

**Manufacturer:**  
Sparmed ApS/CVR.No.: 30898575  
Ryttermarken 2, 3520 Farum, Denmark



ID: COA-07603

## Certificate of Analysis

**Date of issue:** 25.02.2016  
**Product ID:** Oosafe® Plasticware: OOPW-TF04  
**LOT No.:** 07603  
**Expiry Date:** 09/2020  
**Storage conditions:** 20<sup>0</sup>C, dry room, no exposal to sun-light  
**Quality Assurance:**

Proven non-embryotoxic by Mouse Embryo Assay Test. 100% embryo development to the expanded blastocyst stage within 96hours. **PASS**  
Proved stable human sperm motility: ≥70% sperm motility after 24hours proven. **PASS**

Proven non-toxic by Limulus Amebocyte Lysate (LAL) test. Pass criteria <0.03 EU/device **PASS**

Proven RNase DNase test FREE- **PASS**

Sterilization by gamma irradiation. Delivered irradiation dose: 8.6kGy-9.5kGy. Specified irradiation dose: 8.0kGy-10.0kG- **PASS**

Quality control according to the ISO 13485:2012

**Final approval:**

**Stamp:**

Camilla Inesa Nielsen  
Regulatory Affairs Manager





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



140 Hale Street  
 Haverhill, MA 01830  
[qc@embryotech.com](mailto:qc@embryotech.com)

ELI Accession Number: SPAR-4065-1215

Date of completion: 12-22-2015

Lot number: 07603

Reference number: OOPW-TF04, OOPW-TF05

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

Assay system requested by customer: 100µL of culture medium was placed in each test article (2) and overlaid with oil. One-cell mouse embryos (10-11 per test article) were then added to each test article and cultured for 96-hours.

Control assay method and results: 15 1-cell (B6C3F1 X B6D2F1) embryos were cultured in a 100µL drop in a 60x15mm dish using culture medium:

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 method and results: 21 1-cell (B6C3F1 X B6D2F1) embryos were cultured in the test articles:

21 / 21 (100 %)  
 21 / 21 (100 %)

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 and 5.0% CO<sub>2</sub>. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 100 percent of the embryos cultured in the test article developed to the expanded blastocyst stage within 96-hours.

  
 signature  
 Study Director

12-24-2015  
 date

  
 signature  
 Quality Reviewer

12-24-2015  
 date





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 Toppevadvej 34-38, DK-3660  
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ELI Accession Number: S2325-1215SPAR

Date of completion: 12-22-2015

Lot number: 07603

Order numbers: OOPW-TF04, OOPW-TF05, OOPW-HD02,  
 OOPW-HD03, OOPW-SC01, OOPW-CT01,  
 OOPW-AT10, OOPW-OT10

**Description of test article(s):**

Oosafe® 35mm Dish High Wall, 100mm Dish, Sperm Collection Cup,  
 Centrifuge Tube, Andrology Tube, OPU Tube

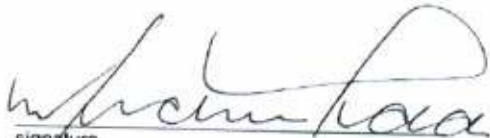
**Assay system requested by customer:** 100µL of sperm wash medium was added to the test articles (8 test articles pooled) and incubated for 30-minutes. Post incubation the sperm wash medium was extracted from the test articles and pooled. The pooled extracted medium was placed in OOPW-TF05 with the sperm and incubated for 24-hour incubation.

**Test Assay method and results:** A non-frozen donor sperm specimen was obtained and used for this assay. The sperm was prepared and the motile fraction separated using a sperm gradient and centrifuge cycle. The motility was noted at the beginning of the assay and again at 24-hours using a measure depth Makler Chamber System. Analyses were performed in sequence each time, with no more than 5-minutes between the test and the control samples.

