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

sparMED
GOosafe in IVF Laboratories

ID: *COA-07603*

Certificate of Analysis

Date of issue:	19.01.2016
Product ID:	Oosafe® Plasticware: OOPW-IC04
LOT No.:	07603
Expiry Date:	09/2020
Storage conditions:	20^0C, 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

CVR: DK 30898575
SparMED ApS
+45 3440 2503
www.sparmed.dk
RYTTERMARKEN 2, 3520 FARUM, DENMARK

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-4065(R2)-1215

Date of completion: 01-04-2016

Lot number: 07603

Reference number: OOPW-IC04

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

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: 21 1-cell ($B_6C_3F_1$ X $B_6D_2F_1$) embryos were cultured in an IVF Petri Dish using culture medium:

21 / 21 (100 %)	1-cell to 2-cell within 24 hr
21 / 21 (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 the test article using culture medium:

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

signature
Study Director

01-05-2016
date

signature
Quality Reviewer

01-05-2016
date

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: 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: SOP/TSG/ELI/008	Specification	Initial	Result % 24hr	SMI Value	Pass/Fail
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% CO_2. Neither the test nor the control showed any signs that the motility was affected during the course of the assay.

signature
Study Director

12-22-2015
date

signature
Quality Reviewer

12-22-2015
date

CERTIFICATE OF ANALYSIS

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

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

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
CSE lot number: 143
LRW lot number: AZA182110

Sensitivity (λ) = 0.03 EU/mL

Control Standard Series			Test Sample Dilutions	NPC		PPC	
2 λ .06	+	+	Undiluted	-	-	+	+
λ .03	+	+	1:2	-	-	+	+
½λ .015	-	-	1:4	-	-	+	+
¼λ .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.

signature
Study Director

12-22-2015
date

signature
Quality Reviewer

12-22-2015
date

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: 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: $MgCl_2$ 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

MO BIO Laboratories, Inc.

info@mobio.com | www.mobio.com | Tel. 800-606-6246 | 2746 Loker Avenue West, Carlsbad, CA 92010

RNase FREE CERTIFICATE OF ANALYSIS

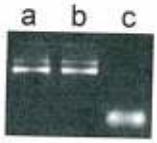
1/11/2016

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

PRODUCTS TESTED	PRODUCT CODE	LOT NUMBER
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: 200µl
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: $MgCl_2$ and NaCl
Salt lot #: S15G2

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

Negative Control (-): DNA and salt standards with 10 µl of unexposed extract solution added
Positive Control (+): DNA and salt standards with 10 µl 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:
2µl gel loading dye + 15µl reaction is loaded on a 1.2% agarose in ½ 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

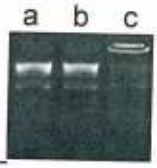
1/11/2016

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

PRODUCTS TESTED	PRODUCT CODE	LOT NUMBER
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/ µl.

Certified by: Chase Wong, 1/11/2016

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