

# CERTIFICATE OF ANALYSIS

**Product:** Blastomere Biopsy Pipettes

**Catalog #:** SBB-20S-30

**Lot Number:** P11054SG

**Expiration Date:** 2024-11-25

**Sterilization:** The products were gamma irradiated at a minimum dose of 27.2 kGy and a maximum dose of 36.4 kGy on Nov. 29, 2021. 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%	95%
This Lot	≥80%	95%

<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: 12/6/2021

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