

# CERTIFICATE OF ANALYSIS

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



ELI accession number: SPAR-9824-0414

Test Date: 04-26-2014

Reference number: OOPW-ST10, OOPW-CW10, OOPW-IC10,  
OOPW-TF10, OOPW-HD10, OOPW-HD01,  
OOPW-FW03, OOPW-TF01, OOPW-IC01,  
OOPW-FW01

Lot number: 07506

Description of test article(s): Oosafe® 60 mm Dish, Center Well Dish, ICSI Dish (2),  
35 mm Dish (2), 100 mm Dish (2), 4 Well Dish Treated  
Surface, 4 Well Dish Non Treated Surface

Assay system requested by customer: A 700µl drop of "embryo-tested" culture medium supplemented with 0.4% BSA was placed in each of the test articles, and incubated for 30 minutes at 37°C in an atmosphere containing 5.0% CO<sub>2</sub>. 1-cell mouse embryos were then added to the 4 Well Dish Treated Surface containing 700uL drops of culture medium, extracted and pooled from the test articles, in 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

19 / 21 ( 90 %)

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% CO<sub>2</sub>. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 90 percent of the embryos cultured in the extracted "embryo tested" culture medium developed to the expanded blastocyst stage within 96-hours.

signature  
Study Director

date

signature  
Quality Reviewer

date