





<b>CERTIFICATE OF ANALYSIS</b>	<b>HbA1c -TURBIDIMETRIC</b>
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<b>REF</b>	3155005	1 x 45 mL	X	3155080 (R1)	X	CT33000 1x45 mL	KR31550 1x45 mL	X
				3155081 (R2a)	X			
				3155082 (R2b)	X			

Cont	Component	
1 x 30 mL	Latex (R1)	X
1 x 10 mL	Antibody (R2a)	X
1 x 5 mL	Antibody (R2b)	X

	2-8°C
<b>LOT</b>	24876
<b>LOT</b>	24877
<b>LOT</b>	24878

<b>IVD</b>	
	2019-03
	2019-03
	2019-03

**PHYSICAL AND CHEMICAL CHARACTERISTICS**

REAGENT	TEST	SPECIFICATIONS	RESULTS
LATEX (R1)	APPEARANCE	Liquid. White homogeneous suspension free of macroscopic or flaky particles	ACCEPTED
	pH	8.0 +/- 0.2	ACCEPTED
ANTIBODY (R2a) (R2b)	APPEARANCE	Liquid. Clear and transparent.	ACCEPTED
	pH	5.45 – 6.05	ACCEPTED

(ACCEPTED / N/A)

**FUNCTIONALITY**

REAGENT	TEST	SPECIFICATIONS	RESULTS
Latex (R1) Antibody (R2a) Antibody (R2b)	ANALYTICAL SENSITIVITY Reference HbA1c Calibrator (IFCC)	$\Delta A_{660nm}$ : 60 - 80 mA / % HbA1c This value depends on the instrument used	ACCEPTED
	LINEARITY RANGE	1.5% to 15% This value depends on the instrument used	ACCEPTED
	ACCURACY, HbA1c Controls	Within range	ACCEPTED

**STABILITY TEST**

REAGENT	Days at 37°C	TOLERANCE	RESULT
LATEX (R1)	7	After a stability study, the specifications remain unchanged	ACCEPTED
ANTIBODY (R2a)			
ANTIBODY (R2b)			

(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	<b>Signed</b> <b>Date of Manufacture:</b> Marta Vilaró 2018-01-05 Quality Control Department
	(APPROVED / NOT APPROVED)	

