

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



ID: COA-07506

## Certificate of Analysis

**Date of issue:** 10.08.2015  
**Product ID:** Oosafe® Plasticware: OOPW-HD01  
**LOT No.:** 07506  
**Expiry Date:** 11/2018  
**Storage conditions:** 20<sup>0</sup>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**

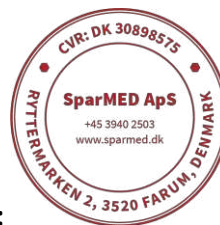
Quality control according to the ISO 13485:2012

**Final approval:**

A handwritten signature in blue ink, appearing to read 'Katrine Nobel'.

\_\_\_\_\_  
Katrine Nobel  
Quality Control Manager

**Stamp:**



# CERTIFICATE OF ANALYSIS

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



**EMBRYOTECH™**  
laboratories

**ELI accession number:** E5580-0414SPAR

**Test Date:** 04-22-2014

**Reference number:** OOPW-ST10, OOPW-CW10, OOPW-IC10,  
OOPW-TF10, OOPW-HD10, OOPW-HD01,  
OOPW-FW03, OOPW-TF01, OOPW-IC01,  
OOPW-FW01

**Lot number:** 07506

**Description of test article(s):** Oosafe® 60 mm Dish, Center Well Dish, ICSI Dish (2),  
35 mm Dish (2), 100 mm Dish (2), 4 Well Dish Treated  
Surface, 4 Well Dish Non Treated Surface

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

**LAL lot number:** 512-11-631

**Sensitivity ( $\lambda$ ) =** 0.03 EU/mL


**CSE lot number:** 139

**LRW lot number:** 99732187


Control Standard Series			Test Sample Dilutions	NPC		PPC	
2 $\lambda$ .06	+	+	Undiluted	-	-	+	+
$\lambda$ .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

04-23-2014  
date

  
signature  
Quality Reviewer

04-23-2014  
date

# CERTIFICATE OF ANALYSIS

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



**EMBRYOTECH™**  
laboratories

ELI accession number: S1886-0414SPAR

Date of completion: 04-23-2014

Reference number: OOPW-ST10, OOPW-CW10, OOPW-IC10,  
OOPW-TF10, OOPW-HD10, OOPW-HD01,  
OOPW-FW03, OOPW-TF01, OOPW-IC01,  
OOPW-FW01

Lot number: 07506

Description of test article(s): Oosafe® 60 mm Dish, Center Well Dish, ICSI Dish (2),  
35 mm Dish (2), 100 mm Dish (2), 4 Well Dish Treated Surface,  
4 Well Dish Non Treated Surface

Assay system requested: 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 materials 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	Result %		SMI	Pass/Fail
SOP/TSG/ELI/008		Initial	24hr	Value	

Test Article	Specification	Initial	24hr	SMI Value	Pass/Fail
Test Article	SMI $\geq$ 0.75	96%	93%	0.99	Pass
Control	$\geq$ 70%	96%	94%	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

04-23-2014  
date

  
signature  
Quality Reviewer

04-23-2014  
date

# CERTIFICATE OF ANALYSIS

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



ELI accession number: SPAR-9824-0414

Test Date: 04-26-2014

Reference number: OOPW-ST10, OOPW-CW10, OOPW-IC10,  
OOPW-TF10, OOPW-HD10, OOPW-HD01,  
OOPW-FW03, OOPW-TF01, OOPW-IC01,  
OOPW-FW01

Lot number: 07506

Description of test article(s): Oosafe® 60 mm Dish, Center Well Dish, ICSI Dish (2),  
35 mm Dish (2), 100 mm Dish (2), 4 Well Dish Treated  
Surface, 4 Well Dish Non Treated Surface

**Assay system requested by customer:** A 700µl drop of "embryo-tested" culture medium supplemented with 0.4% BSA was placed in each of the test articles, and incubated for 30 minutes at 37°C in an atmosphere containing 5.0% CO<sub>2</sub>. 1-cell mouse embryos were then added to the 4 Well Dish Treated Surface containing 700uL drops of culture medium, extracted and pooled from the test articles, in each well and cultured for 96-hours.

