

CERTIFICATE OF ANALYSIS

Product: Blastomere Biopsy Pipettes
Catalog #: SBB-20S-30
Lot Number: N05018SG
Expiration Date: 2023-05-10
Sterilization: The products were gamma irradiated at a minimum dose of 26.3 kGy and a maximum dose of 33.7 kGy on May 22, 2020. The validated sterile assurance level is 10^{-6} .

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

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

² 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: 6/1/2020

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