

SparMED Aps Ryttermarken 2 3520 Farum Denmark



ELI Accession Number: S2686-0916SPAR

Date of completion: 09-21-2016

Lot numbers: 07706

Order numbers: OOPW-FW03

07702

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: SOP/TSG/ELI/008	Specification	Initial	Result % 24hr	SMI Value	Pass/Fail
Test Article	SMI ≥ 0.75	96%	93%	0.98	Pass
Control	≥ 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% CO2. 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.

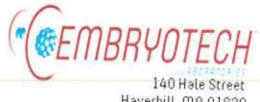
Signature Study Director

Quality Reviewer

-21-2016



SparMED Aps Ryttermarken 2 3520 Farum Denmark



Haverhill, MA 01830 gc@embryotech.com

ELI Accession Number: E7318-0916SPAR

07706

Date of completion: 09-21-2016

Lot number(s): 07702

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 (λ) = 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		
2λ.06	+	+	Undiluted		-	+	
λ.03	+	+	1:2	4		-	
1/2λ .015	-		1:4	_		-	1
1/4λ .0075		-	1:8		2-2	-	+
NWC	-	-	1:16	-1-1	-	+	+

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

Signature

Quality Reviewer

09-22-2016



SparMED Aps Ryttermarken 2 3520 Farum Denmark



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 (BeC3F1 X BeD2F1) embryos were cultured in 0.5mL drops in a 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 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 %) 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 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.

Stgnature Study Director 09-26-2

Date

Signature Quality Reviewer 09-210-2014

Date