

Hyaluronidase Solution

Hyaluronidase Solution is a convenient, ready-to-use solution designed for removing cumulus cells surrounding freshly retrieved oocytes prior to ICSI or other ART procedures.

This solution consists of 80 IU/mL of Hyaluronidase enzyme in a HEPES buffered HTF medium with therapeutic-grade human serum albumin (5mg/mL) and the antibiotic gentamicin sulfate (10µg/mL).

Irvine Scientific has performed extensive efficacy testing on Hyaluronidase Solution using freshly retrieved mouse oocytes and one-cell embryos.

The performance of Irvine Scientific's Hyaluronidase Solution was equivalent to control hyaluronidase solutions, and no toxicity was observed to mouse oocytes and embryos. The development of one-cell embryos to blastocysts was equivalent after exposure to Hyaluronidase Solution as compared to non-exposed controls (in growth medium only). The lot-to-lot performance of Hyaluronidase Solution was consistent for enzyme activity and the removal of cumulus cells from freshly retrieved oocytes within 2 minutes.

In addition to the mouse oocyte and embryo bioassays, Hyaluronidase Solution is also tested for enzyme activity using a standard enzymatic assay for Hyaluronidase. This permits verification of actual enzyme activity, in addition to the functional bioassay of cumulus cell removal and lack of toxicity.

Moreover, stability studies have been conducted to determine the enzymatic activity of Irvine Scientific's Hyaluronidase Solution after storage as recommended at refrigerated temperatures. The results (see Figure 4) show ≥95% of initial enzymatic activity (80 IU/mL) remains after 12 months storage at 2-8°C (refrigerated).

Hyaluronidase Solution, Catalog #90101 6.1. p.d.

- Available in kits of 5 X 1.0 mL
- The shelf life is 12 months when stored sealed at the recommended temperature of 2-8°C.
- Gentamicin sulfate is included as the antibiotic.

Features and Benefits

- Convenient ready-to-use solution for denuding oocytes of cumulus cells prior to ICSI or other ART procedures. Refer to product insert for detailed usage instructions.
- This solution contains HEPES buffered HTF medium to maintain proper pH during cumulus cell removal at ambient atmosphere conditions.

Oocyte Viability (Morphology at 24 hr)

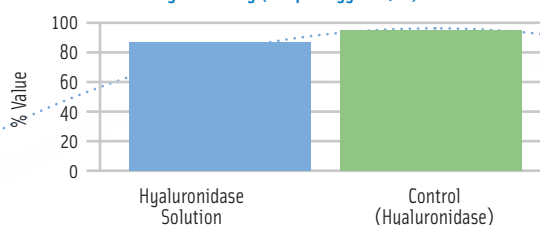


Figure 1. Freshly retrieved mouse oocytes were exposed to Hyaluronidase Solution (IS) or Control Hyaluronidase (in house) for 1-2 minutes with gentle pipetting to remove cumulus cells. Cumulus cells were dissociated within 2 minutes of exposure. Oocytes were then transferred to culture medium (HTF + 0.5% BSA) and viability was evaluated morphologically after 24 hours. The data is expressed as the % of oocytes that appeared normal after 24 hr incubation. Each bar represents the average (\pm SEM) of at least 5 experiments (n=150 embryos total for each condition).

Lot-to-Lot Comparison

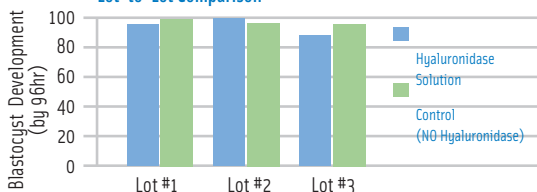


Figure 2. Fresh one-cell mouse embryos were retrieved and exposed to Hyaluronidase Solution for 1-2 minutes with gentle pipetting. Embryos were then washed and cultured in growth medium (HTF + 0.5% BSA) to the blastocyst stage. The data represents the rate of blastocyst development by 96 hours post retrieval for three different lots of Hyaluronidase Solution (n=31 embryos for each lot). Controls were exposed to, and cultured in, growth medium only (no hyaluronidase).

Enzyme Activity, Lot-to-Lot Comparison

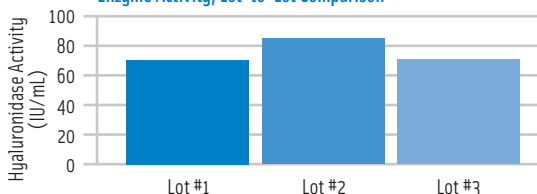


Figure 3. Samples of Hyaluronidase Solution were evaluated by a standard turbidimetric assay to determine specific activity of the enzyme.

Hyaluronidase Solution Stability (Refrigerated: 2-8°C)

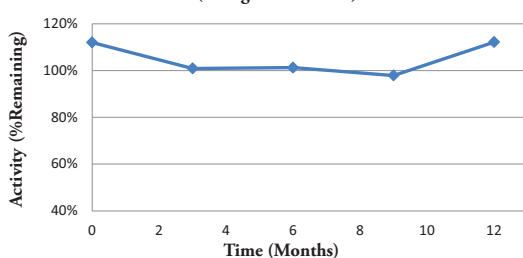


Figure 4. Hyaluronidase activity was determined following refrigerated storage up to 12 months.

Each lot of Hyaluronidase receives a complete laboratory evaluation including mouse embryo testing, endotoxin level, pH, osmolality and sterility testing. All results are provided in a lot-specific Certificate of Analysis.

Irvine Scientific's commitment to excellence is demonstrated by our products' performance and adherence to the industry's highest quality standards. We were one of the first companies in the USA to receive ISO 13485:2003 quality systems certification, the new rigorous international quality assurance standard designed specifically for Medical Devices.

Always refer to product insert for complete instructions for use. For more information on all of our Reproductive Products, call 1 (800) 437 5706.



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