





CERTIFICATE OF ANALYSIS

HEMOGLOBIN DRABKIN

REF	1134015	2 x 5 mL	X	1134050	5 ml/30 un.	x	1934005	1 x 1mL	X
	1134081	1 x 5 L	X				1934006	1 mL/60 uni	

Cont	R1	X	LOT	15706		2019-11		2-30°C	IVD
	Standard	X		LOT					

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST		SPECIFICATIONS	RESULT	
Appearance	R1	Liquid. Free of particles Clear, pale yellow solution	ACCEPTED	X
	CAL	Liquid. Brown-Red colour	ACCEPTED	X

(ACCEPTED / N/A)

FUNCTIONALITY

<p>1. Analytical parameters <i>Blank.</i> Absorbance of Working reagent against water. <i>Sensitivity.</i> $A_{540} / 12 \text{ g/dL Hb}_{\text{Standard}}$ <i>Linearity.</i> Testing levels of analyte known by formulation. <i>Accuracy.</i> Ratio between assigned and obtained Hemoglobin values.</p> <p>2. Stability Testing <i>Fresh Reagents (FR).</i> Items kept at 2-8°C. <i>Stressed Reagents (SR).</i> Items kept at 37°C for a stated period of time.</p>
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INSTRUMENT	SHIMADZU	540 nm against reagent blank
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	0.000-0.010	ACCEPTED	ACCEPTED
Sensitivity	0.315-0.340	ACCEPTED	ACCEPTED
Linearity	Up to 20 g/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 Mayte Lázaro 2017-11-29 Quality Control Dept.
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