



<b>CERTIFICATE OF ANALYSIS</b>	<b>CHOLINESTERASE</b>
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<b>REF</b>	1119005	30 Test	X	1119050	25 ml/ 30 un.	X	1119055	2ml/ 30 un.	X	1119060	3 ml/30 un.	X
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<b>LOT</b>	15488		2019-02		2-8°C
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**QUALITATIVE CONTROL**

TEST		SPECIFICATION	RESULT			
Physical appearance	R1	Dry powder	PASS	X	FAIL	
	R2	Freeze-dried	PASS	X	FAIL	
	R3	Liquid. Clear and transparent. Free of particles.	PASS	X	FAIL	
Solubility	R1	± 5 minutes	PASS	X	FAIL	
	R2	< 2 minutes	PASS	X	FAIL	
pH	R1	7.7 ± 0.2	PASS	X	FAIL	

**QUANTITATIVE CONTROLS**

1.	<b>Analytical parameters</b>	<i>Blank.</i> Absorbance of the working reagent R1 and R2 against water at 405 nm. <i>Linearity.</i> Absorbance of the Internal Standard. <i>Sensitivity.</i> Activity expressed as Δ Amin of 0.001 A units. <i>Accuracy.</i> Ratio average between obtained and assigned values of different Control sera.
2.	<b>Stability Testing</b>	<i>Fresh Reagents (FR).</i> Items kept at 2-8°C. <i>Stressed Reagents (SR).</i> Items kept at 37/45°C for a stated period of time

<b>INSTRUMENT</b>	SHIMAZDU/KROMA
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	< 0,700	PASS	PASS
Linearity	10 KU/L (37°C)	PASS	PASS
Sensitivity	50 U/L	Conforms	Conforms
Accuracy	Within the expected values	PASS	PASS
		(PASS / FAIL)	(PASS / FAIL)

This lot was assayed by the test method described in the manufacturer's package insert.

These results are applicable to this lot and subsequent sublots, for which a capital letter has been assigned after the lot number.

This Certificate of Analysis is a computer printout and has therefore not been signed by hand.

<b>This lot meets our specifications and is released for sale</b>	APPROVED	<b>Signed</b> <b>Date of Manufacture,</b> 2017-01-26 Mayte Lázaro Quality Control
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