

<b>CERTIFICATE OF ANALYSIS</b>	<b>CREATINE KINASE BR (CK-NAC)</b>
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<b>REF</b>	1120010	1 x 25 mL	X	1120081 (R1)	1 x 4 L	X	CT10160	1 x 50 mL	X
	1120005	2 x 50 mL	X	1120086 (R2)	1 x 1 L	X	CT10162	3 x 50 mL	X
	1120060	20 ml/30 un.	x	1120055	20 ml/30 un.	x	KR10160	1 x 40 mL	X
	1120060	20 ml/30 un.	x	1120065	5 ml/30 un.	x	KR10162	5 x 40 mL	X

<b>Cont</b>	<b>R1</b>	<b>X</b>	<b>LOT</b>	15772		2019-05	<b>IVD</b>
	<b>R2</b>	<b>X</b>	<b>LOT</b>	15773		2019-05	2-8°C

**PHYSICAL AND CHEMICAL CHARACTERISTICS**

TEST		SPECIFICATIONS	RESULT	
Appearance	<b>R1</b>	Liquid. Clear and transparent. Free of particles.	ACCEPTED	X
	<b>R2</b>	Liquid. Clear and transparent. Free of particles.	ACCEPTED	X
pH	<b>R1</b>	6.7 ± 0.3	ACCEPTED	X
	<b>R2</b>	8.8 ± 0.3	ACCEPTED	X
	<b>R1 + R2</b>	7.0 ± 0.3	ACCEPTED	X

(ACCEPTED / N/A)

**FUNCTIONALITY**

- 1. Analytical parameters**  
*Blank.* Absorbance of the Working reagent against water.  
*Sensitivity.* Activity expressed as ΔA<sub>min</sub> of 0.001 A units.  
*Linearity.* Absorbance of the Internal Standard.  
*Accuracy.* Ratio average between obtained and assigned values of different Control sera.
- 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>	SHIMADZU/BS300	340 nm against distilled water
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	A <sub>340</sub> <0.400	ACCEPTED	ACCEPTED
Sensitivity	7.0 – 9.0 U/L	ACCEPTED	ACCEPTED
Linearity	Up to 1000 U/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.  
 The 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>Date of Manufacture</b> Mayte Lázaro 2018-02-12 Quality Control Dept.
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