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Date of completion: 12-14-2018

Lot number: N/A

Reference number: N/A

Description of test article(s): Mini Matcher Benchtop Device

Assay system requested by customer: The test article was placed in an incubator next to a culture dish. One cell mouse embryos were placed in the culture dish and cultured for 96-hours. The test article was pressed for 30-seconds, three to four times over a 5-minute period, five times each day of culture to illuminate on the culture dish. There was no impact of the test article on airflow, except for the time frame of illuminating the light which required the incubator door to remain open.

Control assay method and results: 15 1-cell (B6C3F1 X B6D2F1) embryos were cultured in triplicate micro drops of culture medium overlaid with oil in a control incubator (ELI-344):

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 overlaid with oil with the test article placed next to the culture dish in incubator ELI-336:

21 / 21 (100 %)
18 / 21 (86 %)

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. 86 percent of the test embryos cultured in the culture plate next to the test article developed to the expanded blastocyst stage within 96-hours

signature
Study Director

signature
Quality Reviewer

12-19-2018

date

12-19-2018

date

Amended: 12-19-2018