

QC

Certificate of Analysis

embryotools

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REQUESTED BY: MONASH BIOTECH PVT. LTD. (78/2/4, GIDC Makarpura., Vadodara 390010 Gujarat India)

ASSAY REQUESTED BY CUSTOMER: MEA - Standard Mouse embryo assay

OPERATION PROCEDURE: SOP-MEA-00/WI-MEA-05

TYPE OF ASSAY: Indirect

INTERNAL NUMBER: MEA.021.1086.2023

DATE: 17/11/2023 - 21/11/2023

Product information provided by the customer (Embryotools cannot be held responsible for the veracity of this information)

DESCRIPTION OF TEST PRODUCT: MONASH INJECTION MICROPIPETTE

REF: MBIS-0511-35

LOT NUMBER: 2000 IP1603

EXP. DATE: 2026-02

PROTOCOL:

Samples were incubated at 37°C for 60 min with previously tested culture medium. Culture dishes were prepared with the extracted medium in triplicate and equilibrated overnight prior to use. Fresh 1-cell stage mouse embryos were collected from F1 hybrid females (B6/CBA) crossed with males from the same genetic background, washed thoroughly and cultured in the extracted medium in drops of 50ul, in groups of 2, up to Day 5. Control group was prepared following the same set-up and conditions, and embryos cultured in parallel using tested medium not exposed to test samples. Embryo development of test and control group was followed every 24 h and photos were taken and included in this report (annex I).

CONTROL AND TEST ASSAY RESULTS:

Embryo developmental rates of control and tested group.

Embryo development rates					
	n	Day 2 Two-cell stage n (%)	Day 5 Expanded blastocyst stage n (%)	Good Quality (morphology) Blastocysts n (%)	Result
Control	15	15 (100)	13 (86.67)	12 (92.31)	Passed*
MONASH INJECTION MICROPIPETTE (Lot:2000 IP1603)	21	21 (100)	21 (100)	17 (80.95)	Passed*

SUMMARY OF OBSERVATIONS: All test and control embryos were selected randomly from a common pool and cultured at 37.3°C with a tri-gas atmosphere with optimal %CO₂ and %O₂. Embryotools acceptance criteria for this standard test is that more than 80% of mouse embryos develop to the expanded blastocyst stage and pass a visual morphological examination of the inner cell mass (ICM) and trophectoderm (TE) cells. The results of this assay refer to the items tested.

* More than 80% of the test group embryos developed to the expanded blastocyst stage within 5 days, fulfilling acceptance criteria for this test.

These results are representative of the test samples submitted by the customer.

Nuno Costa-Borges, PhD

Scientific Director

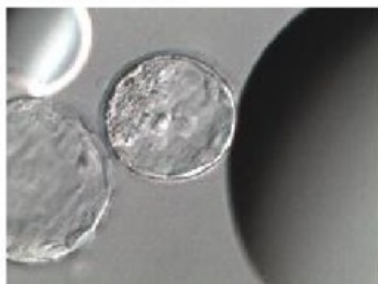
Gloria Calderón, PhD

Quality Assurance

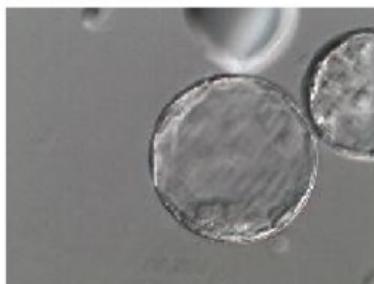


Annex I
Control

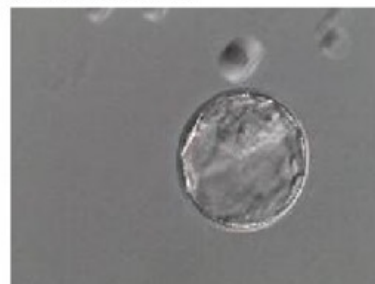
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#3, 21/11/2023 9:40:51