**Results:**

Test method: SOP/TSG/ELI/008	Specification	Initial	Result % 24hr	SMI Value	Pass/Fail
Test Article	SMI ≥ 0.75	95%	95%	1.00	Pass
Control	≥ 70%	95%	95%	N/A	Pass

**Summary of observations:** The motility remained consistent in the test article extract and control while in an incubator atmosphere of 32°C and 5% CO<sub>2</sub>. Neither the test nor the control showed any signs that the motility was affected during the course of the assay.

  
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 Study Director

12-22-2015  
 date

  
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 Quality Reviewer

12-22-2015  
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ELI Accession Number: E6767-1215SPAR

Date of completion: 12-18-2015

Lot number: 07603

Order number(s): OOPW-HD02, OOPW-HD03, OOPW-TF04,  
 OOPW-TF05, OOPW-SC01, OOPW-CT01,  
 OOPW-AT10, OOPW-OT10

Description of test article(s): Oosafe® 100mm Dish, 35mm Dish High Wall, Sperm  
 Collection Cup, Centrifuge Tube, Andrology Tube, OPU Tube

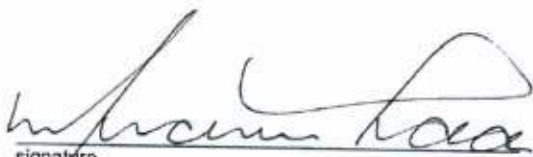
Assay system requested by customer: Endotoxin titer and interference screening using the  
 Gel-Clot method.

LAL lot number: 515-05-733  
 CSE lot number: 143  
 LRW lot number: AZA182110

Sensitivity ( $\lambda$ ) = 0.03 EU/mL

Control Standard Series			Test Sample Dilutions	NPC		PPC	
2 $\lambda$ .06	+	+	Undiluted	-	-	+	+
$\lambda$ .03	+	+	1:2	-	-	+	+
$\frac{1}{2}\lambda$ .015	-	-	1:4	-	-	+	+
$\frac{1}{4}\lambda$ .0075	-	-	1:8	-	-	+	+
NWC	-	-	1:16	-	-	+	+

Summary of observations: The error for the Gel-Clot assay is +/- one two-fold dilution.  
 The test article in this assay indicates an Endotoxin Concentration of < 0.03 EU/device.

  
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12-22-2015  
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12-22-2015  
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## RNase Test Data and Results

Date: 1/7/2016  
Company: Sparmed ApS  
Date received: 1/4/2016

Project #: 113376A  
Contact: Onur Ozturk  
Technician: Chase Wong

PO#: 122715  
Phone: 45- 39 40 2503

Products tested:	Product code:	Lot #:
Oosafe Sperm Collection Cup	OOPW-SC01	07603
Oosafe 35 MM DISH	OOPW-TF04	07603
Oosafe 35 MM DISH	OOPW-TF05	07603
Oosafe CENTER WELL	OOPW-CW04	07603
Oosafe CENTER WELL	OOPW-CW06	07603
Oosafe CENTER WELL	OOPW-CW07	07603
Oosafe 60MM DISH	OOPW-ST02	07603
Oosafe 60MM DISH	OOPW-ST04	07603
Oosafe 60MM DISH	OOPW-ST05	07603
Oosafe ICSI/MSI DISH for Sperm Selection	OOPW-IC02	07603

### Extraction:

Extract solution: DEPC Treated Water  
Lot #: DW15A6  
Volume: 200µl

Number of test items exposed to extract solution: 10  
Special extraction instructions: All items tested pooled

### Procedure and Controls:

RNA: 6.0 kb Poly (A)-tailed  
RNA lot #: 1310020  
Salts: MgCl<sub>2</sub> and NaCl  
Salt lot #: S15G2

RNA standard pool: 3µl of RNA + 12µl Salts.  
Volume of each standard reaction: 5µl  
Volume of extract added to the standard: 10µl  
Total volume: 15µl

Negative Control (-): RNA and salt standards with 10 µl of unexposed extract solution added  
Positive Control (+): RNA and salt standards with 10 µl of extract solution exposed to RNase from a tip touched by ungloved hands  
Incubation periods: 1 hr @ 37°C, followed by 5 minutes at 65°C

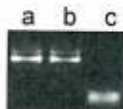
### Gel Electrophoresis:

2µl gel loading dye + 15µl reaction is loaded on a 1.2% agarose in ½ X TAE gel

Gel loading dye lot #: DD006

Electrophoresis: 20 minutes @ 80 volts

### Photographic Results:



Lane (a) Pooled products, (b) unexposed RNA standard as a negative control, (c) RNA standard exposed to RNase as a positive control.

