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Lot number: 07603, 07506

Reference number: OOPW-IC03, OOPW-IC01

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

Assay system requested by customer: 1mL of culture medium was placed in the test article (OOPW-IC03) and incubated at 37°C for 30-minutes. Post incubation three 20µl of the culture medium was extracted from the test article (OOPW-IC01) and placed into another test article. 1-cell mouse embryos were then added to each drop of extract medium in the second test article and cultured for 96-hours.

Control assay method and results: 15 1-cell (B6C3F1 X B6D2F1) embryos were cultured in 0.5mL drops in a non-treated 4-Well Dish using culture medium:

15 / 15 (100 %)
 15 / 15 (100 %)

1-cell to 2-cell within 24 hr
 1-cell to expanded blastocyst within 96 hr

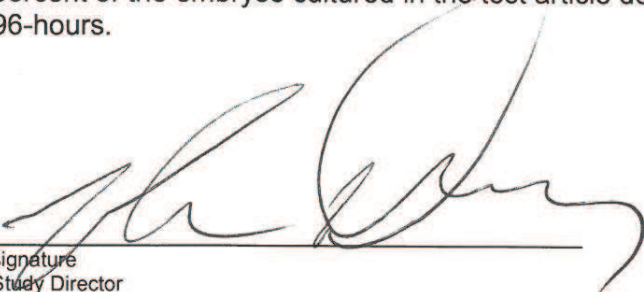
For a valid assay, Embryotech™ requires at least 70% of 1-cell stage control embryos to develop to expanded blastocyst within 96-hours.

Test assay method and results: 21 1-cell (B6C3F1 X B6D2F1) embryos were cultured in one of the test articles using the culture medium from the other test article:

21 / 21 (100 %)
 18 / 21 (86 %)

1-cell to 2-cell within 24 hr
 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. 86 percent of the embryos cultured in the test article developed to the expanded blastocyst stage within 96-hours.



 signature
 Study Director

11-17-2015

 date



 signature
 Quality Reviewer

11-18-2015

 date