

QC

Certificate of Analysis

REQUESTED BY: Regionals for scientific and laboratory industry SASOmed (Shamrohk- baiadeer, AMMAN 01182 Jordan)

ASSAY REQUESTED BY CUSTOMER: MEA - Standard Mouse embryo assay

OPERATION PROCEDURE: SOP-MEA-18

TYPE OF ASSAY: Indirect

INTERNAL NUMBER: MEA.016.1197.2021

DATE: 29/06/2021 - 03/07/2021

DESCRIPTION OF TEST PRODUCT: Safepit 145 / Safepit 300

REF: 0101002/0101004

LOT NUMBER: 21S304001/21S204001

EXP. DATE: 01/05/2025

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. 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. 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				Result
	n	Day 2 Two-cell stage n (%)	Day 5 Expanded blastocyst stage n (%)	Good Quality (morphology) Blastocysts n (%)	
Control	15	15 (100)	14 (93.33)	11 (78.57)	Passed*
Safepit 145 / Safepit 300 (Lot:21S304001/21S204001)	21	21 (100)	21 (100)	18 (85.71)	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 trophoctoderm (TE) cells. The results of this assay refer to the items tested.

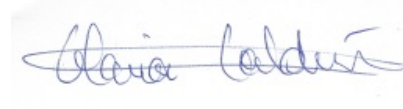
* More than 80% of the test group embryos developed to the expanded blastocyst stage within 5 days, fulfilling acceptance criteria for this test.

Nuno Costa-Borges, PhD



Scientific Director

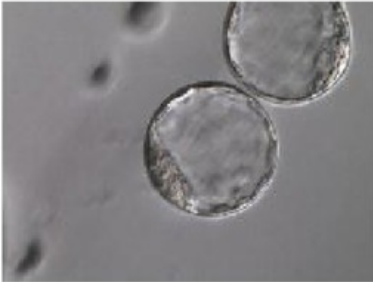
Gloria Calderón, PhD



Quality Assurance

Annex I
Control

#1, 03/07/2021 10:45:40



#2, 03/07/2021 10:45:42



#3, 03/07/2021 10:45:44



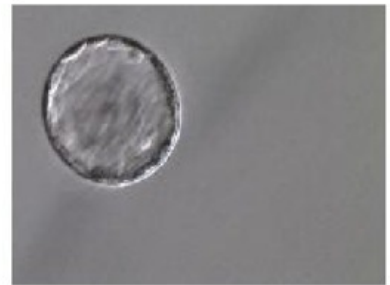
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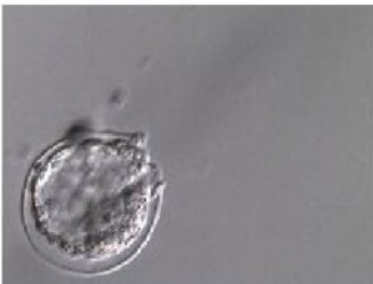
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#7, 03/07/2021 10:46:28



#8, 03/07/2021 10:46:56



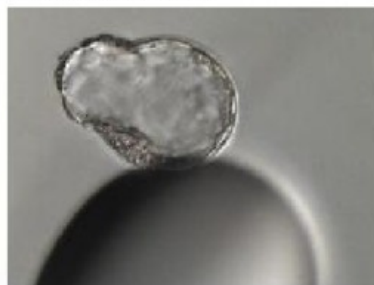
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#10, 03/07/2021 10:47:13



#11, 03/07/2021 10:47:16



#12, 03/07/2021 10:47:31



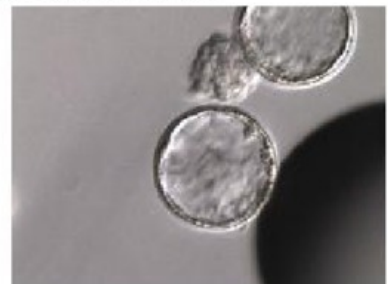
#13, 03/07/2021 10:47:34



#14, 03/07/2021 10:47:49



#15, 03/07/2021 10:47:50



Safepit 145 / Safepit 300
(REF: 0101002/0101004 ; Lot: 21S304001/21S204001)

#1, 03/07/2021 10:38:53



#2, 03/07/2021 10:38:54



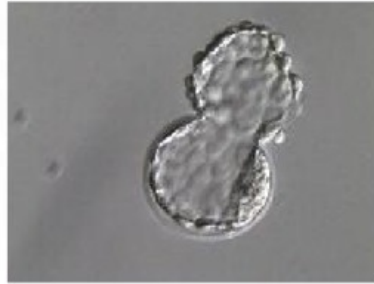
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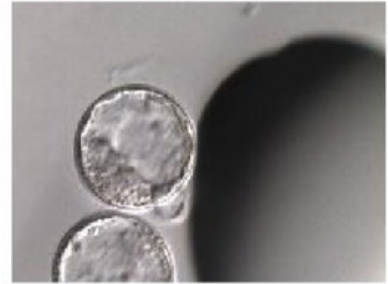
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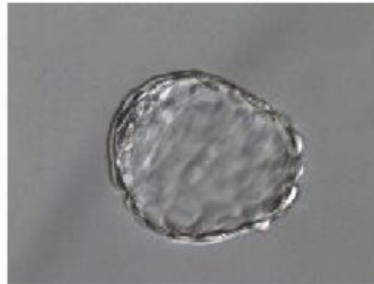
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#7, 03/07/2021 10:39:45



#8, 03/07/2021 10:40:07



#9, 03/07/2021 10:40:09



#10, 03/07/2021 10:40:29



#11, 03/07/2021 10:40:31



#12, 03/07/2021 10:41:00



Safepit 145 / Safepit 300
(REF: 0101002/0101004 ; Lot: 21S304001/21S204001)

#13, 03/07/2021 10:41:06



#14, 03/07/2021 10:41:22



#15, 03/07/2021 10:41:25



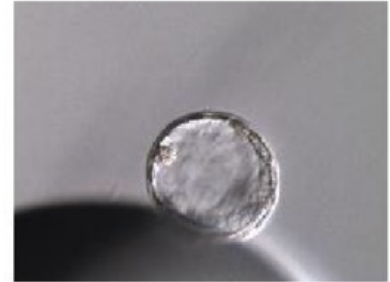
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#17, 03/07/2021 10:41:44



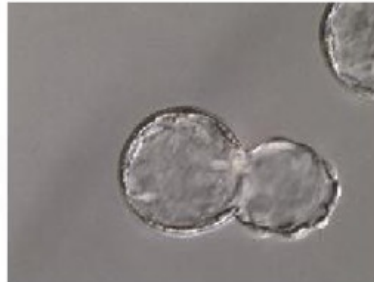
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#19, 03/07/2021 10:42:14



#20, 03/07/2021 10:42:31



#21, 03/07/2021 10:42:35

