

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



ID: COA-07612

Certificate of Analysis

Date of issue: 15.04.2016
Product ID: Oosafe® Plasticware: OOPW-SW02
LOT No.: 07612
Expiry Date: 03/2021
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:

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

Camilla Inesa Nielsen
Regulatory Affairs Manager





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



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

ELI Accession Number: E6983-0416SPAR

Date of completion: 04-05-2016

Lot number(s): 07608
 07610
 07612

Order number(s): OOPW-CT01
 OOPW-SW03
 OOPW-SW02

Description of test article(s):

Oosafe® Centrifuge Tube, 15mL & Oosafe® 6 Well Dish with Straw Holder

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

Control assay materials: Lysate: Lot number 515-05-733, Sensitivity (λ) = 0.03125 EU/mL


Control Standard Endotoxin (CSE): Lot number 143

LAL Reagent Water (LRW): Lot number AZA182110

Results:

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 <0.03125 EU/device.


 signature
 Study Director

04-05-2016
 date


 signature
 Quality Reviewer

04-05-2016
 date



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



140 Hale Street
 Haverhill, MA 01830
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ELI Accession Number: S2461-0416SPAR

Date of completion: 04-07-2016

Lot numbers: 07608
 07610
 07612

Order numbers: OOPW-CT01
 OOPW-SW03
 OOPW-SW02

Description of test article(s):

Oosafe® Centrifuge Tube, 15mL & Oosafe® 6 Well Dish with Straw Holder

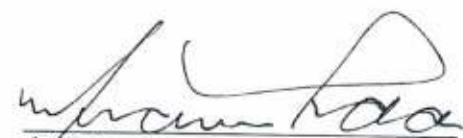
Assay system requested by customer: 200µl of sperm wash medium was added to each well of test articles (SW02 & SW03) and incubated for 30-minutes. Post incubation the sperm wash medium was extracted from the test articles and pooled. 200µl of the pooled extracted medium with sperm was placed into test article (CT01) for a 24-hour incubation. The forward progressive motility was read and recorded at 24-hours.

Results:

Test method:	Specification	Result %	SMI	Pass/Fail
SOP/TSG/ELI/008		Initial	24hr	Value

Test Article	Specification	Result % Initial	Result % 24hr	SMI	Pass/Fail Value
Test Article	SMI ≥ 0.75	100%	98%	0.99	Pass
Control	≥ 70%	100%	99%	N/A	Pass

Summary of observations: The motility remained consistent in the test article extract while in an incubator atmosphere of 32°C and 5% CO₂.


 signature
 Study Director

date 04-08-2016


 signature
 Quality Reviewer

date 04-08-2014



SparMED Aps
Toppevadvej 34-38
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Stenlose, Denmark



ELI Accession Number: SPAR-4637-0416

Date of completion: 04-08-2016

Lot number(s): 07608
07610
07612

Reference number(s): OOPW-CT01
OOPW-SW03
OOPW-SW02

Description of test article(s):

Oosafe® Centrifuge Tube, 15mL & Oosafe® 6 Well Dish with Straw Holder

Assay system requested by customer: 1mL of culture medium was placed in the test article (CT01) and 0.25mL of culture medium was placed in each well of test article (SW03) and incubated at 37°C for 30-minutes. Post incubation the culture medium was extracted from each test article and pooled. 0.25mL of the extracted culture medium was placed into test article (SW02) and overlaid with oil; 1-cell mouse embryos were then placed into 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 non-treated 4-Well 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 %)
20 / 21 (95 %)

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. 95 percent of the embryos cultured in the test article developed to the expanded blastocyst stage within 96-hours.

signature
Study Director

04-08-2016
date

signature
Quality Reviewer

04-08-2016
date

RNase Test Data and Results

Date: 4/8/2016
Company: Sparmed ApS
Date received: 3/8/2016

Project #: 113566A
Contact: Onur Ozturk
Technician: Chase Wong

PO#: 040416-1
Phone: 45- 39 40 2503

Products tested:

