

# QC

## Certificate of Analysis

**REQUESTED BY:** IVF Gen (6 Carter Close, Smithfield 04878 Queensland Australia)

**ASSAY REQUESTED BY CUSTOMER:** MEA - Standard Mouse embryo assay

**OPERATION PROCEDURE:** SOP-MEA-00

**TYPE OF ASSAY:** Indirect

**INTERNAL NUMBER:** MEA.006.342.2016

**DATE:** 09/05/2016 - 13/05/2016

**DESCRIPTION OF TEST PRODUCT:** Culture tubes, 12.0ml

**REF:** GEN82341

**LOT NUMBER:** 29/03/16

**EXP. DATE:** 29/03/2021

### PROTOCOL:

Samples were exposed to previously tested culture medium and incubated for 60 minutes at 37°C. 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 up to Day 5 (96 hours). Control group was prepared following the same set-up and conditions, and embryos cultured in parallel using tested medium not exposed to the sample. 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 Blastocyst stage n (%)	Good Quality (morphology) Blastocysts n (%)	Result
Control	15	15 (100)	15 (100)	15 (100)	<b>Passed*</b>
Culture tubes, 12.0ml (Lot:29/03/16)	21	21 (100)	20 (95.24)	18 (90)	<b>Passed*</b>

**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 %CO<sub>2</sub> and %O<sub>2</sub>. Acceptance criteria of this standard test is ≥80% of mouse embryos must develop to the expanded blastocyst stage and pass a visual morphological examination of the inner cell mass (ICM) and trophectoderm (TE) cells.

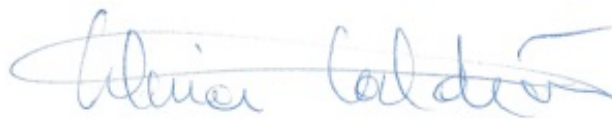
\* More than 80% of the test group embryos developed to the expanded blastocyst stage within 5 days, fulfilling acceptance criteria for this test.

Nuno Costa-Borges, PhD



Scientific Director

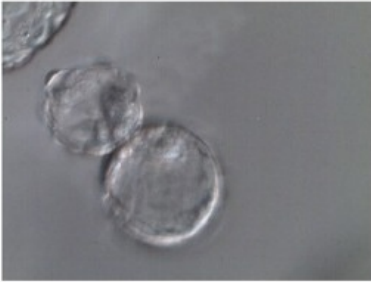
Gloria Calderón, PhD



Quality Assurance

Annex I  
Control

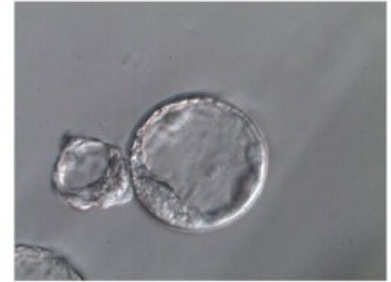
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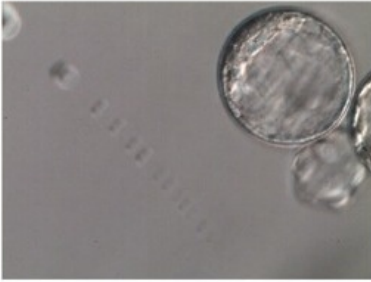
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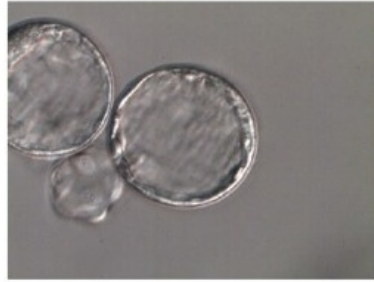
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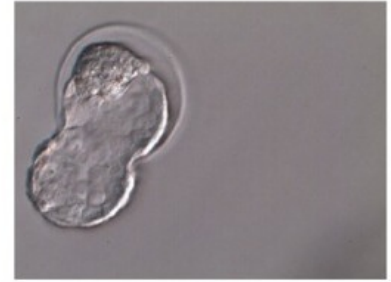
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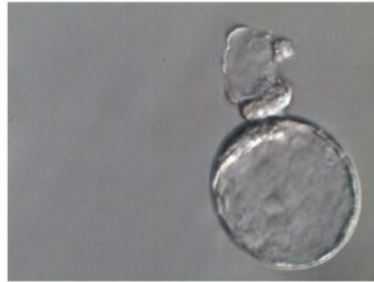
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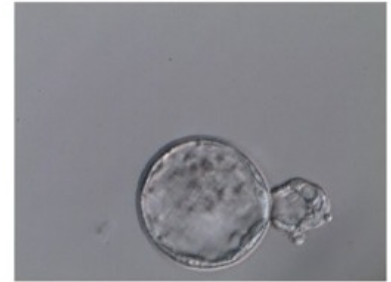
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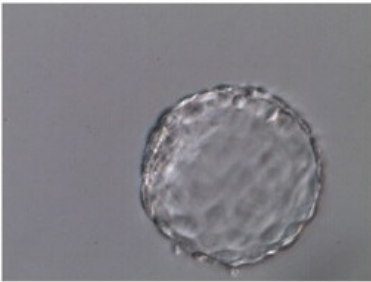
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#10, 13/05/2016 11:01:23



