



LABORATORY TEST REPORT

Microbiología y Calidad Industrial MCI S.A.
 Cédula jurídica 3-101-600184
 Zona Franca Zeta, building No. 33, Montecillos de Alajuela. Costa Rica
 Phone (506) 7005-5497 / (506) 7005-5498 / E-mail: info@mycindustrial.com



Report number: 062-270820(1)

Customer name/ID Aquametric S.A. / 062
Contact name Mauricio Herrera
Facility/address Río Segundo. Alajuela, Costa Rica

Sampling date/time 27-AUG-2020 / 08:36
Sampling procedure reference *IN-007 Rev. D.
Samples reception date/time 27-AUG-2020 / 10:26

Test start date/time 27-AUG-2020 / 17:51
Test finish date/time 27-AUG-2020 / 19:39
Type of test *Bacterial Endotoxin (LAL Test / Kinetic Turbidimetric Technique).
ID Product/Area tested Purification system
Test method reference TM-006 Rev. H.

Test Results

Sample Name	Endotoxin measured (EU/mL)*	Dilution used	Endotoxin result (EU/mL)*	PPC results (Inhibition / Enhancement Test)		Pass /Fail
				Endotoxin recovered (EU/mL)*	Recovery (%)	
Purification system	< 0,0313	1:2	< 0,0625	0,152	122	Pass
	< 0,0313	1:4	< 0,125	0,140	112	Pass
	< 0,0313	1:8	< 0,25	0,138	110	Pass
Negative control (LRW)	Not detected	N/A	N/A	N/A	N/A	Pass
Acceptance criteria						
Alert level	N/A		Action level	2 EU/mL		

Standard curve information				
Concentration range (EU/mL)	Slope	Y Intercept	Middle concentration (EU/mL)	Correlation coefficient
0,0313 – 1,00	-0,248	2,84	0,125	-0,997

* Accredited test / ** Non-accredited test (Accreditation scope available on www.eca.or.cr)



FM-059 Rev. F	THIS TEST REPORT SHALL NOT BE REPRODUCED EXCEPT IN FULL, WITHOUT WRITTEN APPROVAL OF MICROBIOLOGÍA Y CALIDAD INDUSTRIAL MCI S.A. TEST RESULTS ARE APPLICABLE FOR SAMPLES TESTED ONLY. WHEN CUSTOMER PERFORMED THE SAMPLING PROCESS, RESULTS ARE APPLICABLE FOR SAMPLES AS THEY WERE RECEIVED. DECISION RULE AGREED WITH CUSTOMER.	DCR 0694 Page 1/2
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Equipment and materials

Equipment	Description	Identification	Cal. date	Cal. due date
	Pyros Kinetix Flex	P/N 017 / ID 029	APR-20	APR-21
	Repeater pipette	P/N 041 / ID 074	JUL-20	JAN-21
	Automatic pipette	P/N 014 / ID 023	MAR-20	MAR-21
	Automatic pipette	P/N 014 / ID 025	DEC-19	DEC-20
	Thermometer	P/N 001 / ID 133	MAY-20	NOV-20
Materials	Description	Supply ID	Lot number	Exp. date
	LAL reagent water (LRW)	002386	AE25912272	31-JAN-22
	Control Standard Endotoxin	002330	168	11-JUL-23
	LAL Reagent / Pyrotell® T	002349	519-09-941-T	07-OCT-24
	Buffer	002348	1207069	05-DEC-22

Notes Temperature at reception: 4,3 °C.

Approved by

Laboratory Director

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