

# CERTIFICATE OF ANALYSIS

**Product:** ICSI Injection Pipettes  
**Catalog #:** SIC-50V-35  
**Lot Number:** K01001CH  
**Expiration Date:** 2020-01-06  
**Sterilization:** The products were gamma irradiated at a minimum dose of 26.7 kGy and a maximum dose of 37.3 kGy on Jan. 7, 2017. The validated sterile assurance level is  $10^{-6}$ .

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

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

<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.

All assays were performed by an independent laboratory.

Approved by:



Date: 1/16/2017

**Sunlight Medical, Inc.**  
5570 Florida Mining BLVD, Suite 603, Jacksonville, FL 32257, U.S.A.  
Tel: (904) 886 2900 Fax: (904) 363 0958 Email: slm@sunlightmedical.net