

CERTIFICATE OF ANALYSIS	CREATININE E
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REF	KR10150	5 x 45 mL	X	KR10152	11 x 45 mL	X
	CT10152	3 x 45 mL	X	CT10155	12 x 45 mL	X

Cont	R1	X	LOT	15580		2018-12	IVD
	R2	X	LOT	15581		2018-12	

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST		SPECIFICATIONS	RESULT	
Appearance	R1	Liquid. Clear. Yellow. Free of particles.	ACCEPTED	X
	R2	Liquid. Clear. Soft yellow. Free of particles.	ACCEPTED	X

(ACCEPTED / N/A)

FUNCTIONALITY

<p>1. Analytical parameters <i>Blank.</i> Absorbance of Working reagent against water. <i>Sensitivity.</i> $A_{546} / 2.0 \text{ mg Creatinine}_{\text{Standard}}$ <i>Linearity.</i> Higher level established by the analytical performance. <i>Accuracy.</i> Ratio between assigned and obtained Creatinine values.</p> <p>2. Stability Testing <i>Fresh Reagents (FR).</i> Items kept at 2-8°C. <i>Stressed Reagents (SR).</i> Items kept at 37/42°C for a stated period of time.</p>
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INSTRUMENT	SHIMADZU/BS300	546 nm against reagent blank
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	$A_{546} < 0.06$	ACCEPTED	ACCEPTED
Sensitivity	0.050-0,080	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.

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.

This lot meets our specifications and is released for sale	APPROVED	Signed Date of Manufacture Mayte Lázaro 2017-06-14 Quality Control Dept.
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