

CERTIFICATE OF ANALYSIS	D-DIMER TURBIDIMETRIC CALIBRATOR
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REF	3145005	1 x 54 mL		3945005	2 x 1 mL	X
	KR31450	1 x 36 mL		CT39450	2 x 1 mL	X

Cont	Diluent (R1)		LOT				IVD
	Latex (R2)						
	Calibrator	X					
			39313	2015-12		2-8°C	

PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
DILUENT (R1)	APPEARANCE	Liquid. Yellowish. Clear and transparent.	N/A
	pH	7.5 – 8.7	N/A
LATEX (R2)	APPEARANCE	Liquid. Homogeneous suspension, free of macroscopic or flaky particles.	N/A
	pH	8.1 – 8.3	N/A
CALIBRATOR	APPEARANCE	Lyophilized. White.	ACCEPTED

(ACCEPTED / N/A)

FUNCTIONALITY

REAGENT	TEST	SPECIFICATIONS	RESULTS
LATEX (R2) DILUENT (R1)	ANALYTICAL SENSITIVITY, <i>Internal D-Dimer Standard</i>	$\Delta A_{630\text{ nm}} > 0.3 \text{ mA} \cdot \text{min}^{-1} / \text{ng/mL}$ This value depends on the instrument used	N/A
	LINEARITY RANGE	Up to 3300 ng/mL This value depends on the instrument used	N/A
	PROZONE	$\Delta A_{630\text{ nm}}, 45000 \text{ ng/L} : > \Delta A_{630\text{ nm}} 1000 \text{ ng/mL}$	N/A
	ACCURACY, against 6-8 D-Dimer samples and 2 D-Dimer Controls	Agreement between obtained value (OV) and its expected value (EV). Rate OV/EV: 0.9 – 1.1 Control Serums: Within values interval	N/A
CALIBRATOR	ASSIGNED VALUE	2600 ng/mL	ACCEPTED

(ACCEPTED / N/A)

STABILITY TEST

REAGENT	Days at 37°C	TOLERANCE	RESULT
DILUENT (R1)	7	After a stability study, the specifications remain unchanged	N/A
LATEX (R2)			ACCEPTED
CALIBRATOR			

(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	APPROVED	Signed Date of Manufacture: Lluís Cano
	(APPROVED / NOT APPROVED)	10 March 2014 Quality Control Department

