

# CERTIFICATE OF ANALYSIS

SparMED Aps  
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ELI accession number: SPAR-7854-0613

Date of completion: 07-05-2013

Reference number: OOPW-HD10, OOPW-ST10,  
OOPW-CT01, OOPW-IC10,  
OOPW-TF10, OOPW-CW10,  
OOPW-FW04

Lot number: 07302

Description of test article(s): Oosafe® IVF Tested Plasticware

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; 1-cell mouse embryos were then added to each test article (~10-11) and cultured for 96-hours.

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

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 materials and results: 21 1-cell (B6C3F1 X B6D2F1) embryos were cultured in each of the test articles (10-11 embryos per test article) using "embryo-tested" culture medium supplemented with 0.4% BSA:

21 / 21 (100 %)  
20 / 21 ( 95 %)

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

  
signature  
Study Director

07-05-2013  
date

  
signature  
Quality Reviewer

07-05-2013  
date