

<b>CERTIFICATE OF ANALYSIS</b>	<b>D-DIMER TURBIDIMETRIC</b>
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<b>REF</b>	3145005	1 x 54 mL	X	3945005	2 x 1 mL	
	KR31450	1 x 36 mL	X	CT39450	2 x 1 mL	

<b>Cont</b>	<b>Diluent (R1)</b>	X	<b>LOT</b>	31720		2015-12		
	<b>Latex (R2)</b>	X		31721		2015-12		<b>IVD</b>
	<b>Calibrator</b>	X						

**PHYSICAL AND CHEMICAL CHARACTERISTICS**

REAGENT	TEST	SPECIFICATIONS	RESULTS
DILUENT (R1)	APPEARANCE	Liquid. Yellowish. Clear and transparent.	ACCEPTED
	pH	7.5 – 8.7	ACCEPTED
LATEX (R2)	APPEARANCE	Liquid. Homogeneous suspension, free of macroscopic or flaky particles.	ACCEPTED
	pH	8.1 – 8.3	ACCEPTED
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	ACCEPTED
	LINEARITY RANGE	Up to 3300 ng/mL This value depends on the instrument used	ACCEPTED
	PROZONE	$\Delta A_{630\text{ nm}}, 45000 \text{ ng/L} : > \Delta A_{630\text{ nm}} 1000 \text{ ng/mL}$	ACCEPTED
	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	ACCEPTED
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	ACCEPTED
LATEX (R2)			ACCEPTED
CALIBRATOR			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	APPROVED	<b>Signed</b> <b>Date of Manufacture:</b> Lluís Cano  10 March 2014 Quality Control Department
	(APPROVED / NOT APPROVED)	