**Control assay materials and results:** 15 1-cell (B6C3F1 X B6D2F1) embryos were cultured in 700µl drop in a 4-well Dish using "embryo-tested" culture medium supplemented with 0.4% BSA:

15 / 15 (100 %)

1-cell to 2-cell within 24 hr

15 / 15 (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 materials and results:** 21 1-cell (B6C3F1 X B6D2F1) embryos were cultured in the 4 Well Dish Treated Surface, using "embryo-tested" culture medium supplemented with 0.4% BSA, extracted and pooled from each of the test articles:

21 / 21 (100 %)

1-cell to 2-cell within 24 hr

19 / 21 ( 90 %)

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% CO<sub>2</sub>. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 90 percent of the embryos cultured in the extracted "embryo tested" culture medium developed to the expanded blastocyst stage within 96-hours.

signature  
Study Director

04-28-2014  
date

signature  
Quality Reviewer

04-28-2014  
date

## RNase Test Data and Results

Date: 5/28/2014  
Company: SPARMED ApS  
Date received: 5/21/2014

Project #: 112266A  
Contact: Onur OZTURK  
Technician: Laura Gloss

PO#: 140514  
Phone: 0045 39 40 25 03

Products tested:	Product code:	Lot #:
Oosafe 4 Well Dish Treated Surface - Single Pack	OOPW-FW02	07506
Oosafe 4 Well Dish Non-treated Surface Multi Pack	OOPW-FW04	07506
Oosafe Centrifuge Tube	OOPW-CT01	07506
Oosafe Six Well Dish - Single Pack	OOPW-SW01	07506
Oosafe Six Well Dish - Multi Pack	OOPW-SW04	07506
Oosafe Center Well Dish with 2 Compartments - Single Pack	OOPW-CW02	07506
Oosafe Center Well Dish with 2 Compartments - Multi Pack	OOPW-CW03	07506
Oosafe 60mm dish	OOPW-ST10	07506

### Extraction:

Extract solution: DEPC Treated Water  
Lot #: DW14E7  
Volume: 1000 $\mu$ l

Number of test items exposed to extract solution: 10  
Special extraction instructions: Tested products according to extraction protocol #155

### Procedure and Controls:

RNA: 6.0 kb Poly (A)-tailed  
RNA lot #: 1307019  
Salts: MgCl<sub>2</sub> and NaCl  
Salt lot #: S13G12

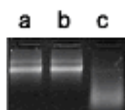
RNA standard pool: 3 $\mu$ l of RNA + 12 $\mu$ l Salts.  
Volume of each standard reaction: 5 $\mu$ l  
Volume of extract added to the standard: 10 $\mu$ l  
Total volume: 15 $\mu$ l

Negative Control (-): RNA and salt standards with 10  $\mu$ l of unexposed extract solution added  
Positive Control (+): RNA and salt standards with 10  $\mu$ l 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:

2 $\mu$ l gel loading dye + 15 $\mu$ l reaction is loaded on a 1.2% agarose in 1/2 X TAE gel  
Gel loading dye lot #: DD005  
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 samples 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

5/29/2014  
Date

*Carl Tsang*

Carl Tsang  
Q.A.

5/29/2014  
Date



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### RNase FREE CERTIFICATE OF ANALYSIS

Date: **5/29/2014**

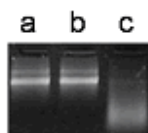
The following samples obtained from **SPARMED ApS** on **5/21/2014** are free of any detectable RNase contamination.

