

QC

Certificate of Analysis

REQUESTED BY: Hunter Scientific Limited (Unit 1, Priors Hall Widdington, Saffron Walden CB11 3SB Essex United Kingdom of Great Britain and Northern Ireland)

ASSAY REQUESTED BY CUSTOMER: SMA - Sperm motility assay

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

TYPE OF ASSAY: Indirect

INTERNAL NUMBER: SMA.016.1248.2021

DATE: 07/07/2021 - 08/07/2021

DESCRIPTION OF TEST PRODUCT: Soda Pasteur Pipette

REF: PPS

LOT NUMBER: 5036

EXP. DATE: 2025-06

PROTOCOL:

A human sperm sample was processed in duplicate using silica-based density gradients (95%, 70% and 45% concentration) and test product incubated with previously tested medium for 60 min at 37°C. Afterwards, the resulting sperm preparation was incubated with the extracted medium (test group) or control tested medium (control group), to achieve a final concentration of approximately 10 million progressive sperms per milliliter. Test and control groups were incubated in parallel in the same incubator chamber at 37.3°C and optimal %CO₂ and %O₂, and sperm motility 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	97.40	1.10	1.50	91.25	2.85	5.90	91.65	1.15	7.20	64.85	19.55	15.60
Soda Pasteur Pipette (lot.:5036)	95.85	1.20	2.80	89.25	4.20	6.55	85.30	3.15	11.55	77.80	11.50	10.70

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

Sperm motility index (SMI) values:

	Sperm motility index			
	0 hours	4 hours	8 hours	24 hours
Soda Pasteur Pipette (lot.:5036)	0.98	0.98	0.93	1.20

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 cut-off value has been used as Embryotools reference to indicate sperm toxicity.

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Scientific Director

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Quality Assurance