HSA (REF #3001/3003) to remove excess hyaluronidase and detached cumulus cells. The oocytes are now ready for the ICSI procedure.

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

### STORAGE INSTRUCTIONS AND STABILITY

Store unopened containers at 2 °C to 8 °C upon receipt. Warm to incubator (37 °C) temperature prior to use. Exposure of the medium to CO<sub>2</sub> should be minimized to avoid pH levels of 7.0 or less. Do not expose to temperatures greater than 39 °C. The product is stable until the expiration date shown on the label.

- Remove desired volume of product using aseptic procedures.
- Once removed, do not return any volume of product to the original container.
- Do not use if the product becomes discolored, cloudy, turbid, or shows any evidence of microbial contamination.

To avoid problems with contamination, handle using aseptic techniques and discard any excess product that remains in the bottle or vial after procedure is completed.

### RELATED PRODUCTS

ART-4008P Oil for Tissue Culture

ART-1023/1024 Quinn's Advantage® Medium with HEPES

ART-3001/3003 Human Serum Albumin 100 mg/mL in normal saline


SAGE In Vitro Fertilization™ has a full line of products for the Reproductive Medicine Specialist. Please call or write for specific information or to receive a copy of our current catalog. For technical questions, or to reach our Customer Service Department, call the SAGE Support Line.

**Call the SAGE SUPPORT LINE:**  
In the U.S.: (800) 243-2974  
International: (203) 601-9818

### EXPLANATION OF SYMBOLS

 Catalog Number

 Batch Code

 Use By (year, month, day)


 Do Not Reuse

 Temperature Limitation  
2 °C 8 °C

 Aseptic Technique Sterilization Membrane Filtered (SAL 10<sup>-3</sup>)

 **ATTENTION:**  
See instructions for use.


 Manufacturer

 **Rx ONLY** U.S. Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).



SAGE In Vitro Fertilization, Inc.  
a CooperSurgical Company  
95 Corporate Drive  
Trumbull, CT 06611 USA

www.coopersurgical.com

 SAGE In Vitro Fertilization  
1979 East Locust Street  
Pasadena, CA 91107 USA