

<b>CERTIFICATE OF ANALYSIS</b>	<b>ALBUMIN</b>
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<b>REF</b>	1101000	2 x 50 mL	CT10020	2 x 40 mL	KR10020	2 x 30 mL	x	1901005	1 x 3 mL	
	1101010	4 x 100 mL	CT10022	6 x 40 mL	KR10022	8 x 30 mL	x	1901011	1 x 1 mL	
			CT10025	10 x 60 mL	KR10025	18 x 30 mL	x			
	1101081	R1 1 x 5 L	1101085	R1 1 x 20 L	1901080	CAL 1x0.5 L	x	1901081	CAL 1x1 L	
	1101050 R1 50 mL / 80 unid.		1101055 R1 100 mL / 40 unid.		1101060 R1 250 mL / 28 unid.		x	1901006	3 ml/60 un.	

<b>Cont</b>	<b>R1</b>	<b>X</b>	<b>LOT</b>	15679		2020-10	<b>IVD</b>
	<b>Standard</b>	<b>X</b>	<b>LOT</b>				2-8°C

**PHYSICAL AND CHEMICAL CHARACTERISTICS**

TEST		SPECIFICATIONS	RESULT	
Appearance	<b>R1</b>	Green. Liquid. Clear. Free of particles.	ACCEPTED	X
	<b>CAL</b>	Liquid. Clear. Free of particles.	ACCEPTED	X
pH	<b>R1</b>	4.2 ± 0.1	ACCEPTED	X

(ACCEPTED / N/A)

**FUNCTIONALITY**

<b>1. Analytical parameters</b>	<p><i>Blank.</i> Absorbance of the Working reagent against water.</p> <p><i>Sensitivity.</i> A<sub>630</sub> / 5 g/dL Albumin<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 Albumin values.</p>
<b>2. Stability Testing</b>	<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>

<b>INSTRUMENT</b>	LIDA BS-300	630 nm against reagent blank
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	A <sub>630</sub> < 0.260	ACCEPTED	ACCEPTED
Sensitivity	0,750 – 1,000	ACCEPTED	ACCEPTED
Linearity	Up to 6 g/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>	<b>APPROVED</b>	<p><b>Signed</b>  <b>Date of Manufacture</b>                  Francesc Guerrero                  2017-10-09                  Quality Control Dept.</p>
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