



<b>CERTIFICATE OF ANALYSIS</b>	<b>UREA BERTHELOT</b>
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<b>REF</b>	1156010	2 x 50 mL	X	1156080 (R1)	1 x 200 mL	X	1156086 (R1)	1 x 800 mL	X	1958005	1 x 3 mL	X
	1156015	4 x 100 mL	X	1156081 (R2)	1 x 4.8 L	X	1156087 (R2)	1 x 19.2 L	X	1958080	1 x 0.5 L	
				1156082 (R3)	1 x 5L	X	1156088 (R3)	1 x 20 L	X	1958081	1 x 1 L	
	1156060	2 ml/30 un	x	1156050	48 ml/60 un	x	1156055	50 ml/60 un	x	1156075	4 ml/30 un	X
	1156065	96 ml/40 un	x	1156070	100 ml/40 un	x						

<b>Cont</b>	<b>R1</b>	<b>X</b>	<b>LOT</b>	15745		2020-01	<b>IVD</b>		2-8°C
	<b>R2</b>	<b>X</b>	<b>LOT</b>	15746		2020-01			
	<b>R3</b>	<b>X</b>	<b>LOT</b>	15747		2020-01			
	<b>Standard</b>	<b>X</b>	<b>LOT</b>						

**PHYSICAL AND CHEMICAL CHARACTERISTICS**

TEST		SPECIFICATIONS	RESULT	
Appearance	R1 R2 R3	Liquid. Clear. Free of particles.	ACCEPTED	X
	CAL	Liquid. Clear. Free of particles.	ACCEPTED	X
pH	R1 R2 R3	<b>R1: 6.8 ± 0.2 R2: 6.9 ± 0.2 R3: 12 ± 0.2</b>	ACCEPTED	X

(ACCEPTED / N/A)

**FUNCTIONALITY**

<p><b>1. Analytical parameters</b></p> <p><i>Blank.</i> Absorbance of Working reagent against water.</p> <p><i>Sensitivity.</i> A<sub>600</sub> / 50 mg Urea<sub>Standard</sub></p> <p><i>Linearity.</i> Higher level established by the analytical performance.</p> <p><i>Accuracy.</i> Ratio between assigned and obtained Urea values.</p> <p><b>2. Stability Testing</b></p> <p><i>Fresh Reagents (FR).</i> Items kept at 2-8°C.</p> <p><i>Stressed Reagents (SR).</i> Items kept at 37/42°C for a stated period of time.</p>
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<b>INSTRUMENT</b>	SHIMADZU	600 nm against reagent blank
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	A <sub>600</sub> ≤ 0.110	ACCEPTED	ACCEPTED
Sensitivity	0.350-0.475	ACCEPTED	ACCEPTED
Linearity	Up to 300 mg/dL	ACCEPTED	ACCEPTED
Accuracy	Within the expected values	ACCEPTED	ACCEPTED

(ACCEPTED / N/A)

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	<p><b>Signed</b></p> <p><b>Date of Manufacture</b></p> <p>Francesc Guerrero</p> <p>2018-01-16</p> <p>Quality Control Dept.</p>
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