

<b>CERTIFICATE OF ANALYSIS</b>	<b>HbA1c-TURBIDIMETRIC- CALIBRATOR</b>
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<b>REF</b>	3955005	4 x 0.25 mL	x			
	CT39550	4 x 0.25 mL	x			

**LOT** 39499  
 2-8°C

2018-09  
**IVD**

**PHYSICAL AND CHEMICAL CHARACYTERISTICS**

REAGENT	TEST	SPECIFICATIONS	RESULTS
HbA1c TURBIDIMETRIC- CALIBRATOR	APPEARANCE	Liquid. Red colour.	ACCEPTED
	pH	8.1 – 8.3	ACCEPTED

(ACCEPTED / N/A)

**FUNCTIONALITY**

REAGENT	TEST	SPECIFICATIONS	RESULTS
HbA1c TURBIDIMETRIC- CALIBRATOR	ASSIGNED VALUE	Data Included in the insert	ACCEPTED
	TOLERANCE	Data Included in the insert	ACCEPTED

(ACCEPTED / N/A)

**STABILITY TEST**

REAGENT	Days at 37°C	TOLERANCE	RESULT
HbA1c TURBIDIMETRIC- CALIBRATOR	7	After a stability study, the specifications remain unchanged	ACCEPTED

(ACCEPTED / N/A)

Components from human origin have been tested and found negative for the presence of antibody to HIV (1/2) as well as HBsAg and HCV. However, handle cautiously as potentially infectious.

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	<b>APPROVED</b>	<b>Signed</b> <b>Date of Manufacture,</b> Marta Vilaró 2017-07-12 Quality Control
	(APPROVED / NOT APPROVED)	

