




CERTIFICATE OF ANALYSIS	ALT / GPT BR Opt.
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REF	1105000	2 x 50 mL	X	1105085 (R1)	1 x 4 L	X	CT10052	3 x 50 mL	X
	1105010	3 x 100 mL	X	1105086 (R2)	1 x 1 L	X	CT10055	12 x 50 mL	X
				1105087 (R1)	1 x 20 L	X	KR10052	5 x 40 mL	X
	1105065	40 ml/ 80 uni.	x	1105088 (R2)	1 x 5 L	X	KR10055	11 x 40 mL	X
	1105060	20 ml/ 80 u	x	1105070	80 ml/ 40 uni.	x	1105075	60 ml/ 40 u	x

Cont	R1	X	LOT	15848		2019-11	IVD
	R2	X	LOT	15849		2019-11	 2-8°C

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST	SPECIFICATIONS	RESULT
Appearance	R1 R2 Liquid. Clear. Free of particles.	ACCEPTED X
pH	R1 + R2 7.3 ± 0.2	ACCEPTED X

(ACCEPTED / N/A)

FUNCTIONALITY

1.	Analytical parameters	<i>Blank.</i> Absorbance of Working reagent against water. <i>Sensitivity.</i> Activity expressed as ΔA_{min} of 0.001 A units. <i>Linearity.</i> Higher level established by the analytical performance. <i>Accuracy.</i> Ratio between assigned and obtained ALT values.
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.

INSTRUMENT	SHIMADZU / BS300	340 nm against distilled water
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	$A_{340} \geq 1.000$	ACCEPTED	ACCEPTED
Sensitivity	3-4 U/L	ACCEPTED	ACCEPTED
Linearity	Up to 500 U/L	ACCEPTED	ACCEPTED
Accuracy	Within 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 Francesc Guerrero 2018-05-02 Quality Control Dept.
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