

<b>CERTIFICATE OF ANALYSIS</b>	<b>CREATININE</b>
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**REF**

1123005	2 x 50 mL	X	1123085 (R1)	1 x 5 L	X	CT10182 3x80mL	X	1923005 (1 x 3mL)	
1123010	4 x 100 mL	X	1123086 (R2)	1 x 5 L	X	CT10185 8x80mL	X	1923080 (1 x 500mL)	
1123020	4 x 250 mL	X	1123087 (R1)	1 x 20 L	X	1123050 50 ml/80 un.	x	1923081 (1 x 1L)	
			1123088 (R2)	1 x 20 L	X	1123055 50 ml/80 un.	x	1923006 3 ml/60 un	
1123060	100 ml/40 un.	x	1123065	100 ml/40 un.	x	1123080 250 ml/28 un.	x	1123085 250 ml/28 un.	x

<b>Cont</b>	<b>R1</b>	<b>X</b>	<b>LOT</b>	15845D		2021-02	<b>IVD</b>		2-30°C
	<b>R2</b>	<b>X</b>		<b>LOT</b>					
	<b>Standard</b>	<b>X</b>		<b>LOT</b>					

**PHYSICAL AND CHEMICAL CHARACTERISTICS**

TEST		SPECIFICATIONS	RESULT	
Appearance	<b>R1</b>	Yellow. Liquid. Clear. Free of particles.	ACCEPTED	X
	<b>R2</b>	Liquid. Clear. Free of particles.	ACCEPTED	X
	<b>CAL</b>	Liquid. Clear. Free of particles.	ACCEPTED	X

(ACCEPTED / N/A)

**FUNCTIONALITY**

<b>1. Analytical parameters</b>	<p><i>Blank.</i> Absorbance of Working reagent against water.</p> <p><i>Sensitivity.</i> A<sub>500</sub> / 2.0 mg/dL Creatinine<sup>Standard</sup></p> <p><i>Linearity.</i> Higher level established by the analytical performance.</p> <p><i>Accuracy.</i> Ratio between assigned and obtained creatinine 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> Working reagent kept at R.T. for a stated period of time.</p>

<b>INSTRUMENT</b>	SHIMADZU / KROMA	510 nm against distilled water
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	A <sub>510</sub> <0.225	ACCEPTED	ACCEPTED
Sensitivity	0.045-0.060	ACCEPTED	ACCEPTED
Linearity	Up to 20 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.

The 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                  2018-04-20                  Quality Control Dept.</p>
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