

## Mouse Embryo Assay Certificate of Analysis

**Product:** Intelligent ICSI Micropipettes

<u>Catalog #:</u> IC.2.50.30.D

Lot Number: HIC241125

Expiration Date: 2027-11-25

Sterilization: The products were gamma irradiated at a minimum dose of 27.0 kGy and a

maximum dose of 36.0kGy on 11/27/2024. The validated sterile assurance level

is  $10^{-6}$ .

Assays	Specification	Results
Endotoxin Assay (LAL Test) <sup>1</sup>	≤0.5 EU/device	<0.03125EU/device
Mouse Embryo Assay (MEA) <sup>2</sup>	% expanded to blastocysts	
Control	80%	100%
This Lot	80%	100%

<sup>&</sup>lt;sup>1</sup>Utilizes the LAL gel clot assay with a sensitivity of 0.03125EU/mL

All assays were performed by an independent laboratory.

Approved by:

Date: 12/9/2024

QF-71-01-05 Rev. A

<sup>&</sup>lt;sup>2</sup>For a valid assay, at least 80% of 2-cell stage control embryos should develop to expanded blastocyst within 72 hours. The product is considered non-toxic if 80% of the embryos exposed to it develop to expanded and/or hatching blastocysts within 72 hours.