### Conclusions:

There is no visible degradation in lanes (a) and (b). Lane (a) represents the product sample and lane (b) represents the negative control. Lane (c), which represents the RNA standard, exposed to RNase as a positive control shows degradation of the RNA. The results suggest that the product sample is free of detectable RNase contamination.

### Recommendations:

Based on this experimental procedure, we can show a definite risk of RNase contamination if your product is touched by un-gloved hands. We suggest that all operations are monitored and personnel are instructed in the importance of avoiding RNase contamination.



Chase Wong  
Lab Technician

1/11/2016  
Date



Carl Tsang  
Q.A.

1/11/2016  
Date



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### RNase FREE CERTIFICATE OF ANALYSIS

1/11/2016

The following sample obtained from **Sparmed ApS** on 1/4/2016 is free of any detectable RNase contamination.

<u>PRODUCTS TESTED</u>	<u>PRODUCT CODE</u>	<u>LOT NUMBER</u>
Oosafe Sperm Collection Cup	OOPW-SC01	07603
Oosafe 35 MM DISH	OOPW-TF04	07603
Oosafe 35 MM DISH	OOPW-TF05	07603
Oosafe CENTER WELL	OOPW-CW04	07603
Oosafe CENTER WELL	OOPW-CW06	07603
Oosafe CENTER WELL	OOPW-CW07	07603
Oosafe 60MM DISH	OOPW-ST02	07603
Oosafe 60MM DISH	OOPW-ST04	07603
Oosafe 60MM DISH	OOPW-ST05	07603
Oosafe ICSI/MSI DISH for Sperm Selection	OOPW-IC02	07603

Product was tested for RNase activity by the following protocol:

Product was extracted in RNase free water. The extract was then added to an RNA standard. The RNA standard was incubated at 37° C for 1 hour then heated to 65° C for 5 minutes. RNA samples were then run on an agarose gel, photographed, and evaluated for degradation.

FIGURE 1.



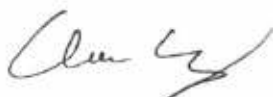
Lane (a) **Pooled products**, (b) unexposed RNA standard as a negative control, (c) RNA standard exposed to RNase as a positive control.

**Conclusions:**

No visible degradation is present in the product sample. The product can therefore be considered RNase free.

**Comments:**

The Test Sensitivity is 10<sup>-9</sup> Kunitz Units/ µl.



Certified by: Chase Wong, 1/11/2016



Q.A. Carl Tsang, 1/11/2016



## DNase Test Data and Results

Date: 1/7/2016  
Company: Sparmed ApS  
Date Received: 1/4/2016

Project #: 113376B  
Contact: Onur Ozturk  
Technician: Chase Wong

PO#: 122715  
Phone: 45- 39 40 2503

### Products tested:

Oosafe Sperm Collection Cup  
Oosafe 35 MM DISH  
Oosafe 35 MM DISH  
Oosafe CENTER WELL  
Oosafe CENTER WELL  
Oosafe CENTER WELL  
Oosafe 60MM DISH  
Oosafe 60MM DISH  
Oosafe 60MM DISH  
Oosafe ICSI/MSI DISH for Sperm Selection

### Product code:

OOPW-SC01  
OOPW-TF04  
OOPW-TF05  
OOPW-CW04  
OOPW-CW06  
OOPW-CW07  
OOPW-ST02  
OOPW-ST04  
OOPW-ST05  
OOPW-IC02

### Lot #:

07603  
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### Extraction:

Extract solution: DEPC Treated Water  
Lot #: DW15A6  
Volume: 200 $\mu$ l

Number of test items exposed to extract solution: 10  
Special extraction instructions: All items tested pooled

### Procedure and Controls:

DNA: 1 kb Ladder  
DNA lot #: 1735579  
Salts: MgCl<sub>2</sub> and NaCl  
Salt lot #: S15G2

DNA standard pool: 3 $\mu$ l of DNA + 12 $\mu$ l Salts.  
Volume of each standard reaction: 5 $\mu$ l  
Volume of extract added to the standard: 10 $\mu$ l  
Total volume: 15 $\mu$ l

Negative Control (-): DNA and salt standards with 10  $\mu$ l of unexposed extract solution added

Positive Control (+): DNA and salt standards with 10  $\mu$ l of extract solution exposed to DNase from a tip exposed to human saliva

Incubation periods: 1 hr @ 37°C, followed by 5 minutes at 65°C

### Gel Electrophoresis:

2 $\mu$ l gel loading dye + 15 $\mu$ l reaction is loaded on a 1.2% agarose in 1/2 X TAE gel

Gel loading dye lot #: DD006

Electrophoresis: 30 minutes @ 80 volts

### Photographic Results:

a b c



Lane (a) Pooled products, (b) unexposed DNA standard as a negative control, (c) DNA standard exposed to DNase as a positive control.

### Conclusions:

There is no visible degradation in lanes (a) and (b). Lane (a) represents the product sample and lane (b) represents the negative control. Lane (c), which represents the DNA standard, exposed to DNase as a positive control shows degradation of the DNA. The results suggest that the product sample is free of detectable DNase contamination.

### Recommendations:

Based on this experimental procedure, we can show a definite risk of DNase contamination if your product is exposed to saliva. We suggest that all operations are monitored and personnel are instructed in the importance of avoiding DNase contamination.

Chase Wong  
Lab Technician

1/11/2016  
Date

Carl Tsang  
Q.A.

1/11/2016  
Date



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### DNase FREE CERTIFICATE OF ANALYSIS

1/11/2016

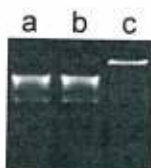
The following sample obtained from **Sparmed ApS** on 1/4/2016 is free of any detectable DNase contamination.

<u>PRODUCTS TESTED</u>	<u>PRODUCT CODE</u>	<u>LOT NUMBER</u>
Oosafe Sperm Collection Cup	OOPW-SC01	07603
Oosafe 35 MM DISH	OOPW-TF04	07603
Oosafe 35 MM DISH	OOPW-TF05	07603
Oosafe CENTER WELL	OOPW-CW04	07603
Oosafe CENTER WELL	OOPW-CW06	07603
Oosafe CENTER WELL	OOPW-CW07	07603
Oosafe 60MM DISH	OOPW-ST02	07603
Oosafe 60MM DISH	OOPW-ST04	07603
Oosafe 60MM DISH	OOPW-ST05	07603
Oosafe ICSI/IMSI DISH for Sperm Selection	OOPW-IC02	07603

Product was tested for DNase activity by the following protocol:

Product was extracted in DNase free water. The extract was then added to a DNA standard. The DNA standard was incubated at 37° C for 1 hour then heated to 65° C for 5 minutes. DNA samples were then run on an agarose gel, photographed, and evaluated for degradation.

FIGURE 1.



Lane (a) **Pooled products**, (b) unexposed DNA standard as a negative control, (c) DNA standard exposed to DNase as a positive control.

**Conclusions:**

No visible degradation is present in the product sample. The product can therefore be considered DNase free.

**Comments:**

The Test Sensitivity is 10<sup>-7</sup> Kunitz Units/ µl.



Certified by: Chase Wong, 1/11/2016



Q.A. Carl Tsang, 1/11/2016