<u>PRODUCTS TESTED</u>	<u>PRODUCT CODE</u>	<u>LOT NUMBER</u>
<b>Oosafe 4 Well Dish Treated Surface - Single Pack</b>	<b>OOPW-FW02</b>	<b>07506</b>
<b>Oosafe 4 Well Dish Non-treated Surface Multi Pack</b>	<b>OOPW-FW04</b>	<b>07506</b>
<b>Oosafe Centrifuge Tube</b>	<b>OOPW-CT01</b>	<b>07506</b>
<b>Oosafe Six Well Dish - Single Pack</b>	<b>OOPW-SW01</b>	<b>07506</b>
<b>Oosafe Six Well Dish - Multi Pack</b>	<b>OOPW-SW04</b>	<b>07506</b>
<b>Oosafe Center Well Dish with 2 Compartments - Single Pack</b>	<b>OOPW-CW02</b>	<b>07506</b>
<b>Oosafe Center Well Dish with 2 Compartments - Multi Pack</b>	<b>OOPW-CW03</b>	<b>07506</b>
<b>Oosafe 60mm dish</b>	<b>OOPW-ST10</b>	<b>07506</b>

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<sup>-9</sup> Kunitz Units/ μl.



Certified by: Laura Gloss, 5/29/2014



Q.A. Carl Tsang, 5/29/2014

## DNase Test Data and Results

Date: 5/28/2014  
Company: SPARMED ApS  
Date Received: 5/21/2014

Project #: 112266B  
Contact: Onur OZTURK  
Technician: Laura Gloss

PO#: 140514  
Phone: 0045 39 40 25 03

Products tested:	Product code:	Lot #:
Oosafe 4 Well Dish Treated Surface - Single Pack	OOPW-FW02	07506
Oosafe 4 Well Dish Non-treated Surface Multi Pack	OOPW-FW04	07506
Oosafe Centrifuge Tube	OOPW-CT01	07506
Oosafe Six Well Dish - Single Pack	OOPW-SW01	07506
Oosafe Six Well Dish - Multi Pack	OOPW-SW04	07506
Oosafe Center Well Dish with 2 Compartments - Single Pack	OOPW-CW02	07506
Oosafe Center Well Dish with 2 Compartments - Multi Pack	OOPW-CW03	07506
Oosafe 60mm dish	OOPW-ST10	07506

### Extraction:

Extract solution: DEPC Treated Water      Number of test items exposed to extract solution: 10  
Lot #: DW14E7      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 #: 1501015      Volume of each standard reaction: 5µl  
Salts: MgCl<sub>2</sub> and NaCl      Volume of extract added to the standard: 10µl  
Salt lot #: S13G12      Total volume: 15µl

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

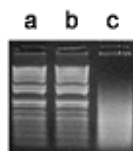
Positive Control (+): DNA and salt standards with 10 µl of extract solution exposed to DNase from a tip exposed to human saliva

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 #: DD005      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

5/29/2014  
Date

*Carl Tsang*

Carl Tsang  
Q.A.

5/29/2014  
Date



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### DNase FREE CERTIFICATE OF ANALYSIS

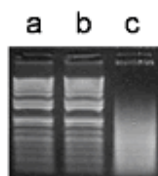
Date: **5/29/2014**

The following samples obtained from **SPARMED ApS** on **5/21/2014** are free of any detectable DNase contamination.

<u>PRODUCTS TESTED</u>	<u>PRODUCT CODE</u>	<u>LOT NUMBER</u>
<b>Oosafe 4 Well Dish Treated Surface - Single Pack</b>	<b>OOPW-FW02</b>	<b>07506</b>
<b>Oosafe 4 Well Dish Non-treated Surface Multi Pack</b>	<b>OOPW-FW04</b>	<b>07506</b>
<b>Oosafe Centrifuge Tube</b>	<b>OOPW-CT01</b>	<b>07506</b>
<b>Oosafe Six Well Dish - Single Pack</b>	<b>OOPW-SW01</b>	<b>07506</b>
<b>Oosafe Six Well Dish - Multi Pack</b>	<b>OOPW-SW04</b>	<b>07506</b>
<b>Oosafe Center Well Dish with 2 Compartments - Single Pack</b>	<b>OOPW-CW02</b>	<b>07506</b>
<b>Oosafe Center Well Dish with 2 Compartments - Multi Pack</b>	<b>OOPW-CW03</b>	<b>07506</b>
<b>Oosafe 60mm dish</b>	<b>OOPW-ST10</b>	<b>07506</b>

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<sup>-7</sup> Kunitz Units/ µl.



