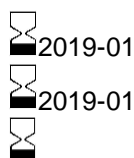


**CERTIFICATE OF ANALYSIS** **SODIUM**

REF	1151010	2 x 60 mL	X	1151015	1 x 30 mL	X	KR10340	1 x 40 mL	X
	CT10340	1 x 30 mL	X	CT10342	3 x 30 mL	X	1151050	R1	X
	1151055	R2	X	1151060	R1	X	1151065	R2	X
	1151050	40 ml/20 un.	x	1151055	40 ml/10 un	x	1151060	20 ml/10 un	x
	1151065	10 ml/10 un.							

Cont	R1	X
	R2	X
	Standard	X

LOT	15713
LOT	15714



IVD	2-8°C
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**PHYSICAL AND CHEMICAL CHARACTERISTICS**

TEST	SPECIFICATIONS	RESULT
Appearance	R1 Colorless to Light Yellow Liquid	ACCEPTED X
	R2 Colorless to Light Yellow Liquid	ACCEPTED X
	CAL Liquid. Clear and transparent	ACCEPTED X

(ACCEPTED / N/A)

**FUNCTIONALITY**

- Analytical parameters**  
*Sensitivity. Lower detection limit*  
*Linearity. High end of measuring range*  
*Accuracy. Ratio average between obtained and assigned values of different Control sera.*
- 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.*

<b>INSTRUMENT</b>	CECIL CE 2021 / KROMA	405 nm
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Sensitivity	80 mmol/L	ACCEPTED	ACCEPTED
Linearity	Up to 180 mmol/L	ACCEPTED	ACCEPTED

(ACCEPTED / N/A)

CONTROLS	EXPECTED RESULTS (mmol/L)	RESULTS (mmol/L)
Linear Control 1	140.9 ± 21.1	139.9
Linear Control 2	159.5 ± 23.9	164.6
Third Party Control 1	145.0 ± 7.0	145.5
Third Party Control 2	156.0 ± 8.0	160.0

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.

<b>This lot meets our specifications and is released for sale</b>	APPROVED	<b>Signed -Date of Manufacture:</b> Alicia Abellan Quality Control Department 21 November 2017
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