

## Mouse Embryo Assay Certificate of Analysis

**Product:** Intelligent ICSI Micropipettes

<u>Catalog #:</u> IC.1.50.35.A

Lot Number: HIC241225

**Expiration Date:** 2027-12-25

Sterilization:

The products were gamma irradiated at a minimum dose of 27.2 kGy and a sterile assurance of 24.8 kGy and 12/20/2024. The validated sterile assurance of 24.8 kGy and 2.2 kGy and 2.2 kGy and 3.2 k

maximum dose of 34.8kGy on 12/29/2024. 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: 1/9/2025

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.