# CERTIFICATE OF ANALYSIS

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

EMBRYOTECH LABORATORIES
140 Hale Street
Haverhill, MA 01830
qc@embryotech.com

**ELI Accession Number:** SPAR-3841-1115

**Date of completion:** 11-17-2015

**Lot numbers:** 07603, 07506

**Reference numbers:** OOPW-FW04, OOPW-HD10
OOPW-CT01, OOPW-SC01

**Description of test article(s):**
Oosafe® 4 Well Dish, 100mm Dish, Centrifuge Tube and Sperm Collection Cup

**Assay system requested by customer:** 1mL of culture medium was placed in each of the test articles (3) (OOPW-HD10, OOPW-CT01, OOPW-SC01) and incubated at 37°C for 30-minutes. Post incubation the culture medium was extracted from each test article and pooled. 0.5mL of the extracted culture medium was expelled into each well of the test article (4-well NonTreated dish); 1-cell mouse embryos were then added to each well of the test article and cultured for 96-hours.

**Control assay method and results:** 15 1-cell ($B_6C_3F_1$ X $B_6D_2F_1$) embryos were cultured in 0.5mL drops in a non-treated 4-Well Dish using 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 1-cell stage control embryos to develop to expanded blastocyst within 96-hours.*

**Test assay method and results:** 21 1-cell ($B_6C_3F_1$ X $B_6D_2F_1$) embryos were cultured in one of the test articles using the extracted culture medium:

| | |
|---|---|
| 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 and 5.0% $CO_2$. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 90 percent of the embryos cultured in the test article developed to the expanded blastocyst stage within 96-hours.

signature
Study Director

11-17-2015
date

signature
Quality Reviewer

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**ELI Accession Number:** SPAR-3841-1115 **Date of completion:** 11-17-2015

**Lot number:** 07603, 07506 **Reference number:** OOPW-IC03, OOPW-IC01

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

**Assay system requested by customer:** 1mL of culture medium was placed in the test article (OOPW-IC03) and incubated at 37°C for 30-minutes. Post incubation three 20µl of the culture medium was extracted from the test article (OOPW-IC01) and placed into another test article. 1-cell mouse embryos were then added to each drop of extract medium in the second test article and cultured for 96-hours.

**Control assay method and results:** 15 1-cell ($B_6C_3F_1$ X $B_6D_2F_1$) embryos were cultured in 0.5mL drops in a non-treated 4-Well Dish using 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 1-cell stage control embryos to develop to expanded blastocyst within 96-hours.*

**Test assay method and results:** 21 1-cell ($B_6C_3F_1$ X $B_6D_2F_1$) embryos were cultured in one of the test articles using the culture medium from the other test article:

| | |
|---|---|
| 21 / 21 (100 %) | 1-cell to 2-cell within 24 hr |
| 18 / 21 ( 86 %) | 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% $CO_2$. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 86 percent of the embryos cultured in the test article developed to the expanded blastocyst stage within 96-hours.

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**Lot number:** 07603 **Reference number:** OOPW-TF03, OOPW-TF02

**Description of test article(s):** Oosafe® 35mm Dish, High Wall

**Assay system requested by customer:** 1mL of culture medium was placed in the test article (OOPW-TF03) and incubated at 37°C for 30-minutes. Post incubation three 20µl of the culture medium was extracted from the test article (OOPW-TF02) and placed into another test article. 1-cell mouse embryos were then added to each drop of extract medium in the second test article and cultured for 96-hours.

**Control assay method and results:** 15 1-cell ($B_6C_3F_1$ X $B_6D_2F_1$) embryos were cultured in 0.5mL drops in a non-treated 4-Well Dish using 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 1-cell stage control embryos to develop to expanded blastocyst within 96-hours.*

**Test assay method and results:** 21 1-cell ($B_6C_3F_1$ X $B_6D_2F_1$) embryos were cultured in one of the test articles using the culture medium from the other test article:

| | |
|---|---|
| 21 / 21 (100 %) | 1-cell to 2-cell within 24 hr |
| 18 / 21 ( 86 %) | 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% $CO_2$. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 86 percent of the embryos cultured in the test article developed to the expanded blastocyst stage within 96-hours.

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**ELI Accession Number:** SPAR-3841-1115

**Date of completion:** 11-17-2015

**Lot number:** 07506

**Reference number:** OOPW-ST01

**Description of test article(s):** Oosafe® 60mm Dish

**Assay system requested by customer:** 1mL of culture medium was placed in the test article. 1-cell mouse embryos were then added to each well of the test article and cultured for 96-hours.

**Control assay method and results:** 15 1-cell ($B_6C_3F_1$ X $B_6D_2F_1$) embryos were cultured in 1mL drops in a non-treated 4-Well Dish using 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 1-cell stage control embryos to develop to expanded blastocyst within 96-hours.*

**Test assay method and results:** 21 1-cell ($B_6C_3F_1$ X $B_6D_2F_1$) embryos were cultured in one of the test articles using the culture medium from the other test article:

| | |
|---|---|
| 21 / 21 (100 %) | 1-cell to 2-cell within 24 hr |
| 18 / 21 ( 86 %) | 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% $CO_2$. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 86 percent of the embryos cultured in the test article developed to the expanded blastocyst stage within 96-hours.

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**Lot number:** 07603

**Reference number:** OOPW-CW05

**Description of test article(s):** Oosafe® Center Well Dish with 2 Compartments Label Area Grip

**Assay system requested by customer:** 1mL of culture medium was placed in the center well of test article. 1-cell mouse embryos were then added to center well of the test article and cultured for 96-hours.

**Control assay method and results:** 15 1-cell ($B_6C_3F_1$ X $B_6D_2F_1$) embryos were cultured in 1mL drops in a non-treated 4-Well Dish using 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 1-cell stage control embryos to develop to expanded blastocyst within 96-hours.*

**Test assay method and results:** 21 1-cell ($B_6C_3F_1$ X $B_6D_2F_1$) embryos were cultured in one of the test articles using the culture medium from the other test article:

| | |
|---|---|
| 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 and 5.0% $CO_2$. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 90 percent of the embryos cultured in the test article developed to the expanded blastocyst stage within 96-hours.

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