

Manufacturer:
Sparmed ApS/CVR.No.: 30898575
Toppevadvej 34-38, 3660 Stenløse, Denmark



ID: COA-07551

Certificate of Analysis

Date of issue: 10.08.2015
Product ID: Oosafe® Plasticware: OOPW-ST10
LOT No.: 07551
Expiry Date: 12/2019
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**

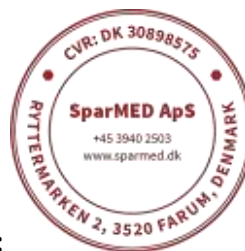
Quality control according to the ISO 13485:2012

Final approval:

A handwritten signature in blue ink, appearing to read 'Katrine Nobel', written over a horizontal line.

Katrine Nobel
Quality Control Manager

Stamp:





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



ELI Accession Number: SPAR-2347-0215

Date of completion: 02-12-2015

Lot number: 07551

Reference number: OOPW-IC10, OOPW-CW03
OOPW-TF03, OOPW-ST10
OOPW-HD10

Description of test article(s): Oosafe® ICSI Dish, Center Well Dish, 35mm, 60mm and 100mm Dish

Control assay method and results: 15 1-cell (B₆C₃F₁ X B₆D₂F₁) embryos were cultured in 1mL of culture medium in a center-well control dish:

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 1mL of 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 in an atmosphere containing 5.0% CO₂. 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

02-12-2015

date



signature
Quality Reviewer

2/12/2015

date



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

ELI Accession Number: S2065-0215SPAR

Date of completion: 02-10-2015

Lot number: 07551

Reference number: OOPW-IC10, OOPW-CW03
OOPW-TF03, OOPW-ST10
OOPW-HD10

Description of test article(s): Oosafe® ICSI Dish, Center Well Dish, 35mm, 60mm and 100mm Dish

Assay system requested by customer: Human Sperm was placed in each test article and incubated at room temperature for 24-hours. Post incubation the sperm was pooled from each test article and a 10µl sample was extracted for analysis.


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
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Test Article	SMI \geq 0.75	98%	98%	1.00	Pass
Control	\geq 70%	98%	98%	N/A	Pass

Summary of observations: The motility remained consistent in the tube containing the test media while on the bench at room temperature. Both the test article and control showed no sign of affecting motility during the course of the assay.


signature
Study Director

02-11-2015
date


signature
Quality Reviewer

02-11-2015
date



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



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

ELI Accession Number: E6131-0215SPAR

Date of completion: 02-10-2015

Lot number: 07551

Reference number: OOPW-IC10, OOPW-TF03
 OOPW-ST10, OOPW-CW03
 OOPW-HD10

Description of test article(s):

Oosafe® ICSI Dish, 35mm Dish, 60mm Dish, Center Well Dish, 100mm Dish

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

LAL lot number: 513-05-647

Sensitivity (λ) = 0.03 EU/mL


CSE lot number: 139

LRW lot number: 99732187

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	-	-	+	+

NOTE: These results are not to be used for end product release.

Summary: 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

02-11-2015
 date


 signature
 Quality Reviewer

02-11-2015
 date

RNase Test Data and Results

Date: 2/17/2015
Company: SPARMED ApS
Date received: 2/13/2015

Project #: 112738A
Contact: Onur OZTURK
Technician: Laura Gloss

PO#: 130214-1
Phone: 00 45 28 90 47 34

Products tested:	Product code:	Lot #:
Oosafe ICSI Dish	OOPW-IC10	07551
Oosafe Center Well Dish with 2 Compartments	OOPW-CW03	07551
Oosafe 35 mm Dish	OOPW-TF03	07551
Oosafe 100 mm Dish	OOPW-HD10	07551
Oosafe 60 mm Dish	OOPW-ST10	07551

Extraction:

Extract solution: DEPC Treated Water Number of test items exposed to extract solution: 10
Lot #: DW14G21 Special extraction instructions: Tested products according to extraction protocol #155.
Volume: 1000µl

Procedure and Controls:

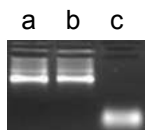
RNA: 6.0 kb Poly (A)-tailed	RNA standard pool: 3µl of RNA + 12µl Salts.
RNA lot #: 1312021	Volume of each standard reaction: 5µl
Salts: MgCl ₂ and NaCl	<u>Volume of extract added to the standard: 10µl</u>
Salt lot #: S13G12	Total volume: 15µl

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) product samples, (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 samples 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 are 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.

