

# CERTIFICATE OF ANALYSIS

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



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Catalog number: OOPW-IC01  
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Lot number: 07206  
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Description of test article(s): ICSI Dish and Specimen Cup

**Assay system requested by customer:** A 1mL drop of "embryo-tested" culture medium supplemented with 0.4% BSA was placed in the test article (specimen cup) and incubated for 30-minutes. Post incubation the "embryo-tested" culture medium was extracted from the test article and 3-20µl drops of the extract were placed in the test article (ICSI dish) and overlaid with oil; 1-cell mouse embryos were then added to each extract drop of media and cultured for 96-hours.

**Control assay materials and results:** 15 1-cell (B6C3F1 X B6D2F1) embryos were cultured in 3-20µl drops of "embryo-tested" culture medium supplemented with 0.4% BSA in a ICSI Dish:


15 / 15 (100 %)	1-cell to 2-cell within 24 hr
14 / 15 ( 93 %)	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 3-20µl drops of "embryo-tested" culture medium supplemented with 0.4% BSA in the test:

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>. 93 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 90 percent of the test embryos incubated and cultured in the test articles developed to the expanded blastocyst stage within 96-hours.

  
signature  
Study Director

02-19-2013  
date

  
signature  
Quality Reviewer

02-19-2013  
date