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ELI Accession Number: S2283-1015SPAR

Date of completion: 10-30-2015

Lot numbers: 08/2018, 09/2018

Reference number: N/A

Description of test articles: Oosafe CO₂ Incubator Disinfectant, Oosafe Hand Disinfectant

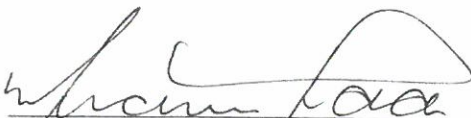
Assay system requested by customer: An incubator was cleaned with the test article (Incubator Disinfectant). Post cleaning 1mL of the test article (Hand Disinfectant) was placed in a corresponding Petri dish and placed in the cleaned incubator. A prepared sperm sample was then placed in the cleaned incubator with the test articles for 24-hours

Test Assay method 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 the sperm gradient in a centrifuge cycle. 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 sample.

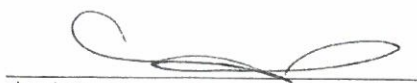
Results:

	<u>Initial motility</u>	<u>24hour motility</u>
Test Article (incubator ELI-068)	90 %	90 %
Control (incubator ELI-248)	90 %	90 %

Summary of observations: The motility of the sperm remained consistent in the incubator ELI-068 (that was cleaned with and that contained the test articles) and the incubator ELI-248 (the control sperm). Both the test and control showed no sign of affecting motility during the course of the assay.

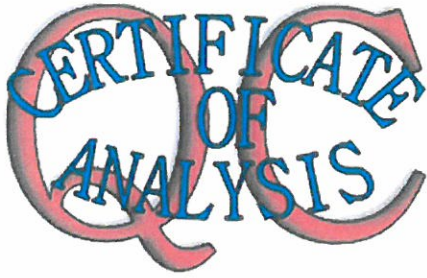

 signature
 Study Director

11-09-2015
 date


 signature
 Quality Reviewer

11.9.2015
 date

Amended: 11-09-2015



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ELI Accession Number: SPAR-3751-1015

Date of completion: 11-02-2015

Lot numbers: 08/2018, 09/2018

Reference number: N/A

Description of test articles: Oosafe CO₂ Incubator Disinfectant, Oosafe Hand Disinfectant

Assay system requested by customer: An incubator was cleaned with the test article CO₂ Incubator Disinfectant. Post cleaning 1mL of test article Hand Disinfectant was placed in a Petri dish and placed in the cleaned incubator. A culture plate was set up and one-cell mouse embryos were cultured in the cleaned incubator with the test article for 96-hours.

Control assay method and results: 15 1-cell (B6C3F₁ X B6D2F₁) embryos were cultured in triplicate micro drops of culture medium in control incubator ELI-243:

15 / 15 (100 %)
 15 / 15 (100 %)

1-cell to 2-cell within 24 hr
 1-cell to expanded blastocyst within 96 hr

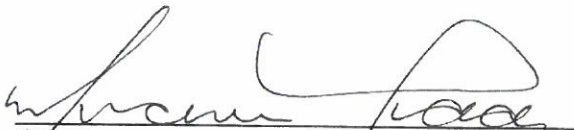
For a valid assay, *Embryotech™* requires at least 70% of 1-cell control embryos to develop to expanded blastocyst within 96-hours.

Test assay method and results: 21 1-cell (B6C3F₁ X B6D2F₁) embryos were cultured in triplicate micro drops of culture medium while in an incubator ELI-068 containing the Petri dish filled with the test article:

21 / 21 (100 %)
 19 / 21 (90 %)

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. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 90 percent of the embryos cultured in an incubator previously cleaned and containing the test article developed to the expanded blastocyst stage within 96-hours.


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11-02-2015
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