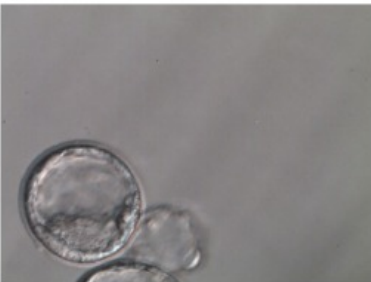
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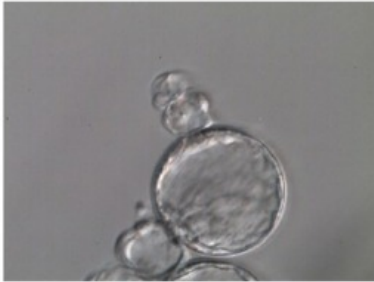


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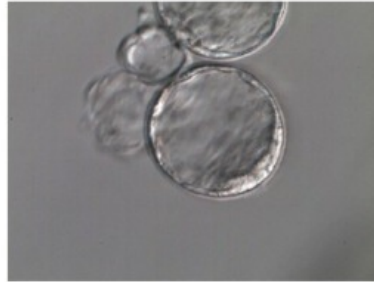


Culture tubes, 12.0ml  
(REF: GEN82341 ; Lot: 29/03/16)

