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ELI Accession Number: SPAR-4065-1215

Date of completion: 12-22-2015

Lot numbers: 07603

Reference numbers: OOPW-SC01, OOPW-CT01
 OOPW-AT10, OOPW-OT10

Description of test article(s):

Oosafe® Sperm Collection Cup, Centrifuge Tube, Andrology Tube, OPU Tube

Assay system requested by customer: 1mL of culture medium was placed in each of the test articles (3) (OOPW-SC01, OOPW-CT01, OOPW-AT10) and incubated at 37°C for 30-minutes. Post incubation the culture medium was extracted from each test article and pooled. 1mL of the extracted culture medium was expelled into the fourth test article OOPW-OT10 overlaid with oil. One-cell mouse embryos were then added to each well of the 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 60x15mm 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 extracted culture medium:

21 / 21 (100 %)
 21 / 21 (100 %)

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

signature
 Study Director

12-24-2015
 date

signature
 Quality Reviewer

12-24-2015
 date