

QC

Certificate of Analysis

REQUESTED BY: IVF Prime, inc (Asagi Öveçler neighborhood 1328 street 13/9 Çankaya, Ankara 06460 Turkey)

ASSAY REQUESTED BY CUSTOMER: MEA - Standard Mouse embryo assay

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

TYPE OF ASSAY: Indirect

INTERNAL NUMBER: MEA.011.285.2018

DATE: 26/09/2018 - 01/10/2018

DESCRIPTION OF TEST PRODUCT: EmbryoShield

REF: ES001

LOT NUMBER: 0717ES

EXP. DATE: n/a

PROTOCOL:

Test inline filtre was connected to a benchtop incubator. Culture dishes were prepared with previously tested culture medium and mineral oil, and equilibrated in the same incubator overnight under optimal conditions, prior to use. After equilibration, pH was measured (7.286). 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 up to Day 6 (120 hours). Control group was prepared following the same set-up and conditions, and embryos cultured in parallel in a separate incubator, not exposed to the test filtre. 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:

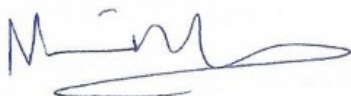
Embryo developmental rates of control and tested group.

	Embryo development rates				Result
	n	Day 2 Two-cell stage n (%)	Day 6 Expanded blastocyst stage n (%)	Good Quality (morphology) Blastocysts n (%)	
Control	15	15 (100)	14 (93.33)	13 (92.86)	Passed*
EmbryoShield (Lot:0717ES)	21	21 (100)	21 (100)	20 (95.24)	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 6 days, fulfilling acceptance criteria for this test.