Oosafe Centrifuge tube
Oosafe 6 well Dish With Straw Holder Single Pack
Oosafe 6 well Dish With Straw Holder Multi Pack

Product code:	Lot #:
OOPW-CT01	07608
OOPW-SW02	07612
OOPW-SW03	07610

Extraction:

Extract solution: LAL Water
Lot #: 0000496596
Volume: 200 μ l

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

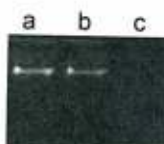
Gel Electrophoresis:

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) OOPW-CT01, 07608, (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

4/13/2016
Date

Carl Tsang
Q.A.

4/13/2016
Date



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RNase FREE CERTIFICATE OF ANALYSIS

4/13/2016

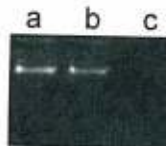
This certifies that the following sample obtained from **Sparmed ApS** on 3/8/2016 is free of any detectable RNase contamination.

Lots tested:

Product:	Product code:	Lot #:
Oosafe Centrifuge tube	OOPW-CT01	07608
Oosafe 6 well Dish With Straw Holder Single Pack	OOPW-SW02	07612
Oosafe 6 well Dish With Straw Holder Multi Pack	OOPW-SW03	07610

Product was tested for RNase activity by the following protocol:
 Product was extracted in RNase free water. All product extracts were pooled. 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) OOPW-CT01, 07608, (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. Therefore, the product can be considered RNase free.

Comments:

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



Certified by Chase Wong, 4/13/2016



Q.A. Carl Tsang, 4/13/2016

DNase Test Data and Results

Date: 4/8/2016
Company: Sparmed ApS
Date Received: 3/8/2016

Project #: 113566B
Contact: Onur Ozturk
Technician: Chase Wong

PO#: 040416-1
Phone: 45- 39 40 2503

Products tested:

Oosafe Centrifuge tube
Oosafe 6 well Dish With Straw Holder Single Pack
Oosafe 6 well Dish With Straw Holder Multi Pack

Product code:
OOPW-CT01
OOPW-SW02
OOPW-SW03

Lot #:
07608
07612
07610

Extraction:

Extract solution: LAL Water
Lot #: 0000496596
Volume: 200 μ l

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

Procedure and Controls:

DNA: 1 kb Ladder
DNA lot #: 1726315
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

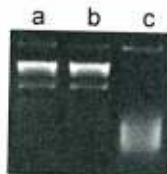
Gel Electrophoresis:

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:



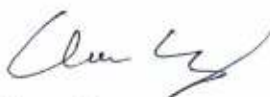
Lane (a) OOPW-CT01, 07608, (b) unexposed DNA standard as a negative control, (c) DNA standard exposed to DNase as a positive control.

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

4/13/2016
Date



Carl Tsang
Q.A.

4/13/2016
Date



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DNase FREE CERTIFICATE OF ANALYSIS

4/13/2016

This certifies that the following sample obtained from **Sparmed ApS** on 3/8/2016 is free of any detectable DNase contamination.

Lots tested:

Product:

Oosafe Centrifuge tube

Oosafe 6 well Dish With Straw Holder Single Pack

Oosafe 6 well Dish With Straw Holder Multi Pack

Product code:

OOPW-CT01

OOPW-SW02

OOPW-SW03

Lot #:

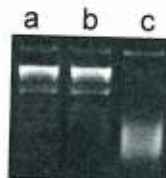
07608

07612

07610

Product was tested for DNase activity by the following protocol:
Product was extracted in DNase free water. All product extracts were pooled. 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) OOPW-CT01, 07608, (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. Therefore, the product can be considered DNase free.

Comments:

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



Certified by Chase Wong, 4/13/2016



Q.A. Carl Tsang, 4/13/2016