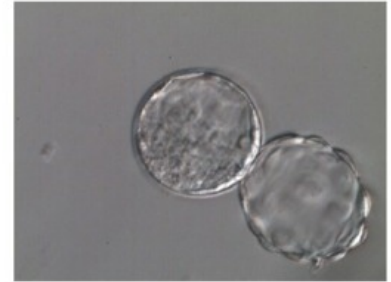
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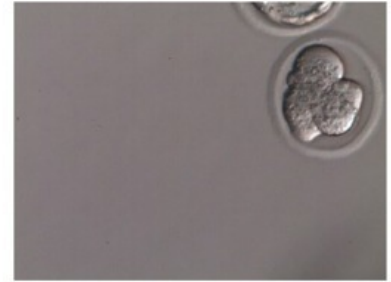
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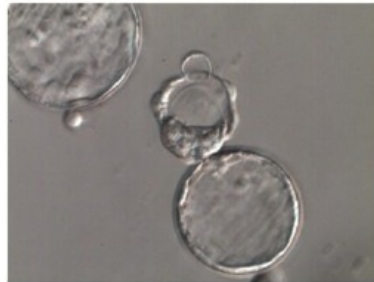
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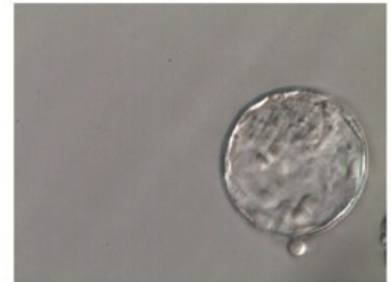
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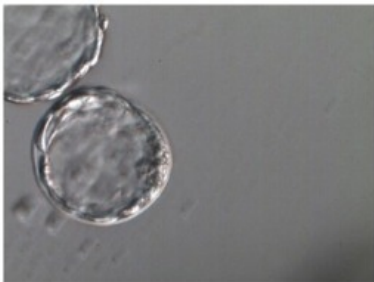
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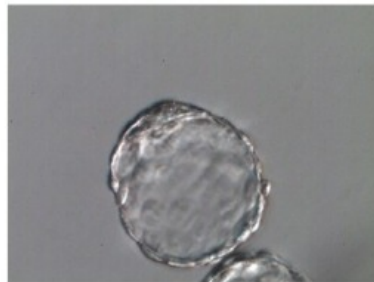
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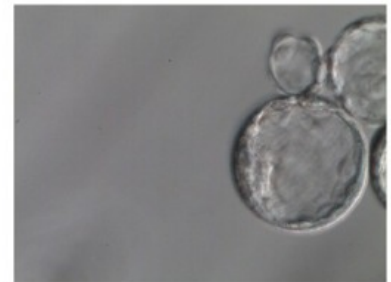
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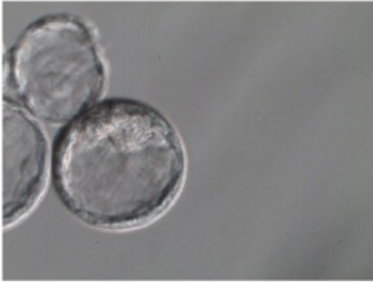


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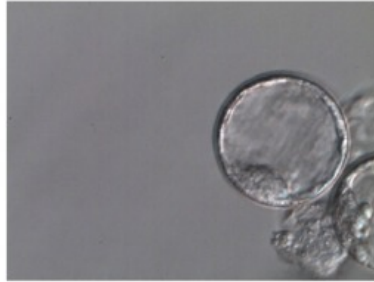


Culture tubes, 12.0ml  
(REF: GEN82341 ; Lot: 29/03/16)

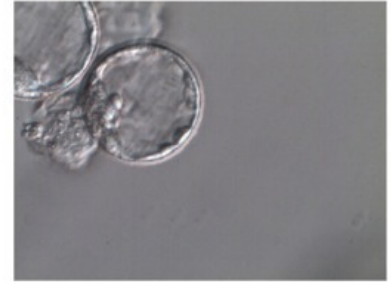
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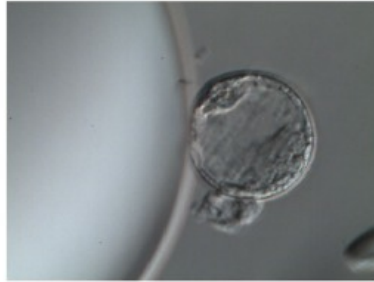
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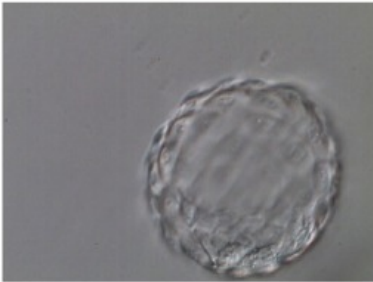
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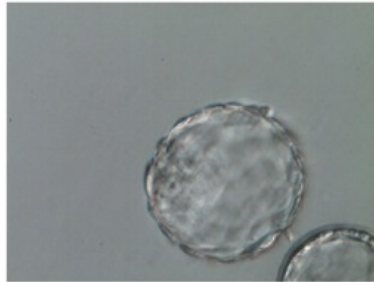
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