Certified by: Laura Gloss, 5/29/2014



Q.A. Carl Tsang, 5/29/2014



## RNase Test Data and Results

Date: 5/28/2014  
Company: SPARMED ApS  
Date received: 5/21/2014

Project #: 112266C  
Contact: Onur OZTURK  
Technician: Laura Gloss

PO#: 140514  
Phone: 0045 39 40 25 03

Products tested:	Product code:	Lot #:
Oosafe Center well Dish	OOPW-ST10	07506
Oosafe ICSI Dish - Multi Pack	OOPW-CW10	07506
Oosafe ICSI Dish - Single Pack	OOPW-IC10	07506
Oosafe 35mm Dish - Multi Pack	OOPW-IC01	07506
Oosafe 35mm Dish - Single Pack	OOPW-TF10	07506
Oosafe 100mm Dish - Multi Pack	OOPW-TF01	07506
Oosafe 100mm Dish - Single Pack	OOPW-HD10	07506
Oosafe 4 Well Dish Treated Surface	OOPW-HD01	07506
Oosafe 4 Well Dish Non Treated Surface	OOPW-FW03	07506
Oosafe Center well Dish	OOPW-FW01	07506

### Extraction:

Extract solution: DEPC Treated Water  
Lot #: DW14E7  
Volume: 1000µl

Number of test items exposed to extract solution: 10  
Special extraction instructions: Tested products according to extraction protocol #155

### Procedure and Controls:

RNA: 6.0 kb Poly (A)-tailed  
RNA lot #: 1307019  
Salts: MgCl<sub>2</sub> and NaCl  
Salt lot #: S13G12

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

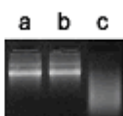
### Gel Electrophoresis:

2µl gel loading dye + 15µl reaction is loaded on a 1.2% agarose in ½ X TAE gel

Gel loading dye lot #: DD005

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 samples 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

5/29/2014  
Date

*Carl Tsang*

Carl Tsang  
Q.A.

5/29/2014  
Date



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## RNase FREE CERTIFICATE OF ANALYSIS

Date: **5/29/2014**

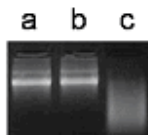
The following samples obtained from **SPARMED ApS** on **5/21/2014** are free of any detectable RNase contamination.

<u>PRODUCTS TESTED</u>	<u>PRODUCT CODE</u>	<u>LOT NUMBER</u>
Oosafe Center well Dish	OOPW-ST10	07506
Oosafe ICSI Dish - Multi Pack	OOPW-CW10	07506
Oosafe ICSI Dish - Single Pack	OOPW-IC10	07506
Oosafe 35mm Dish - Multi Pack	OOPW-IC01	07506
Oosafe 35mm Dish - Single Pack	OOPW-TF10	07506
Oosafe 100mm Dish - Multi Pack	OOPW-TF01	07506
Oosafe 100mm Dish - Single Pack	OOPW-HD10	07506
Oosafe 4 Well Dish Treated Surface	OOPW-HD01	07506
Oosafe 4 Well Dish Non Treated Surface	OOPW-FW03	07506
Oosafe Center well Dish	OOPW-FW01	07506

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/  $\mu$ l.



Certified by: Laura Gloss, 5/29/2014



Q.A. Carl Tsang, 5/29/2014

## DNase Test Data and Results

Date: 5/28/2014  
Company: SPARMED ApS  
Date Received: 5/21/2014

Project #: 112266D  
Contact: Onur OZTURK  
Technician: Laura Gloss

PO#: 140514  
Phone: 0045 39 40 25 03

Products tested:	Product code:	Lot #:
Oosafe Center well Dish	OOPW-ST10	07506
Oosafe ICSI Dish - Multi Pack	OOPW-CW10	07506
Oosafe ICSI Dish - Single Pack	OOPW-IC10	07506
Oosafe 35mm Dish - Multi Pack	OOPW-IC01	07506
Oosafe 35mm Dish - Single Pack	OOPW-TF10	07506
Oosafe 100mm Dish - Multi Pack	OOPW-TF01	07506
Oosafe 100mm Dish - Single Pack	OOPW-HD10	07506
Oosafe 4 Well Dish Treated Surface	OOPW-HD01	07506
Oosafe 4 Well Dish Non Treated Surface	OOPW-FW03	07506
Oosafe Center well Dish	OOPW-FW01	07506

