



<b>CERTIFICATE OF ANALYSIS</b>	<b>LIPASE</b>
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<b>REF</b>	1143005	1 x 60 mL	X	KR10430	1 x 36 mL	X	1943005	CAL 1 unit	X
	1143080	1x1 L	x	1143081	1 x 0.2 L	X	1143050	50 ml/60 un.	x
	1143055	10 ml/ 30 un.	x	1143060	25 ml/60 un.	x	1143065	5 ml/30 un.	x

<b>Cont</b>	<b>R1</b>	<b>X</b>	<b>LOT</b>	15777A		2019-10	<b>IVD</b>	
	<b>R2</b>	<b>X</b>		15778		2019-11	<b>IVD</b>	
	<b>Standard</b>	<b>X</b>						

**PHYSICAL AND CHEMICAL CHARACTERISTICS**

TEST	SPECIFICATIONS	RESULT		
Appearance	<b>R1</b>	Liquid. Clear. Free of particles.	ACCEPTED	X
	<b>R2</b>	Orange. Liquid. Emulsion. Free of particles.	ACCEPTED	X
	<b>CAL</b>	Lyophilized	ACCEPTED	X

(ACCEPTED / N/A)

**FUNCTIONALITY**

- 1. Analytical parameters**  
*Blank.* Absorbance of Working reagent against water.  
*Sensitivity.* 10 replicates of normal saline and reported as the "mean zero value + 3 SD".  
*Linearity.* Higher level established by the analytical performance.  
*Accuracy.* Ratio between assigned and obtained Lipase values.
- 2. Stability Testing**  
*Fresh Reagents (FR).* Items kept at 2-8°C.  
*Stressed Reagents (SR).* Items kept at 37°C for a stated period of time.

<b>INSTRUMENT</b>	CECIL CE 2021 / KROMA	580 nm against distilled water
<b>TEST</b>	<b>SPECIFICATIONS</b>	<b>RESULTS</b>
Blank	0.400-0.490	ACCEPTED
Sensitivity	5 U/L	ACCEPTED
Linearity	Up to 250 U/L	ACCEPTED
Accuracy	38 ± 5 U/L 84 ± 13 U/L 71 ± 7 U/L 315 ± 47 U/L	37 U/L 86 U/L 76 U/L 324 U/L

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</b> <b>Manufactured date:</b> Mayte Lázaro Quality Control 12 February 2018
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