



QC

Certificate of Analysis

REQUESTED BY: IVF Prime, inc (Çamlica Mah. Anadolu Bulvari No: 20 - Timko Sokak AA Blok, Ankara 06200 Yenimahalle 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.018.1081.2022

DATE: 09/06/2022 - 13/06/2022

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

DESCRIPTION OF TEST PRODUCT: EmbryoSafe Hand Disinfectant

REF: ESHD001 - ESHD002 LOT NUMBER: 2022/06ESHD EXP. DATE: 06/2024

PROTOCOL:

Culture dishes were prepared with previously tested 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 up to Day 5. A separate dish filled with test product was placed inside the same incubator chamber for the whole duration of the assay. Control group was prepared following the same set-up and conditions, and embryos cultured in parallel in a separated incubator, without presence of 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 Expanded blastocyst stage n (%)	Good Quality (morphology) Blastocysts n (%)	Result
Control	15	15 (100)	14 (93.33)	13 (92.86)	Passed*
EmbryoSafe Hand Disinfectant (Lot:2022/06ESHD)	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 trophectoderm (TE) cells. The results of this assay refer to the items tested.

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

Nuno Costa-Borges, PhD

Gloria Calderón, PhD

Quality Assurance

Scientific Director



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



Annex I Control



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#2, 13/06/2022 8:58:05



#3, 13/06/2022 8:58:08



#4, 13/06/2022 8:58:26



#5, 13/06/2022 8:58:33



#6, 13/06/2022 8:58:54



#7, 13/06/2022 8:58:59



#8, 13/06/2022 8:59:29



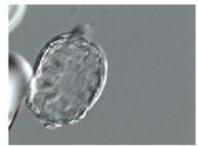
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#10, 13/06/2022 8:59:46



#11, 13/06/2022 8:59:52



#12, 13/06/2022 9:00:07



#13, 13/06/2022 9:00:09



#14, 13/06/2022 9:00:29









EmbryoSafe Hand Disinfectant

(REF: ESHD001 - ESHD002; Lot: 2022/06ESHD)



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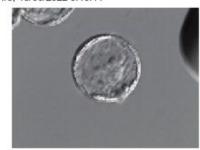




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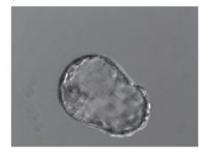
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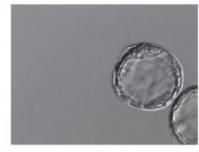
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#5, 13/06/2022 9:10:40



#6, 13/06/2022 9:10:57



#7, 13/06/2022 9:11:02



#8, 13/06/2022 9:11:21



#9, 13/06/2022 9:11:28



#10, 13/06/2022 9:11:46



#11, 13/06/2022 9:11:48



#12, 13/06/2022 9:12:10





EmbryoSafe Hand Disinfectant

(REF: ESHD001 - ESHD002 ; Lot: 2022/06ESHD)



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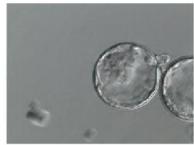
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#15, 13/06/2022 9:12:34



#16, 13/06/2022 9:12:56



#17, 13/06/2022 9:12:58



#18, 13/06/2022 9:13:14



#19, 13/06/2022 9:13:22



#20, 13/06/2022 9:13:52



#21, 13/06/2022 9:13:54