Laura Gloss

Laura Gloss
Lab Technician

2/18/2015
Date

Carl Tsang

Carl Tsang
Q.A.

2/18/2015
Date



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RNase FREE CERTIFICATE OF ANALYSIS

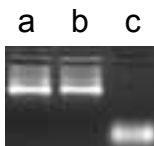
2/18/2015

The following samples obtained from **SPARMED ApS** on **2/13/2015** are free of any detectable RNase contamination.

<u>PRODUCTS TESTED</u>	<u>PRODUCT CODE</u>	<u>LOT NUMBER</u>
Oosafe ICSI Dish	OOPW-IC10	07551
Oosafe Center Well Dish with 2 Compartments	OOPW-CW03	07551
Oosafe 35 mm Dish	OOPW-TF03	07551
Oosafe 100 mm Dish	OOPW-HD10	07551
Oosafe 60 mm Dish	OOPW-ST10	07551

Products were tested for RNase activity by the following protocol:
 Products were 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) **product samples**, (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 samples. The products can therefore be considered RNase free.

Comments:

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



Certified by: Laura Gloss, 2/18/2015



Q.A. Carl Tsang, 2/18/2015

DNase Test Data and Results

Date: 2/17/2015
Company: SPARMED ApS
Date Received: 2/13/2015

Project #: 112738B
Contact: Onur OZTURK
Technician: Laura Gloss

PO#: 130214-1
Phone: 00 45 28 90 47 34

Products tested:	Product code:	Lot #:
Oosafe ICSI Dish	OOPW-IC10	07551
Oosafe Center Well Dish with 2 Compartments	OOPW-CW03	07551
Oosafe 35 mm Dish	OOPW-TF03	07551
Oosafe 100 mm Dish	OOPW-HD10	07551
Oosafe 60 mm Dish	OOPW-ST10	07551

Extraction:

Extract solution: DEPC Treated Water Number of test items exposed to extract solution: 10
Lot #: DW14G21 Special extraction instructions: Tested products according to extraction protocol #155.
Volume: 1000µl

Procedure and Controls:

DNA: 1 kb Ladder	DNA standard pool: 3µl of DNA + 12µl Salts.
DNA lot #: 1620721	Volume of each standard reaction: 5µl
Salts: MgCl ₂ and NaCl	<u>Volume of extract added to the standard: 10µl</u>
Salt lot #: S13G12	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

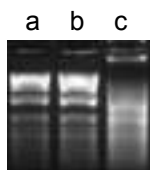
Gel Electrophoresis:

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) product samples, (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 samples 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 samples are 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.

Laura Gloss

Laura Gloss
Lab Technician

2/18/2015
Date

Carl Tsang

Carl Tsang
Q.A.

2/18/2015
Date



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DNase FREE CERTIFICATE OF ANALYSIS

2/18/2015

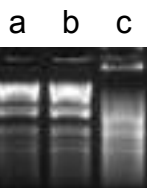
The following samples obtained from **SPARMED ApS** on **2/13/2015** are free of any detectable DNase contamination.

<u>PRODUCTS TESTED</u>	<u>PRODUCT CODE</u>	<u>LOT NUMBER</u>
Oosafe ICSI Dish	OOPW-IC10	07551
Oosafe Center Well Dish with 2 Compartments	OOPW-CW03	07551
Oosafe 35 mm Dish	OOPW-TF03	07551
Oosafe 100 mm Dish	OOPW-HD10	07551
Oosafe 60 mm Dish	OOPW-ST10	07551

Products were tested for DNase activity by the following protocol:

Products were 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) **product samples**, (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 samples. The products can therefore be considered DNase free.

Comments:

The Test Sensitivity is 10^{-7} Kunitz Units/ μ l.



Certified by: Laura Gloss, 2/18/2015



Q.A. Carl Tsang, 2/18/2015