

CERTIFICATE OF ANALYSIS

HEMOGLOBIN STANDARD 12 g/dL

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

Cont	R1		LOT			IVD	
	Standard	X	LOT	19781			2018-04  2-8°C

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST		SPECIFICATIONS	RESULT	
Appearance	R1	Liquid. Free of particles Clear, pale yellow solution	N/A	
	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 R.T./-20°C for a stated period of time.</p>
--

INSTRUMENT	SHIMAZDU	540 nm against reagent blank
------------	----------	------------------------------

TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	0.000-0.010	N/A	N/A
Sensitivity	0.315-0.340	ACCEPTED	ACCEPTED
Linearity	Up to 20 g/dL	N/A	N/A
Accuracy	Within the expected values	ACCEPTED	ACCEPTED

(ACCEPTED / N/A)

HEMOGLOBIN STANDARD 12 g/dL has been manufactured following practices for minimizing the risk of transmitting animal spongiform encephalopathy agents, under guidance of EMA/410/01 guidance.
The bovine raw material used to manufacture this product is obtained from cattle herds raised in the USA from USDA approved facilities. The animals are less than 30 months of age at time of slaughter and receive ante- and post-mortem inspection under a veterinarian's supervision.
Product meets European Union requirements for untreated technical blood products: APHIS facility MO-TEC-0004.

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 2016-04-25 Quality Control Dept.
--	----------	--

