

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-IC05
LOT No.: 07603
Expiry Date: 10/2020
Storage conditions: 20⁰C, 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:

A handwritten signature in blue ink, appearing to read "C. Nielsen".

Camilla Inesa Nielsen
Regulatory Affairs Manager





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



140 Hale Street
 Haverhill, MA 01830
qci@embryotech.com

ELI Accession Number: SPAR-4363-0216

Date of completion: 02-20-2016

Lot number: 07603

Reference number: OOPW-IC05

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

Assay system requested by customer: Three 20µl drops of the culture medium was placed in the test article and overlaid with oil. 21 one-cell mouse embryos (7 per drop) were placed in each drop and cultured for 96-hours.

Control assay method and results: 15 1-cell (B6C3F1 X B6D2F1) embryos were cultured in 2mL drop of culture medium overlaid with oil in a 60x15mm Dish Reference number 150270:

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 three 20µl drops of the culture medium overlaid with oil in the test article:


20 / 21 (95 %)
 19 / 21 (90 %)

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% CO₂. 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

02-22-2016
 date


 signature
 Quality Reviewer

02-22-2016
 date



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140 Hale Street
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ELI Accession Number: S2325-1215SPAR

Date of completion: 12-22-2015

Lot number: 07603

Order numbers: OOPW-IC02, OOPW-IC04, OOPW-IC05,
 OOPW-ST02, OOPW-ST04, OOPW-ST05,
 OOPW-CW04, OOPW-CW06, OOPW-CW07

Description of test article(s):

Oosafe® ICSI/IMSI Dish for Sperm Selection, 60mm Dish, Center Well Dish

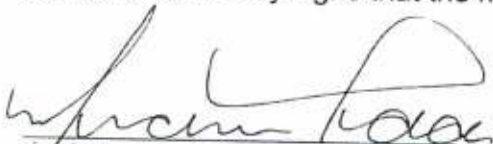
Assay system requested by customer: 100µL of sperm wash medium was added to the test articles (9 test articles pooled) and incubated for 30-minutes. Post incubation the sperm wash medium was extracted from the test articles and pooled. The pooled extracted medium was placed in OOPW-CW07 with the sperm 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:	Specification	Initial	Result % 24hr	SMI Value	Pass/Fail
SOP/TSG/ELI/008					
Test Article	SMI ≥ 0.75	95%	93%	0.98	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% CO₂. Neither the test nor the control showed any signs that the motility was affected during the course of the assay.


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12-22-2015
 date


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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-IC02, OOPW-IC04, OOPW-IC05,
 OOPW-ST02, OOPW-ST04, OOPW-ST05,
 OOPW-CW04, OOPW-CW06, OOPW-CW07

Description of test article(s):

Oosafe® ICSI/IMSI Dish for Sperm Selection, 60mm Dish, Center Well Dish

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

LAL lot number: 515-05-733

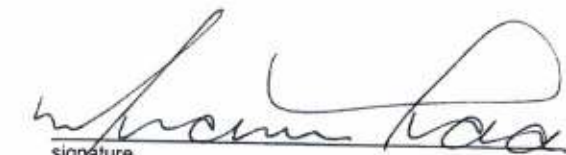
Sensitivity (λ) = 0.03 EU/mL

CSE lot number: 143

LRW lot number: AZA182110

Control Standard Series			Test Sample Dilutions	NPC		PPC	
2 λ .06	+	+	Undiluted	-	-	+	+
λ .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 #: 113377A
Contact: Onur Ozturk
Technician: Chase Wong

PO#: 122715
Phone: 00 45 28 90 47 34

Products tested:	Product code:	Lot #:
Oosafe ICSI/IMSI DISH for Sperm Selection	OOPW-IC04	07603
Oosafe ICSI/IMSI DISH for Sperm Selection	OOPW-IC05	07603
Oosafe 100 mm Dish	OOPW-HD02	07603
Oosafe 100 mm Dish	OOPW-HD03	07603
Oosafe Centrifuge Tube	OOPW-CT01	07603
Oosafe OPU Tube	OOPW-OT10	07603
Oosafe Andrology Tube	OOPW-AT10	07603

Extraction:

Extract solution: DEPC Treated Water
Lot #: DW15A6
Volume: 200 μ l

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: MgCl₂ and NaCl
Salt lot #: S15G2

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

Negative Control (-): RNA and salt standards with 10 μ l of unexposed extract solution added

Positive Control (+): RNA and salt standards with 10 μ l of extract solution exposed to RNase from a tip touched by un-gloved hands

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

Gel Electrophoresis:

2 μ l gel loading dye + 15 μ l reaction is loaded on a 1.2% agarose in 1/2 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 ICSI/IMSI DISH for Sperm Selection	OOPW-IC04	07603
Oosafe ICSI/IMSI DISH for Sperm Selection	OOPW-IC05	07603
Oosafe 100 mm Dish	OOPW-HD02	07603
Oosafe 100 mm Dish	OOPW-HD03	07603
Oosafe Centrifuge Tube	OOPW-CT01	07603
Oosafe OPU Tube	OOPW-OT10	07603
Oosafe Andrology Tube	OOPW-AT10	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 10⁻⁹ 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 #: 113377B
Contact: Onur Ozturk
Technician: Chase Wong

PO#: 122715
Phone: 00 45 28 90 47 34

Products tested:	Product code:	Lot #:
Oosafe ICSI/IMSI DISH for Sperm Selection	OOPW-IC04	07603
Oosafe ICSI/IMSI DISH for Sperm Selection	OOPW-IC05	07603
Oosafe 100 mm Dish	OOPW-HD02	07603
Oosafe 100 mm Dish	OOPW-HD03	07603
Oosafe Centrifuge Tube	OOPW-CT01	07603
Oosafe OPU Tube	OOPW-OT10	07603
Oosafe Andrology Tube	OOPW-AT10	07603

Extraction:

Extract solution: DEPC Treated Water
Lot #: DW15A6
Volume: 200 μ 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: MgCl₂ and NaCl
Salt lot #: S15G2

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

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

Positive Control (+): DNA and salt standards with 10 μ 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

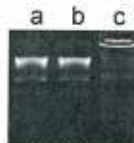
Gel Electrophoresis:

2 μ l gel loading dye + 15 μ 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:



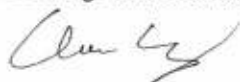
Lane (a) Pooled products, (b) unexposed DNA standard as a negative control, (c) DNA standard exposed to DNase as a positive control.

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

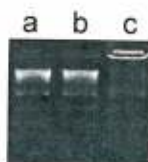
The following sample obtained from **Sparmed ApS** on **1/4/2016** is free of any detectable DNase contamination.

<u>PRODUCTS TESTED</u>	<u>PRODUCT CODE</u>	<u>LOT NUMBER</u>
Oosafe ICSI/IMSI DISH for Sperm Selection	OOPW-IC04	07603
Oosafe ICSI/IMSI DISH for Sperm Selection	OOPW-IC05	07603
Oosafe 100 mm Dish	OOPW-HD02	07603
Oosafe 100 mm Dish	OOPW-HD03	07603
Oosafe Centrifuge Tube	OOPW-CT01	07603
Oosafe OPU Tube	OOPW-OT10	07603
Oosafe Andrology Tube	OOPW-AT10	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^{-7} Kunitz Units/ μ l.



Certified by: Chase Wong, 1/11/2016



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