Nuno Costa-Borges, PhD



Scientific Director

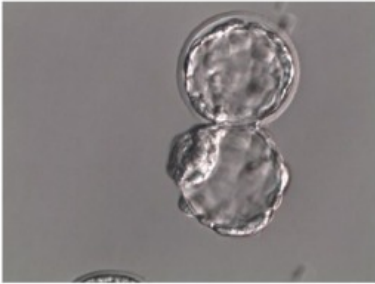
Gloria Calderón, PhD



Quality Assurance

Annex I
Control

#1, 01/10/2018 11:22:39



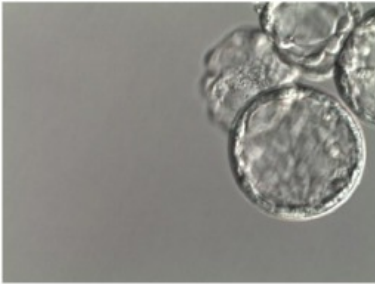
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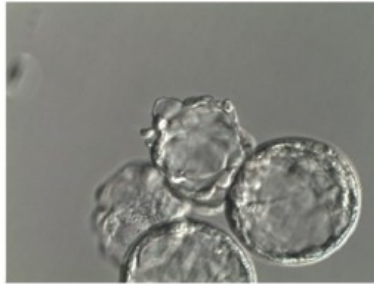
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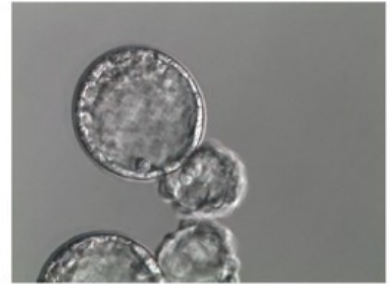
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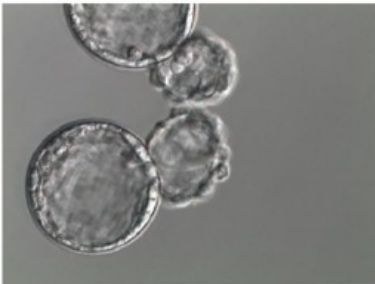
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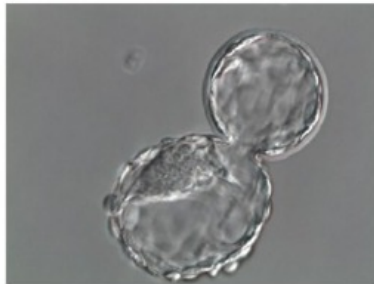
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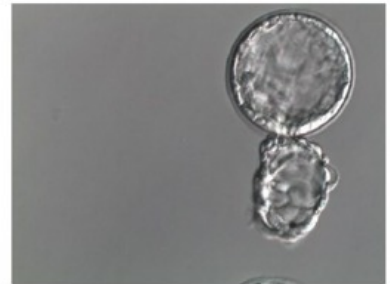
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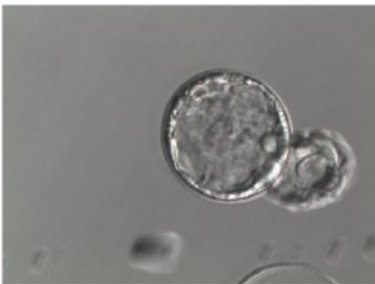
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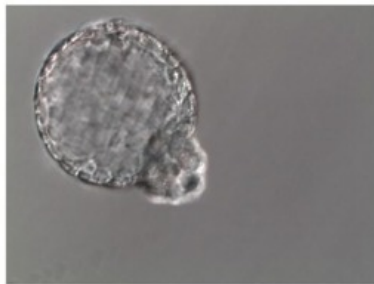
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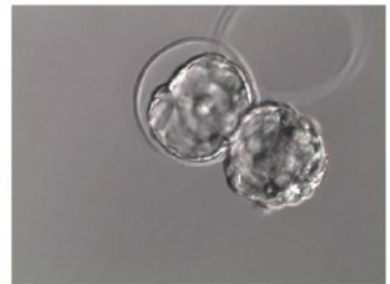
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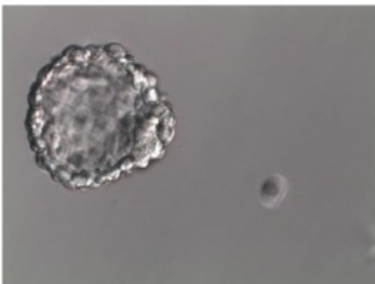
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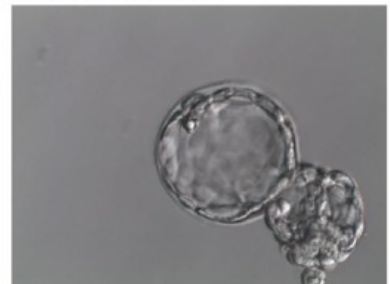
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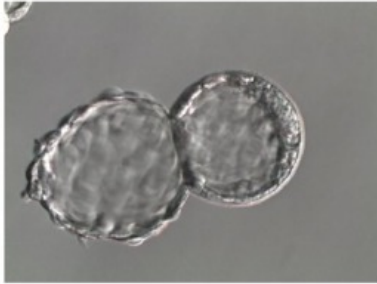


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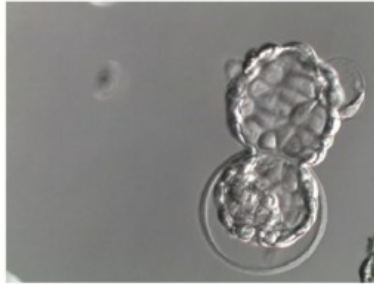


EmbryoShield
(REF: ES001 ; Lot: 0717ES)

