



SparMED Aps  
Ryttermarken 2  
3520 Farum  
Denmark



140 Hale Street  
Haverhill, MA 01830  
[qc@embryotech.com](mailto:qc@embryotech.com)

ELI Accession Number: S2686-0916SPAR

Date of completion: 09-21-2016

Lot numbers: 07706  
07702

Order numbers: OOPW-FW03  
OOPW-CW04

Description of test article(s): Oosafe® 4 Well Dish-Treated Surface and Center Well Dish with 2 Compartments, Label Area Grip

Assay system requested by customer: Sperm wash medium with sperm was added to the test articles (2 test articles pooled) and incubated for 24-hours. Post incubation the sperm wash medium with sperm was extracted from the test articles and pooled. The forward progressive motility was read and recorded at 24-hours.

**Results:**

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

Test Article	Specification	Initial	Result % 24hr	SMI Value	Pass/Fail
Test Article	SMI $\geq$ 0.75	96%	93%	0.98	Pass
Control	$\geq$ 70%	96%	95%	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% CO<sub>2</sub>. The control sperm had a 95% forward progressive motility at 24-hours. The test article sperm had a 93% forward progressive motility at 24-hours.

  
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Signature  
Study Director

09-21-2016  
Date

  
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Signature  
Quality Reviewer

09-21-2016  
Date



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**EMBRYOTECH**  
LABORATORIES  
140 Hale Street  
Haverhill, MA 01830  
[qc@embryotech.com](mailto:qc@embryotech.com)

ELI Accession Number: E7318-0916SPAR

Date of completion: 09-21-2016

Lot number(s): 07702  
07706

Reference number(s): OOPW-CW04  
OOPW-FW03

Description of test article(s): Oosafe® Center Well Dish with 2 Compartments, Label Area Grip and 4 Well Dish-Treated Surface

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

Control assay materials: Lysate: Lot number 515-08-746, Sensitivity ( $\lambda$ ) = 0.03125 EU/mL


Control Standard Endotoxin (CSE): Lot number 148

LAL Reagent Water (LRW): Lot number AZA182110


**Results:**

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	-	-	+	+

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

09-22-2016  
Date

  
Signature  
Quality Reviewer

09-22-2016  
Date



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ELI Accession Number: SPAR-5550-0916

Date of completion: 09-24-2016

Lot number: 07706

Reference number: OOPW-FW03

Description of test article(s): Oosafe® 4 Well Dish - Treated Surface

Assay system requested by customer: 0.5mL of culture medium was placed in the each well of the test article and overlaid with oil. 5-6 one cell mouse embryos were added to each well of the test article and cultured for 96-hours.

Control assay method and results: 15 one cell (B6C3F1 X B6D2F1) embryos were cultured in 0.5mL drops in a 4-Well Dish using culture medium:

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 one cell stage control embryos to develop to expanded blastocyst within 96-hours.

Test assay method and results: 21 one cell (B6C3F1 X B6D2F1) embryos were cultured in each well containing culture medium overlaid with oil in the test article:


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% CO<sub>2</sub>. 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.

  
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Signature  
Study Director

09-26-2016  
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Signature  
Quality Reviewer

09-26-2016  
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Date