



SparMED Aps
Ryttermarken 2
3520 Farum
Denmark



140 Hale Street
Haverhill, MA 01830
qc@embryotech.com

ELI Accession Number: SPAR-1215-0219

Date of completion: 02-10-2019

Lot number: 07984

Reference number: OOPW-IC03

Description of test article(s): Oosafe® ICSI/IMSI Dish for Sperm Selection

Assay system requested by customer: Three 20µl drops of the culture medium was placed in the test article and overlaid with oil. 21 one cell mouse embryos (7 per drop) were placed in each drop and cultured for 96-hours.

Control assay method and results: 15 one cell (B6C3F1 X B6D2F1) embryos were cultured in 1mL drops of culture medium overlaid with oil in an OPU Tube:

15 / 15 (100 %)

1-cell to 2-cell within 24 hr

15 / 15 (100 %)

1-cell to expanded blastocyst within 96 hr

For a valid assay, Embryotech™ requires at least 70% of one cell stage 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 the test article using culture medium:

21 / 21 (100 %)

1-cell to 2-cell within 24 hr

21 / 21 (100 %)

1-cell to expanded blastocyst within 96 hr

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 embryos cultured in the test article developed to the expanded blastocyst stage within 96-hours.

Signature
Study Director

02-11-2019
Date

Signature
Quality Reviewer

02-11-2019
Date