

0245-04

ICSI Cumulase®

Product No.:

1612

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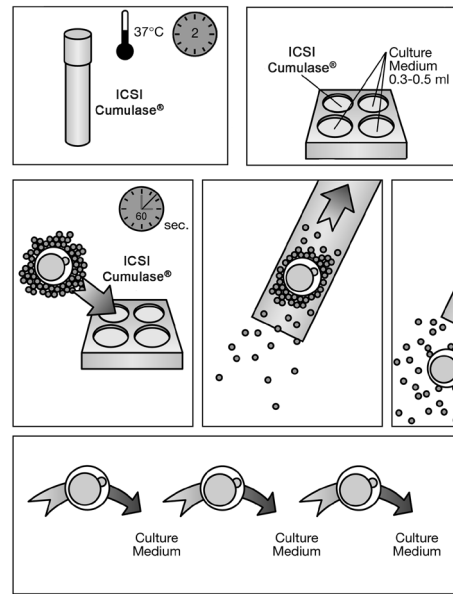
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ICSI Cumulase®

Intended use

ICSI Cumulase® is for the removal of the cumulus complex and corona radiata surrounding the oocyte in preparation for ICSI.

Composition

Recombinant Human Hyaluronidase (rHuPH20)
40-120 U/mL
Human serum albumin (HSA)
Glucose
Sodium pyruvate
Physiological salts
HEPES

Quality control testing

Sterility tested (Ph.Eur., USP)
Osmolality tested (Ph.Eur., USP)
pH tested (Ph.Eur., USP)
Endotoxin tested ≤ 0.1 EU/mL (Ph.Eur., USP)
1 cell Mouse Embryo Assay (MEA) ≥ 80%
Blastocysts by 96h
Enzyme activity 40-120 U/mL

Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.origio.com.

Storage instructions and stability

Store in original container at 2-8°C, protected from light.
Do not freeze.
Discard excess (unused) media following warming.
The product is provided in vials intended for single use.
When stored as directed by the manufacturer

the product is stable until the expiry date shown on the vial label.

Precautions and warnings

Do not use the product if:

1. Product packaging appears damaged or if the seal is broken.
 2. Expiry date has been exceeded.
- Do not re-use.

Caution: All blood products should be treated as potentially infectious. Source material used to manufacture this product were tested and found non-reactive for HbsAg and negative for Anti-HIV-1/-2, HIV-1, HBV, and HCV. Furthermore source material have been tested for parvovirus B19 and found to be non-elevated. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

Caution: US federal law restricts this device to sale by or on the order of a physician (Rx only).

Notes:

After retrieval of the oocytes, it is recommended that the oocyte rest in equilibrated culture medium for a minimum of 2 hours before denudation.
ICSI Cumulase® is HEPES buffered and pH-stable for use outside the incubator without prior equilibration. ICSI Cumulase® does not contain bicarbonate and should therefore not be placed in the CO₂ incubator without cap on.

Instructions for use

1. Warm ICSI Cumulase® to 37°C for 2 hours with cap on.
2. Fill one of the wells in a four-well dish with the content of one vial ICSI Cumulase® and the other three wells with your preferred, equilibrated culture medium.
3. Place one or several oocyte-cumulus complex(es) in the well with ICSI Cumulase®. After 60 seconds, gently aspirate the oocyte up and down until the oocyte(s) are denuded.
4. Transfer the oocyte(s) to a well with culture medium.
5. Wash the oocyte(s) thoroughly by transferring them between several wells of culture medium.
6. The oocyte(s) are then transferred to the injection dish and placed in individual microdrops covered with equilibrated Liquid Paraffin.

It is recommended to leave the oocyte(s) in culture medium for a short period before proceeding with ICSI.