### Extraction:

Extract solution: DEPC Treated Water  
Lot #: DW14E7  
Volume: 1000µl

Number of test items exposed to extract solution: 10  
Special extraction instructions: Tested products according to extraction protocol #155

### Procedure and Controls:

DNA: 1 kb Ladder  
DNA lot #: 1501015  
Salts: MgCl<sub>2</sub> and NaCl  
Salt lot #: S13G12

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

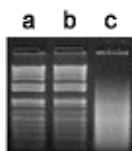
### Gel Electrophoresis:

2µl gel loading dye + 15µl reaction is loaded on a 1.2% agarose in ½ X TAE gel

Gel loading dye lot #: DD005

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

5/29/2014  
Date

*Carl Tsang*

Carl Tsang  
Q.A.

5/29/2014  
Date



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### DNase FREE CERTIFICATE OF ANALYSIS

Date: **5/29/2014**

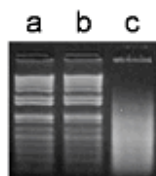
The following samples obtained from **SPARMED ApS** on **5/21/2014** are free of any detectable DNase contamination.

<u>PRODUCTS TESTED</u>	<u>PRODUCT CODE</u>	<u>LOT NUMBER</u>
<b>Oosafe Center well Dish</b>	<b>OOPW-ST10</b>	<b>07506</b>
<b>Oosafe ICSI Dish - Multi Pack</b>	<b>OOPW-CW10</b>	<b>07506</b>
<b>Oosafe ICSI Dish - Single Pack</b>	<b>OOPW-IC10</b>	<b>07506</b>
<b>Oosafe 35mm Dish - Multi Pack</b>	<b>OOPW-IC01</b>	<b>07506</b>
<b>Oosafe 35mm Dish - Single Pack</b>	<b>OOPW-TF10</b>	<b>07506</b>
<b>Oosafe 100mm Dish - Multi Pack</b>	<b>OOPW-TF01</b>	<b>07506</b>
<b>Oosafe 100mm Dish - Single Pack</b>	<b>OOPW-HD10</b>	<b>07506</b>
<b>Oosafe 4 Well Dish Treated Surface</b>	<b>OOPW-HD01</b>	<b>07506</b>
<b>Oosafe 4 Well Dish Non Treated Surface</b>	<b>OOPW-FW03</b>	<b>07506</b>
<b>Oosafe Center well Dish</b>	<b>OOPW-FW01</b>	<b>07506</b>

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/  $\mu$ l.



Certified by: Laura Gloss, 5/29/2014



Q.A. Carl Tsang, 5/29/2014

## RNase Test Data and Results

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Date: 3/10/2014  
Company: SPARMED ApS  
Date received: 3/7/2014

Project #: 112118A  
Contact: ONUR OZTURK  
Technician: Laura Gloss

PO#: 080314-01  
Phone: 4539402503

**Products tested:**  
Oosafe 60 mm Dish  
Oosafe Center Well Dish  
Oosafe Sperm Collection Cup

**Product code:**  
OOPW-ST01  
OOPW-CW01  
OOPW-SC01

**Lot #:**  
07506  
07506  
07506

### Extraction:

Extract solution: DEPC Treated Water  
Lot #: DW14A21  
Volume: 1000 $\mu$ l

Number of test items exposed to extract solution: 10  
Special extraction instructions: Extracted products according to extraction protocol #155.

