






CERTIFICATE OF ANALYSIS	ACID PHOSPHATASE
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REF	1100005	4 x 10 mL	1100050 R1. 40 mL/30 un.	1100055 R2. 20 mL/30 un.	1100060 R3. 10 mL/30 un.	1100065 R4. 3 mL/30 un.	1100080 R1 1 L 1100081 R2 0,5 L 1100082 R3 100 v 1100083 R4 75 mL
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Cont	R1	X	LOT	15587		2019-06	IVD  2-8°C	
	R2	X		LOT	15588			2019-06
	R3	X		LOT	15589			2019-06
	R4	X		LOT	15590			2019-06

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST	SPECIFICATION	RESULT		
Appearance	R1	Liquid. Clear. Free of particles.	ACCEPTED	X
	R2	Liquid. Clear. Free of particles.	ACCEPTED	X
	R3	Powder	ACCEPTED	X
	R4	Liquid. Clear. Free of particles.	ACCEPTED	X
Solubility	R1+R3 R2+R3	Complete <10 minutes	ACCEPTED	X
pH	R1+R2	5.2 ± 0.2	ACCEPTED	X

(ACCEPTED / N/A)

FUNCTIONALITY

1. Analytical parameters	<i>Blank.</i> Absorbance of the 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 ACP values.
2. Stability Testing	<i>Fresh Reagents (FR).</i> Items kept at 2-8°C. <i>Stressed Reagents (SR).</i> Monoreagent kept at 2-8°C for a stated period of time

INSTRUMENT	SHIMADZU/BS300	405 nm against distilled water
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TEST	SPECIFICATIONS	RESULTS			
		FR		SR	
		Total	Prostatic	Total	Prostatic
Blank	A ₄₀₅ < 0.400	ACCEPTED	ACCEPTED	ACCEPTED	ACCEPTED
Sensitivity	8 U/L	ACCEPTED	ACCEPTED	ACCEPTED	ACCEPTED
Linearity	Up to 150 U/L	ACCEPTED	ACCEPTED	ACCEPTED	ACCEPTED
Accuracy	Within the expected values	ACCEPTED	ACCEPTED	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 2017-06-26 Quality Control Dept.
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