



CERTIFICATE OF ANALYSIS	GLYCATED HbA1c CHROMATOGRAPHY IN TUBE
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REF	3155105	25 det	X
	3155110	100 det	x

	Component	
	Reagent 1	X
	Reagent 2	X
	Standard HbA1c 10%	x

LOT 31115
 2-8°C

 2020-01
IVD

PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
Reagent 1	APPEARANCE	Resin	ACCEPTED
Reagent 2	APPEARANCE	Colourless liquid	ACCEPTED
Standard HbA1c 10%	APPEARANCE	Lyophilized	ACCEPTED

(ACCEPTED / N/A)

FUNCTIONALITY

REAGENT	TEST	SPECIFICATIONS	RESULTS
Internal Control L1	Accuracy	7.5±1.5%	8.5%
Internal Control L2	Accuracy	15.5±3.0%	16.8%

(ACCEPTED / N/A)

This lot was tested by test methods described in the manufacturer's package insert. These results are applicable to this lot and sequential sublots, for which a capital letter have 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, Alicia Abellan Quality Control Department 18 January 2018
	(APPROVED / NOT APPROVED)	