



## CERTIFICATE OF ANALYSIS

## HEMOGLOBIN MR

REF	1163005	4 x 100 mL	X	1163050	100 ml/40 un.	x	1934005	1 x 1mL	X
							1934001	30 x 1 mL	

LOT	14277	 2014-07	 2-30°C	IVD
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## QUALITATIVE CONTROLS

TEST		SPECIFICATIONS	RESULT	
Physical appearance	R1	Liquid. Free of particles. Clear, pale yellow solution.	Complying	X

## QUANTITATIVE CONTROLS

## 1. Analytical parameters

*Blank.* Absorbance of Working reagent against water.

*Sensitivity.*  $A_{540} / g \text{ Hb}_{\text{Standard}}$

*Linearity.* Testing levels of analyte known by formulation.

*Accuracy.* Ratio between assigned CRM-522 and obtained Hb value.

## 2. Stability Testing

*Fresh Reagents (FR).* Items kept at 15-25°C for 1 month.

*Stressed Reagents (SR).* Items kept at -20°C for a stated period of time.

## REAGENT CONTROL IDENTIFICATION

Hemoglobin	R1	LOT	14277
Hemoglobin Standard 12 g/dL	CAL	LOT	19572
CRM-522 20.1 g/dL		LOT	02

INSTRUMENT	CECIL CE2021	$A_{540}$
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	$A_{540} < 0.02$	0.002	0.006
Sensitivity	$0.027 A / g \text{ Hb}_{\text{Standard}}$	Conforms	Conforms
Linearity	Up to 20 g/dL	Conforms	Conforms
Accuracy	Ratio $\frac{\text{CRM-522}}{\text{Hb}_{\text{Standard}}} = 1.6 \pm 0.05$	Conforms	Conforms

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 2012-11-13 Quality Control Dept.
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