Hyaluronidase in FertiCult™ Flushing medium

MEDIA FOR USE IN ART PROCEDURES STERILE A

Hyaluronidase in FertiCult™ Flushing medium is sterilised by sterile filtration

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GENERAL INFORMATION

Hyaluronidase in FertiCult™ Flushing medium contains 80 IU /ml pharmaceutical grade hyaluronidase from bovine origin, in FertiCult Flushing medium™. The product is ready for use.

Hyaluronidase in FertiCult™ Flushing medium is used in the oocyte denudation process. Hyaluronidase digests the hyaluronic acid between the cumulus cells, which makes it easier to remove the cumulus mechanically.

MATERIAL INCLUDED IN THE KIT

Product Code: HYA001

1ml Hyaluronidase in FertiCult™ Flushing medium

Product Code: HYA010

10ml Hyaluronidase in FertiCult™ Flushing medium

MATERIAL NOT INCLUDED IN THE KIT

- Incubator (no CO_2)
- Petri dishes
- Glass pipettes
- Microscope
- FertiCult™ Mineral Oil

PRE-USE CHECKS

- Do not use the product if it becomes cloudy, or shows any evidence of microbial contamination
- Do not use the product if seal of the container is opened or defect when the product is delivered

INSTRUCTIONS FOR USE

1 Warm hyaluronidase to a temperature of 37°C.

2 Prepare a dish containing 1 droplet of hyaluronidase in FertiCult™ Flushing medium (100 µL) and 3-5 droplets (100µL) of FertiCult™ Flushing medium for oocyte washing (all under light paraffin oil e.g. FertiCult™ Mineral Oil).

3 Place oocytes in the hyaluronidase (up to 5 oocytes maximum) for about 30 seconds.

4 Using a fine glass pipette, transfer the partially denuded oocytes in the first washing droplet.

5 Remove the corona by pipetting the oocytes.

6 Use the other droplets to further wash the denuded oocytes.

Note: Do not incubate in a CO_2 incubator. Hyaluronidase in FertiCult™ Flushing medium is HEPES-buffered. Incubation in a CO_2 incubator will lower the pH below 7.

PRODUCT SPECIFICATIONS AND QUALITY CONTROL

Hyaluronidase in FertiCult™ Flushing medium is manufactured according to these specifications:

- pH: 7.30 - 7.60 (release criteria under air)
- Osmolality: 270 - 290 mOsm/kg
- Endotoxin: < 1.00 EU/ml
- Sterility: Sterile
- Mouse-embryo test: ≥ 80% blastocysts after 96 hours culture (exposure at zygote stage)
- Use of Ph Eur or USP grade products if applicable
- A certificate of analysis and MSDS are available upon request

STORAGE INSTRUCTIONS

- Store between 2-8°C
- Do not freeze before use
- Keep away from (sun)light
- The products can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C
- Do not use after expiry date

WARNINGS AND 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.

Handle all specimens as if capable of transmitting HIV or hepatitis. Always wear protective clothing when handling specimens.

The above media do not contain antibiotics, always work under strict hygienic conditions (e.g. LAF-bench ISO Class 5) to avoid contamination, or add your own antibiotics (gentamicin sulphate) at 10mg per liter.

Don't use media if liquid is cloudy.

BOVINE SOURCED HYALURONIDASE

The pharmaceutical grade hyaluronidase used in this product is derived from bovine testis and is certified with a TSE risk evaluation Certificate of Suitability (CEP).

The animals from which the hyaluronidase is derived, are determined "*fit for human consumption*" and originate from countries with "*negligible BSE risk*", as determined Resolution No. 20 "Recognition of the Bovine Spongiform Encephalopathy Risk Status of Member Countries (2013)", adopted by the OIE.

According to the WHO guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies (2010), testes from bovine source are classified as Category IC material (i.e. "Tissues with no detected infectivity").

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