

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: SMA - Sperm motility assay

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

TYPE OF ASSAY: Indirect

INTERNAL NUMBER: SMA.018.1088.2022

DATE: 14/06/2022 - 15/06/2022

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:

A human sperm sample was processed in duplicate using silica-based density gradients (95%, 70% and 45% concentration). Afterwards, the resulting sperm preparation was diluted with previously tested medium to achieve a final concentration of approximately 10 million progressive sperms per milliliter. Test and control groups were incubated in parallel in different incubators at 37.3°C and optimal %CO₂ and %O₂, and a separate dish filled with test product was placed inside the test incubator chamber for the whole duration of the assay. Sperm motility was assessed at 0, 4, 8 and 24 hours after processing. Sperms were classified according to their mobility patterns in progressive (PS), non-progressive (NPS) and immobile (IS).

CONTROL AND TEST ASSAY RESULTS:

Motility evaluation of control and tested group.

	Motility evaluation											
	0 hours			4 hours			8 hours			24 hours		
	PS%	NPS%	IS%	PS%	NPS%	IS%	PS%	NPS%	IS%	PS%	NPS%	IS%
Control	93.20	4.35	2.25	85.70	4.05	10.25	91.95	1.35	6.70	80.45	2.20	17.35
EmbryoSafe Hand Disinfectant (lot.:2022/06ESHD)	93.20	4.55	2.25	89.90	3.00	7.10	86.10	3.30	10.60	73.30	5.50	21.20

* progressive (PS), non-progressive (NPS) and immobile (IS)

Sperm motility index (SMI) values:

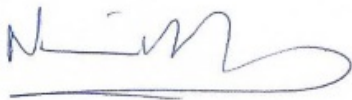
	Sperm motility index			
	0 hours	4 hours	8 hours	24 hours
EmbryoSafe Hand Disinfectant (lot.:2022/06ESHD)	1.00	1.05	0.94	0.91

SUMMARY OF OBSERVATIONS: Test and control samples were incubated in the same incubator at 37.3°C with a tri-gas atmosphere with optimal %CO₂ and %O₂. The results of this assay refer to the items tested.

Sperm motility index (SMI) corresponds to the value obtained by dividing the percentage of motile sperms in the test group by the percentage of motile sperms in the control group. Values <0.75 by 8 h post incubation are considered as indicators of poor assisted reproduction outcomes. This this cut-off value has been used as Embryotools reference to indicate sperm toxicity.

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

Nuno Costa-Borges, PhD



Scientific Director

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Quality Assurance