

CERTIFICATE OF ANALYSIS

SparMED Aps
Toppevadvej 34-38
DK-3660
Stenlose, Denmark



ELI accession number: SPAR-9866-0514

Test Date: 05-16-2014

Reference number: OOPW-SW01, OOPW-SW04, OOPW-CW02,
OOPW-FW02, OOPW-FW04, OOPW-CT01,
OOPW-CW03

Lot number: 07506

Description of test article(s): Oosafe® 6 Well Dish (2), Center Well Dish (2),
4 Well Dish Treated, 4 Well Dish-NonTreated, Centrifuge Tube

Assay system requested by customer: "Embryo-tested" culture medium supplemented with 0.4% BSA was placed in the 6 Well Dishes (2), the Center Well Dishes (2), the 4-Well NonTreated Dish, and the Centrifuge Tube. The test articles were incubated for 30 minutes at 37°C in an atmosphere containing 5.0% CO₂. Post incubation, the "embryo-tested" culture medium was extracted from each of the test articles and pooled. 700µL drops of the extracted culture medium was added to each well of the 4 Well Treated Surface Dish and 1-cell mouse embryos were then added to each well and cultured for 96-hours.

Control assay materials and results: 15 1-cell (B₆C₃F₁ X B₆D₂F₁) embryos were cultured in 700µl drop in a 4-well Dish using "embryo-tested" culture medium supplemented with 0.4% BSA:

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 1-cell stage control embryos to develop to expanded blastocyst within 96-hours.

Test assay materials and results: 21 1-cell (B₆C₃F₁ X B₆D₂F₁) embryos were cultured in the 4 Well Dish Treated Surface, using "embryo-tested" culture medium supplemented with 0.4% BSA, extracted and pooled from each of the test articles:

21 / 21 (100 %)

1-cell to 2-cell within 24 hr

20 / 21 (95 %)

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 in an atmosphere containing 5.0% CO₂. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 95 percent of the embryos cultured in the extracted "embryo tested" culture medium developed to the expanded blastocyst stage within 96-hours.


signature
Study Director

05-16-2014
date


signature
Quality Reviewer

05-16-2014
date