

Certificate of Analysis

Date of issue: 22 Nov 2017

Product ID: Oosafe® Plasticware: OOPW-IC03

LOT No.: 07791

Expiry date: 2022-04

Storage Conditions: 20°C, dry room, no exposal to sun-light

Quality Assurance:

Analyses	Results
Proven non-embryotoxic by Mouse Embryo Assay Test. Over 80% embryo development to the expanded blastocyst stage within 96 hours.	Passed
Proved stable human sperm motility: $\geq 75\%$ sperm motility after 24 hours proven.	Passed
Proven non-toxic by Limulus Amebocyte Lysate (LAL) test. Pass criteria < 0.03 EU/device.	Passed
Sterilization by gamma irradiation. Delivered irradiation dose: 8.6 kGy-9.5 kGy. Specified irradiation dose: 8.0 kGy-10.0 kGy.	Passed

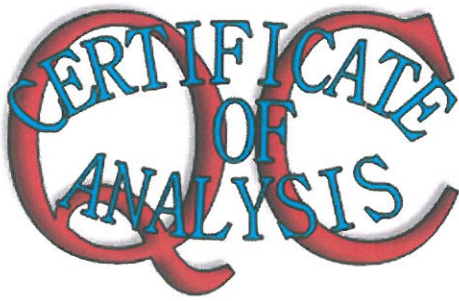
Quality control according to the ISO 13485:2012

GOosafe with SparMED!

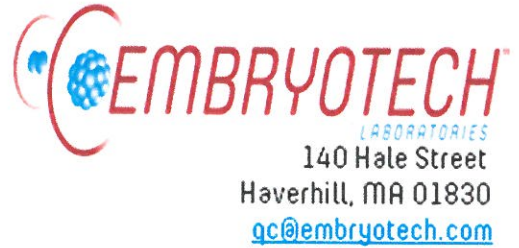
Date: 22 Nov 2017

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ELI Accession Number: S3137-1017SPAR

Date of completion: 10-25-2017

Lot number: 07791, 07820

Order numbers: OOPW-IC03, OOPW-FW03,
OOPW-FW04, OOPW-AT10

Description of test article(s): Oosafe® ICSI/IMSI Dish for Sperm Selection,
Oosafe® 4 Well Dish- Treated Surface,
Oosafe® 4 Well Dish-Non Treated Surface,
Oosafe® Andrology Tube 5ml

Assay system requested by customer: Sperm wash medium was added to the test articles OOPW-IC03, OOPW-FW03, and OOPW-FW04 and incubated for 30 minutes. Post incubation the sperm wash medium was extracted from the test articles and pooled into OOPW-AT10. Sperm was added to the test article and incubated for 24 hours. The forward progressive motility was read and recorded at 24-hours.

Results:

Test method:	Specification	Initial	Result % 24hr	SMI Value	Pass/Fail
SOP/TSG/ELI/008					
Test Article	SMI \geq 0.75	96%	94%	0.98	Pass
Control	\geq 70%	96%	96%	N/A	Pass

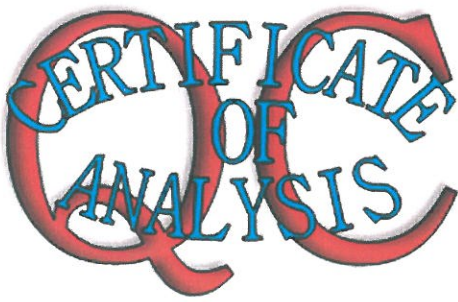
Summary of observations: All test and control sperm was prepared from the same donor and incubated in the same incubator at 32°C and 5% CO₂. The control sperm had a 96% forward progressive motility at 24-hours. The test article sperm had a 94% forward progressive motility at 24-hours.

Signature
Study Director

10-26-2017
Date

Signature
Quality Reviewer

10-26-2017
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ELI Accession Number: E8135-1017SPAR

Date of completion: 10-25-2017

Lot number(s): 07791, 07820

Reference number(s): OOPW-IC03, OOPW-FW03
OOPW-FW04, OOPW-AT10

Description of test article(s): Oosafe® ICSI/IMSI Dish for Sperm Selection,
Oosafe® 4 Well Dish-Treated Surface,
Oosafe® 4 Well Dish-Non Treated Surface,
Oosafe® Andrology Tube

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

Control assay materials: Lysate: Lot number 515-12-761, Sensitivity (λ) = 0.03125 EU/mL

Control Standard Endotoxin (CSE): Lot number 148

LAL Reagent Water (LRW): Lot number AAJ207283

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	-	-	+	+

SparMED requires a pass limit of <20 EU/device

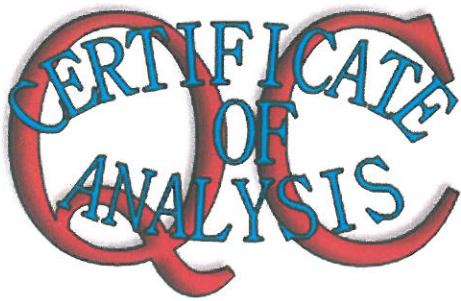
Summary of observations: The error for the Gel-Clot assay is +/- one two-fold dilution. The test article in this assay indicates an Endotoxin Concentration of <0.03125 EU/device.

Signature
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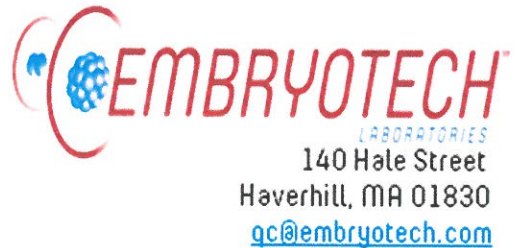
10-27-2017
Date

Signature
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10-27-2017
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ELI Accession Number: SPAR-7689-1017

Date of completion: 10-28-2017

Lot number: 07791

Reference number: OOPW-IC03

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

Assay system requested by customer: 3 20µL of culture medium was placed in the center well of the test article and overlaid with oil. One 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 of culture medium overlaid with oil in a 4-well Dish Reference number 144444:

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 method and results: 21 1-cell (B6C3F1 X B6D2F1) 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% 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

10-30-2017
Date



Signature
Quality Reviewer

10-30-2017
Date