Manufacturer:

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

ID: COA-07603



Certificate of Analysis

Date of issue: 19.02.2016

Product ID: Oosafe® Plasticware: OOPW-AT10

LOT No.: 07603

Expiry Date: 09/2020

Storage conditions: 20°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

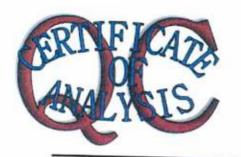
Quality control according to the ISO 13485:2012

Final approval:

Stamp:

Camilla Inesa Nielsen Regulatory Affairs Manager





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



ELI Accession Number: SPAR-4065-1215

Date of completion: 12-22-2015

Lot numbers: 07603

Reference numbers: OOPW-SC01, OOPW-CT01

OOPW-AT10, OOPW-OT10

Description of test article(s):

Oosafe® Sperm Collection Cup, Centrifuge Tube, Andrology Tube, OPU Tube

Assay system requested by customer: 1mL of culture medium was placed in each of the test articles (3) (OOPW-SC01, OOPW-CT01, OOPW-AT10) and incubated at 37°C for 30-minutes. Post incubation the culture medium was extracted from each test article and pooled. 1mL of the extracted culture medium was expelled into the fourth test article OOPW-OT10 overlaid with oil. One-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 (B6C3F1 X B6D2F1) embryos were cultured in 0.5mL drops 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 one of the test articles using the extracted culture medium:

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% CO2. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 10 percent of the embryos cultured in the test article developed to the expanded blastocyst stage within

signature Study Director 12-24-2015

signature Quality Reviewer



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

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

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:

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SOP/TSG/ELI/008	Specification	Initial	Result % 24hr	SMI Value	Pass/Fail	
Test Article	SMI ≥ 0.75	95%	95%	1.00		
Control	≥ 70%			1.00	Pass	
27,11101	2 1 0 76	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.

signature Study Director

date

signature Quality Reviewer 12-22-2015

date



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



ac@embryotech.com

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 St	andard S	Series	Test Sample Dilutions	N	PC	P	PC
2λ.06	+	+	Undiluted	-		+	1
λ.03	+	+	1:2			+	1
1/2λ .015	-	0	1:4		-	+	-
¼λ .0075	-	-	1:8	124		1	-
NWC	-	-	1:16		-	+	1

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

signature

Quality Reviewer

12-22-2015

RNase Test Data and Results

Date: 1/7/2016 Project #: 113377A PO#: 122715

Company: Sparmed ApS Contact: Onur Ozturk Phone: 00 45 28 90 47 34

Date received: 1/4/2016 Technician: Chase Wong

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 Number of test items exposed to extract solution: 10

Lot #: DW15A6 Special extraction instructions: All items tested pooled

Volume: 200µl

Procedure and Controls:

RNA: 6.0 kb Poly (A)-tailed RNA standard pool: 3µl of RNA + 12µl Salts. RNA lot #: 1310020 Volume of each standard reaction: 5µl Salts: MgCl₂ and NaCl Volume of extract added to the standard: 10µl

Salt lot #: S15G2 Total volume: 15µl

Negative Control (-): RNA and salt standards with 10 μ I 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:

a b

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

1/11/2016



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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 Oosafe ICSI/IMSI DISH for Sperm Selection Oosafe ICSI/IMSI DISH for Sperm Selection Oosafe 100 mm Dish Oosafe 100 mm Dish Oosafe Centrifuge Tube Oosafe OPU Tube Oosafe Andrology Tube	PRODUCT CODE OOPW-IC04 OOPW-IC05 OOPW-HD02 OOPW-HD03 OOPW-CT01	LOT NUMBER 07603 07603 07603 07603 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:

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

Certified by: Chase Wong, 1/11/2016

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

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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:

Oosafe ICSI/IMSI DISH for Sperm Selection Oosafe ICSI/IMSI DISH for Sperm Selection Oosafe 100 mm Dish Oosafe 100 mm Dish **Oosafe Centrifuge Tube** Oosafe OPU Tube Oosafe Andrology Tube

Product code: OOPW-IC04 OOPW-IC05 OOPW-HD02 OOPW-HD03 OOPW-CT01 OOPW-OT10 OOPW-AT10

07603

Lot #:

07603

07603

Extraction:

Extract solution: DEPC Treated Water

Lot #: DW15A6 Volume: 200ul

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

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

Salt lot #: S15G2 Total volume: 15ul

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

OA

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 Oosafe Centrifuge Tube	OOPW-HD03	07603
Oosafe OPU Tube	OOPW-CT01	07603
	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/ µI.

Certified by: Chase Wong, 1/11/2016

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