

CERTIFICATE OF ANALYSIS	SLE-LATEX
-------------------------	-----------

REF	2430005	50 Tests	x		
	2924350	0,5 mL	x		
	2924381	50 mL			

Cont	R	X
	Control (+)	X
	Control (-)	X

LOT 24126  
2-8°C

2018-10  
IVD

### PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
SLE-LATEX (R)	APPEARANCE	Homogeneous suspension free of macroscopic or flaky particles.	ACCEPTED
	COLOUR	White	
	pH	7.5 +/- 0.2	
CONTROL (+)	APPEARANCE	Liquid solution. Clear and yellowish	ACCEPTED
CONTROL (-)	APPEARANCE	Liquid solution. Clear and transparent.	ACCEPTED

(ACCEPTED / N/A)

### FUNCTIONALITY

REAGENT	TEST	SPECIFICATIONS	RESULTS
SLE-LATEX (R)	Sensitivity, against an Internal Standard	Titer: 1/4 ± 1 dil	ACCEPTED
	Positive Control	3+	
	Negative Control	Negative	
CONTROL (+)	Tested with SLE-Latex	3+	ACCEPTED
CONTROL (-)	Tested with SLE-Latex	Negative	ACCEPTED

(ACCEPTED / N/A)

### STABILITY TEST (7 days at 37°C)

REAGENT	TOLERANCE	RESULT
SLE-LATEX	After a stability study, the specifications remain unchanged	ACCEPTED
CONTROL (+)		ACCEPTED
CONTROL (-)		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 Pilar Montolio 2016-10-17 Quality Control Dept.
	(APPROVED / NOT APPROVED)	

