

CERTIFICATE OF ANALYSIS	FRUCTOSAMINE STANDARD
-------------------------	-----------------------

REF	CT19460	2 x 30 mL		1146081	1 x 1L		1946050	1 x 3 mL	X
	KR10460	2 x 30 mL					1946080	1 x 100 mL	

Cont	R1		LOT			IVD	
	Standard	X	LOT	19863		2019-10	2-8°C

### PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST		SPECIFICATIONS	RESULT	
Appearance	R1	Liquid. Clear. Free of particles.	N/A	
	CAL	Liquid. Clear. Free of particles.	ACCEPTED	X
pH	R1	10.3 ± 0.2	N/A	
Concentration	CAL	Fructosamine: 436 µmol/L	ACCEPTED	X

(ACCEPTED / N/A)

### FUNCTIONALITY

1. <b>Analytical parameters</b> <i>Blank.</i> Absorbance of the Working reagent against water. <i>Linearity.</i> Higher level established by the analytical performance. <i>Accuracy.</i> Ratio between assigned and obtained Fructosamine values.
2. <b>Stability Testing</b> <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	BS300/ KROMA	530 nm
------------	--------------	--------

TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	A <sub>530</sub> < 0.050	N/A	N/A
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 2017-09-27 Quality Control Dept.
--	----------	--