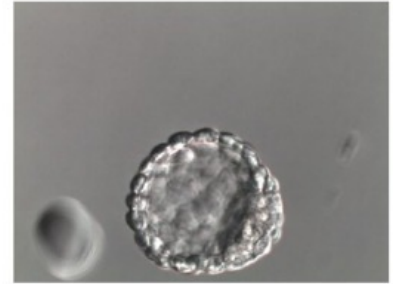
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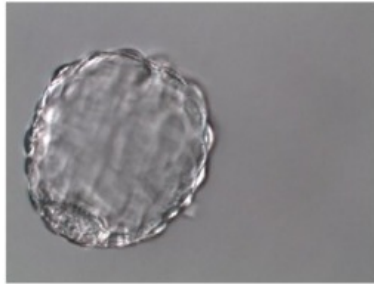
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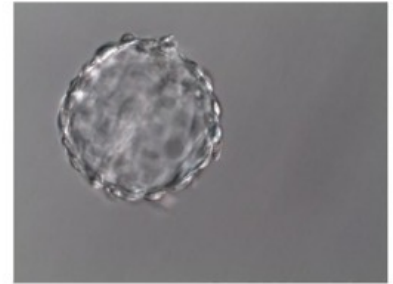
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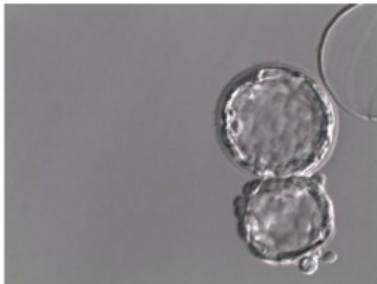
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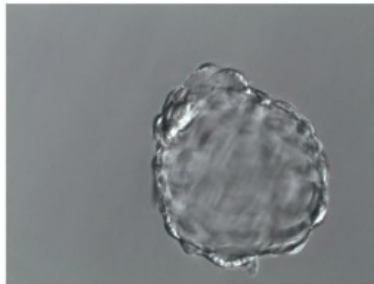
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#8, 01/10/2018 10:57:17



#9, 01/10/2018 10:57:19



#10, 01/10/2018 10:57:31



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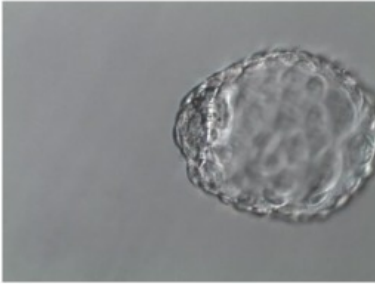


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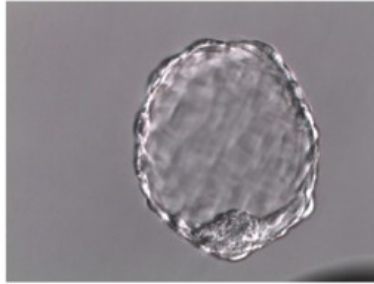


EmbryoShield
(REF: ES001 ; Lot: 0717ES)

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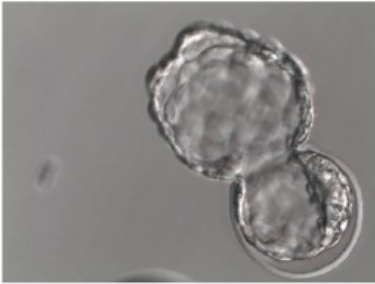
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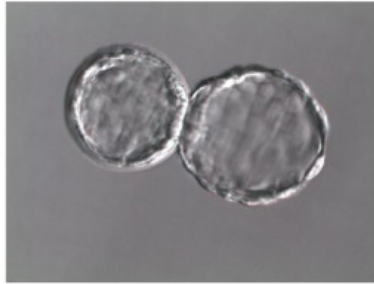
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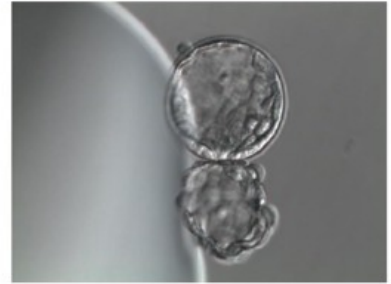
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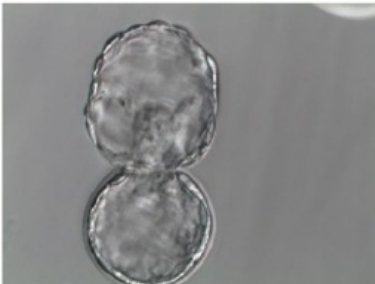
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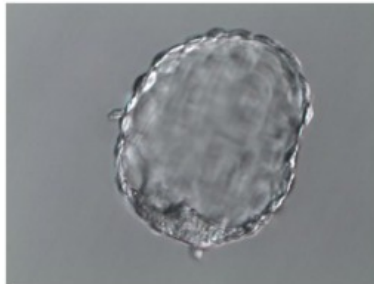
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