### Procedure and Controls:

RNA: 6.0 kb Poly (A)-tailed  
RNA lot #: 1307019  
Salts: MgCl<sub>2</sub> and NaCl  
Salt lot #: S13G12

RNA standard pool: 5 $\mu$ l of RNA + 20 $\mu$ l Salts.  
Volume of each standard reaction: 5 $\mu$ l  
Volume of extract added to the standard: 10 $\mu$ l  
Total volume: 15 $\mu$ l

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

Positive Control (+): RNA and salt standards with 10  $\mu$ 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

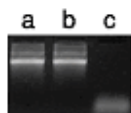
### Gel Electrophoresis:

2 $\mu$ l gel loading dye + 15 $\mu$ l reaction is loaded on a 1.2% agarose in 1/2 X TAE gel

Gel loading dye lot #: DD007

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 samples 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

3/11/2014  
Date

*Carl Tsang*

Carl Tsang  
Q.A.

3/11/2014  
Date

**RNase FREE CERTIFICATE OF ANALYSIS**

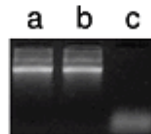
**3/11/2014**

The following samples obtained from **SPARMED ApS** on **3/7/2014** are free of any detectable RNase contamination.

<u>PRODUCTS TESTED</u>	<u>PRODUCT CODE</u>	<u>LOT NUMBER</u>
<b>Oosafe 60 mm Dish</b>	<b>OOPW-ST01</b>	<b>07506</b>
<b>Oosafe Center Well Dish</b>	<b>OOPW-CW01</b>	<b>07506</b>
<b>Oosafe Sperm Collection Cup</b>	<b>OOPW-SC01</b>	<b>07506</b>

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<sup>-9</sup> Kunitz Units/ µl.

*Laura Gloss*

Certified by: Laura Gloss, 3/11/2014

*Carl Tsang*

Q.A. Carl Tsang, 3/11/2014

## DNase Test Data and Results

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Date: 3/10/2014  
Company: SPARMED ApS  
Date Received: 3/7/2014

Project #: 112118B  
Contact: ONUR OZTURK  
Technician: Laura Gloss

PO#: 080314-01  
Phone: 4539402503

**Products tested:**  
Oosafe 60 mm Dish  
Oosafe Center Well Dish  
Oosafe Sperm Collection Cup

**Product code:**  
OOPW-ST01  
OOPW-CW01  
OOPW-SC01

**Lot #:**  
07506  
07506  
07506

### Extraction:

Extract solution: DEPC Treated Water  
Lot #: DW14A21  
Volume: 1000 $\mu$ l

Number of test items exposed to extract solution: 10  
Special extraction instructions: Extracted products according to extraction protocol #155.

### Procedure and Controls:

DNA: 1 kb Ladder  
DNA lot #: 1501015  
Salts: MgCl<sub>2</sub> and NaCl  
Salt lot #: S13G12

DNA standard pool: 5 $\mu$ l of DNA + 20 $\mu$ l Salts.  
Volume of each standard reaction: 5 $\mu$ l  
Volume of extract added to the standard: 10 $\mu$ l  
Total volume: 15 $\mu$ l

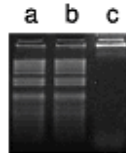
Negative Control (-): DNA and salt standards with 10  $\mu$ l of unexposed extract solution added  
Positive Control (+): DNA and salt standards with 10  $\mu$ l of extract solution exposed to DNase from a tip exposed to human saliva  
Incubation periods: 1 hr @ 37°C, followed by 5 minutes at 65°C

### Gel Electrophoresis:

2 $\mu$ l gel loading dye + 15 $\mu$ l reaction is loaded on a 1.2% agarose in 1/2 X TAE gel  
Gel loading dye lot #: DD007

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

3/11/2014  
Date

*Carl Tsang*

Carl Tsang  
Q.A.

3/11/2014  
Date

**DNase FREE CERTIFICATE OF ANALYSIS**

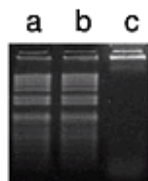
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<b>Oosafe Sperm Collection Cup</b>	<b>OOPW-SC01</b>	<b>07506</b>

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