

## SparMED Aps Ryttermarken 2 3520 Farum Denmark



ELI Accession Number: SPAR-7689-1017

Date of completion: 10-28-2017

Lot number: 07791

Reference number: OOPW-IC03

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

Assay system requested by customer:  $3\ 20\mu L$  of culture medium was placed in the center well of the test article and overlaid with oil. One cell mouse embryos were then placed into the test article and cultured for 96-hours.

**Control assay method and results:** 15 1-cell (B<sub>6</sub>C<sub>3</sub>F<sub>1</sub> X B<sub>6</sub>D<sub>2</sub>F<sub>1</sub>) embryos were cultured in 0.5ml drops of culture medium overlaid with oil in a 4-well Dish Reference number 144444:

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, <u>Embryotech™</u> requires at least 70% of 1-cell stage control embryos to develop to expanded blastocyst within 96-hours.

Test assay method and results: 21 1-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% CO<sub>2</sub>. 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

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Signature

Quality Reviewer

10-30-2017

Date