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#5, 21/11/2023 9:41:11



#6, 21/11/2023 9:41:24



#7, 21/11/2023 9:41:32



#8, 21/11/2023 9:41:51



#9, 21/11/2023 9:41:53



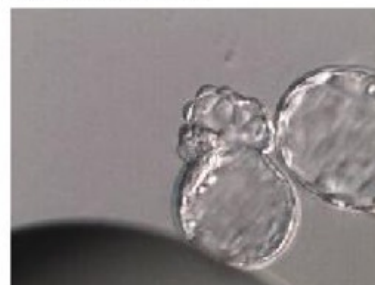
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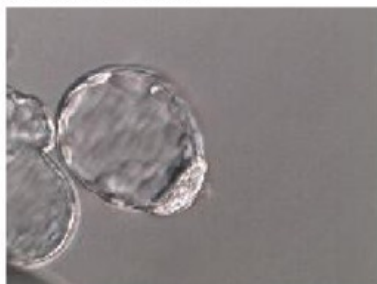
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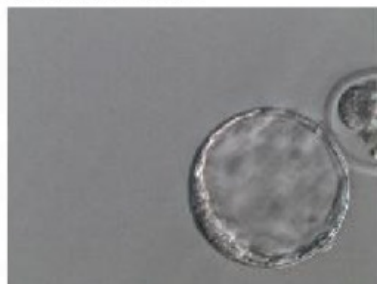
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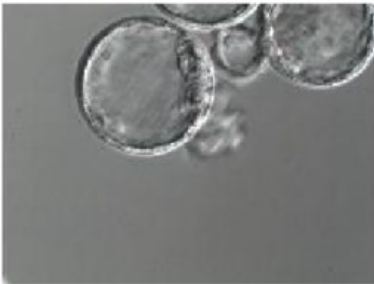
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MONASH INJECTION MICROPIPETTE
(REF: MBIS-0511-35 ; Lot: 2000 IP1603)

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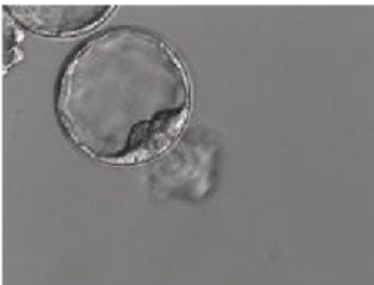
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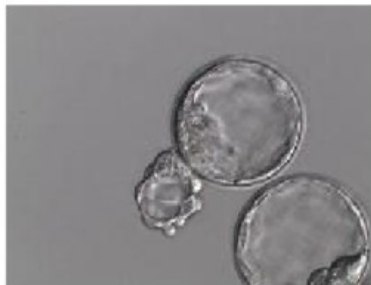
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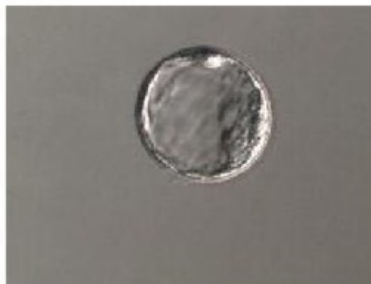
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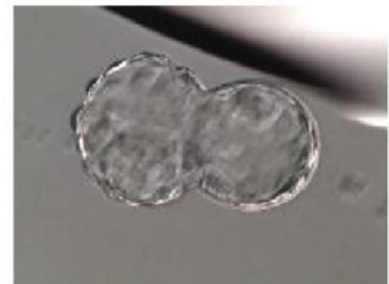
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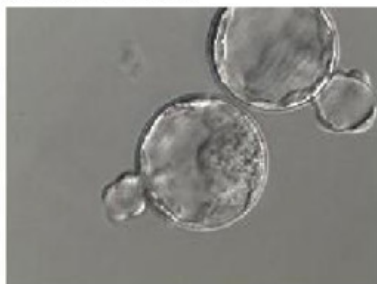
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MONASH INJECTION MICROPIPETTE
(REF: MBIS-0511-35 ; Lot: 2000 IP1603)

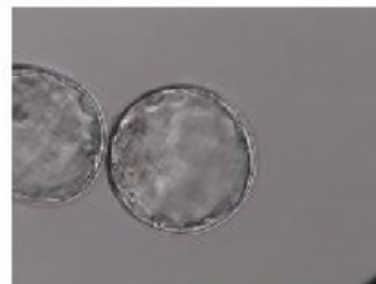
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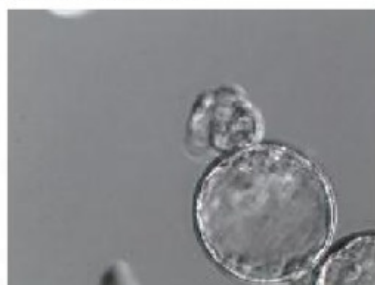
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