

CERTIFICATE OF ANALYSIS	CALCIUM OCC
--------------------------------	--------------------

REF								
1115000	2 x 50 mL	X	1115085 (R1)	1 x 5 L	X	1913005 (3 mL)	X	
1115010	4 x 100 mL	X	1105086 (R2)	1 x 5 L	X	1913011 (1 mL)		
			1115087 (R1)	1 x 20 L	X	1913080 (1 x 0.5 L)		
			1115088 (R2)	1 x 20 L	X	1913081 (1 x 1 L)		
1115050	50 ml / 80 un.	x	1115055	50 ml / 80 un.	x			
1115060	100 ml/ 40 un.	x	1115065	100 ml/ 40 un.	x			

Cont	R1	X	LOT	15687A		2020-09	IVD		2-30°C
	R2	X		LOT					
	Standard	X		LOT					

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST		SPECIFICATIONS	RESULT	
Appearance	R1	Liquid. Slightly yellow.	ACCEPTED	X
	R2	Liquid. Clear. Free of particles.	ACCEPTED	X
	CAL	Liquid. Clear. Free of particles.	ACCEPTED	X

(ACCEPTED / N/A)

FUNCTIONALITY

- 1. Analytical parameters**
Blank. Absorbance of the Working reagent against water.
Sensitivity. A₅₇₀ / 10 mg/dL Calcium standard.
Linearity. Higher level established by the analytical performance.
Accuracy. Ratio between assigned and obtained Calcium values.
- 2. Stability Testing**
Fresh Reagents (FR). Items kept at 2-8°C.
Stressed Reagents (SR). Working reagent kept at 2-8°C for 5 days.

INSTRUMENT	SHIMADZU /KROMA	570 nm against reagent blank
-------------------	-----------------	------------------------------

TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	A ₅₇₀ < 0.500	ACCEPTED	ACCEPTED
Sensitivity	0.300 – 0.500	ACCEPTED	ACCEPTED
Linearity	Up to 22 mg/dL	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 Francesc Guerrero 2017-10-24 Quality Control Dept.
---	----------	---

