

# CERTIFICATE OF ANALYSIS

**Product:** Blastomere Biopsy Pipettes

**Catalog #:** SBB-20X-00

**Lot Number:** N09037FA

**Expiration Date:** 2023-09-25

**Sterilization:** The products were gamma irradiated at a minimum dose of 28.1 kGy and a maximum dose of 35.7 kGy on Oct. 3, 2020. 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: 10/12/2020

**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