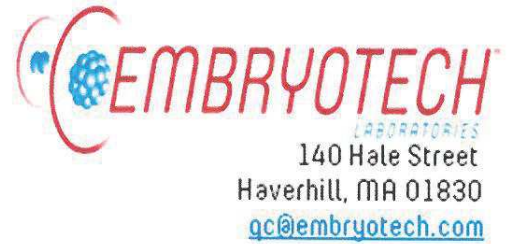


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ELI Accession Number: SPAR-6493-0317

Date of completion: 03-26-2017

Lot number: 07730

Reference number: OOPW-IC02

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

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

Control assay method and results: 15 one cell (B₆C₃F₁ X B₆D₂F₁) embryos were cultured in a 1mL drop of culture medium:

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

03-27-2017
Date


Signature
Quality Reviewer

03-27-2017
Date