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ELI Accession Number: SHI-8391-0622

Date of completion: 06-11-2022

Lot number: P22E26-09

Reference number: A-OVM-SL 17/35

Description of test articles: ACE Single Lumen Ovum Pickup Needle 17G, 35cm

Assay system requested by customer: 1 mL of culture medium supplemented with 0.4% BSA was flushed in and out of the test article three times and incubated at 37°C and 5% CO₂ for 30-minutes. Post incubation three 12.5µl drops of the culture medium extracted from the test article was placed in the wells of a multi-well dish and overlaid with oil. 21 one-cell mouse embryos were added to the wells and cultured for 96-hours.

Control assay method and results: 21 one-cell (B6C3F1 X B6D2F1) embryos were cultured in triplicate micro drops of culture medium supplemented with 0.4% BSA:

21 / 21 (100 %)	1-cell to 2-cell within 24 hr
21 / 21 (100 %)	1-cell to expanded blastocyst within 72 hr

For a valid assay, Embryotech™ requires at least 80% of one-cell control embryos to develop to expanded blastocyst within 96-hours.

Test assay method and results: 21 one-cell (B6C3F1 X B6D2F1) embryos were cultured in triplicate micro drops of extracted culture medium supplemented with 0.4% BSA:

21 / 21 (100 %)	1-cell to 2-cell within 24 hr
21 / 21 (100 %)	1-cell to expanded blastocyst within 96 hr

Pass/Fail = Pass

Summary of observations: All test and control embryos were selected randomly from a common pool of freshly collected embryos and were cultured in the same incubator at 37°C and 5.0% CO₂. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 100 percent of the test embryos cultured in the extracted culture medium developed to the expanded blastocyst stage within 96- hours.



 Signature
 Study Director

06-13-2022


 Date



 Signature
 Quality Reviewer

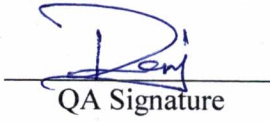
06-13-2022

 Date

	FORMS & FORMATS		DEPARTMENT: QA	
	CERTIFICATE OF ANALYSIS- OVUM PICK UP NEEDLES			COA/058
	REV NO.: 00	ISSUE NO.: 04	EFFECTIVE DATE: 30/09/2020	Page 1 of 1

Prepared by: Sujit Panigrahi <small>DocuSigned by: Sujit Panigrahi 0C568C8B40844E0...</small> 30/09/2020	Reviewed by: Hardik Chavda <small>DocuSigned by: Hardik Chavda 38FEAFF58B824C0...</small> 30/09/2020	Approved by: Rajesh R <small>DocuSigned by: Rajesh R FD7C7E8DC2CD4E2...</small> 30/09/2020
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This is to certify that Ovum Pick up Needles described below was manufactured, inspected and packed in accordance with our written specifications, under applicable controls of a documented Quality system.

Product Name		
ACE Ovum Pick-Single Lumen Ovum Pickup Needle 17G, 35cm		
Reference Number	Lot Number	Expiration Date
A-OVM-SL 17/35	P22E26-09	2027-04
Indications for use: Allwin Ovum Pickup Needles are used for laparoscopic or ultrasound guided transvaginal retrieval of oocytes from ovarian follicles.		
R_x Caution: Federal Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.		
Parameters	Acceptance Criteria	Result
Mouse Embryo Assay (MEA)	≥ 80%	PASS
Endotoxin Testing	≤ 20 EU/device	PASS
Conclusion: <input checked="" type="checkbox"/> Release <input type="checkbox"/> Reject	 QA Signature	<u>15/06/2022</u> Date