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ELI Accession Number: IIL-5636-0421

Date of completion: 04-19-2021

Lot number: 0192102A

Reference number: LBL019

Description of test article(s): FOR CRYO USE Label

Assay system requested by customer: The test article is placed on a culture plate. One cell mouse embryos are placed in the culture plate and cultured for 96-hours.

Control assay method and results: 21 one cell (B6C3F1 X B6D2F1) embryos were cultured in triplicate micro drops of culture medium overlaid with oil in control incubator (ELI-350):

21 / 21 (100 %)

1-cell to 2-cell within 24 hr

21 / 21 (100 %)

1-cell to expanded blastocyst within 96 hr

For a valid assay, Embryotech™ requires at least 80% of one cell 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 triplicate micro drops of culture medium overlaid with oil with the test article adhered to the outside of the culture plate in incubator ELI-366:

21 / 21 (100 %)

1-cell to 2-cell within 24 hr

21 / 21 (100 %)

1-cell to expanded blastocyst within 96 hr

Pass/Fail = Pass

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


Signature
Study Director

04-19-2021
Date


Signature
Quality Reviewer

04-19-2021
Date