

CERTIFICATE OF ANALYSIS	D-DIMER TURBIDIMETRIC CONTROL D-DIMER CONTROL SET
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REF 3945010 (L1+L2) 2 x 0.5 mL X

Cont	D-Dimer Control	LOT		
	L-1	X	39311	2015-12
	L-2	X	39312	2015-12

IVD
 2-8°C

PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
D-DIMER Controls L-1 and L-2	APPEARANCE	Lyophilized. White.	ACCEPTED
	pH	8.2 ± 0.1	ACCEPTED

(ACCEPTED / N/A)

FUNCTIONALITY

REAGENT	TEST	SPECIFICATIONS	RESULTS
D-DIMER Controls L-1 and L-2	ASSIGNED VALUE	L-1: 430 ng/mL L-2: 1030 ng/mL	ACCEPTED
	RANGE	L-1: 322 – 538 ng/mL L-2: 825 – 1235 ng/mL	ACCEPTED

(ACCEPTED / N/A)

STABILITY TEST

REAGENT	Days at 37°C	TOLERANCE	RESULT
D-DIMER Controls L-1 and L-2	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	APPROVED	Signed Date of Manufacture: Lluís Cano
	(APPROVED / NOT APPROVED)	10 March 2014 Quality Control Department

