

CERTIFICATE OF ANALYSIS	ALKALINE PHOSPHATASE BR
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REF	1103005	2 x 50 mL	X	1103085 (R1)	1 x 4 L	X	CT10042	3 x 50 mL	X
	1103010	3 x 100 mL	X	1103086 (R2)	1 x 1 L	X	CT10045	12 x 50 mL	X
				1103087 (R1)	1 x 20 L	X	KR10042	5 x 40 mL	X
				1103088 (R2)	1 x 5 L	X	KR10045	11 x 40 mL	X

Cont	R1	X	LOT	15758		2019-07	IVD	
	R2	X	LOT	15759		2019-07		2-8°C

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST		SPECIFICATIONS	RESULT	
Appearance	R1	Liquid. Clear. Free of particles.	ACCEPTED	X
	R2	Slightly yellow. Liquid. Clear. Free of particles.	ACCEPTED	X
pH	R1 + R2	10.1 ± 0.2	ACCEPTED	X

(ACCEPTED / N/A)

FUNCTIONALITY

1. Analytical parameters	<p><i>Blank.</i> Absorbance of the Working reagent against water.</p> <p><i>Linearity.</i> Higher level established by the analytical performance.</p> <p><i>Sensitivity.</i> Activity expressed as Δ Amin of 0.001 A units.</p> <p><i>Accuracy.</i> Ratio between assigned and obtained ALP values.</p>
2. Stability Testing	<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>

INSTRUMENT	SHIMADZU/BS300	405 nm against distilled water
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	$A_{405} < 1.000$	ACCEPTED	ACCEPTED
Sensitivity	3.3 U/L	ACCEPTED	ACCEPTED
Linearity	Up to 800 U/L	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	<p>Signed Date of Manufacture Francesc Guerrero 2018-02-01 Quality Control Dept.</p>
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