



CERTIFICATE OF ANALYSIS	ASLO-LATEX
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REF

2340005	50 tests	X	2340015	50 tests(w/o control)	X	2340081 (1 L)	X	2923181 (100 mL)	
2340010	100 tests	X	2340020	100 tests (w/o control)	X	2340082 (0.25 L)	X	2923182 (50 mL)	
2340030	150 tests	X	2340027	150 tests (w/o control)	X	2340085 (5 L)	X	2923185 (1 L)	

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

LOT	23291
	2-8°C

	2019-11
IVD	

PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
ASLO-LATEX (R)	APPEARANCE	Homogeneous suspension free of macroscopic or flaky particles.	ACCEPTED
	COLOUR	White	
	pH	8.0 +/- 0.5	
CONTROL (+)	APPEARANCE	Liquid solution. Clear and transparent.	ACCEPTED
CONTROL (-)	APPEARANCE	Liquid solution. Clear and transparent.	ACCEPTED

(ACCEPTED / N/A)

FUNCTIONALITY

REAGENT	TEST	SPECIFICATIONS	RESULTS
ASLO-LATEX (R)	Sensitivity, against WHO International Reference Material 97/662	200 IU/mL ± 25%	ACCEPTED
	Positive Control	3+	
	Negative Control	Negative	
CONTROL (+)	Tested with ASLO-Latex	3+	ACCEPTED
CONTROL (-)	Tested with ASLO-Latex	Negative	ACCEPTED

(ACCEPTED / N/A)

STABILITY TEST (7 days at 37°C)

REAGENT	TOLERANCE	RESULT
ASLO-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 of Manufacture: Marta Vilaró 2017-10-16 Quality Control Dept.
	(APPROVED / NOT APPROVED)	

