

CERTIFICATE OF ANALYSIS	FRUCTOSAMINE MR
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REF	CT19460	2 x 30 mL	X	1146081	1 x 1L	X	1946050	1 x 3 mL	X
	KR10460	2 x 30 mL	X				1946080	1 x 100 mL	

Cont	R1	X	LOT	15647		2019-09	IVD	
	Standard	X	LOT					2-8°C

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST		SPECIFICATIONS	RESULT	
Appearance	R1	Liquid. Clear. Free of particles.	ACCEPTED	X
	CAL	Liquid. Clear. Free of particles.	ACCEPTED	X
pH	R1	10.3 ± 0.2	ACCEPTED	X
Concentration	CAL	Fructosamine: XX.XX µmol/L	ACCEPTED	X

(ACCEPTED / N/A)

FUNCTIONALITY

1. Analytical parameters	Blank. Absorbance of the Working reagent against water. Linearity. Higher level established by the analytical performance. Accuracy. Ratio between assigned and obtained Fructosamine values.
2. Stability Testing	Fresh Reagents (FR). Items kept at 2-8°C. Stressed Reagents (SR). Items kept at 37/42°C for a stated period of time.

INSTRUMENT	SHIMADZU / KROMA/LIDA	530 nm
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	$A_{530} < 0.050$	ACCEPTED	ACCEPTED
Linearity	Up to 800 µmol/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	Signed Date of Manufacture Mayte Lázaro 2017-08-24 Quality Control Dept.
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