

CERTIFICATE OF ANALYSIS	ASLO-TURBIDIMETRIC
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REF

3110025	1 x 50 mL	X	3110080 (R1)	X	(3110026) R1 3110050	x	3931105	CT31100 1x50 mL	X	KR31100 1x40 mL	X
3110030	2 x 50 mL	X	3110081 (R2)	X	(3110026) R2 3110056	x	3931120	CT31112 3x50 mL	X	KR31102 5x40 mL	X
3110035	2 x 200 mL	X	3110085 (R1)	X	(3110036) R1 3110071	x		CT31115 12x50 mL	X		
			3110082 (R2)	X	(3110036) R2 3110076	x					

Cont	Diluent (R1)	X
	Latex (R2)	X
	Calibrator	X

LOT	31124
LOT	31125
LOT	



2019-10

2019-10

IVD

2-8°C

PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
DILUENT (R1)	APPEARANCE	Liquid. Clear and transparent.	ACCEPTED
	pH	7.5 +/- 0.1	ACCEPTED
LATEX (R2)	APPEARANCE	Liquid. Homogeneous suspension free of macroscopic or flaky particles.	ACCEPTED
	pH	9.8 – 10.2	ACCEPTED
CALIBRATOR	APPEARANCE	Liquid. Yellowish, clear and transparent.	ACCEPTED

(ACCEPTED / N/A)

FUNCTIONALITY

REAGENT	TEST	SPECIFICATIONS	RESULTS
LATEX (R2) DILUENT (R1)	ANALYTICAL SENSITIVITY, Reference International Stand. for anti-streptolysin O NIBSC Code: 97/662	$\Delta A_{540\text{ nm}} = 0.8 \text{ mA}\cdot\text{mL}/\text{IU}$ This value depends on the instrument used	ACCEPTED
	LINEARITY RATE	Up to 800 IU/mL This value depends on the instrument used	ACCEPTED
	PROZONE	$\Delta A_{540\text{ nm}}, 2000 \text{ IU}/\text{mL} > \Delta A_{540\text{ nm}}, 800 \text{ IU}/\text{mL}$	ACCEPTED
	ACCURACY, against 6-8 human sera and 2 ASO Control Sera	Agreement between obtained value (OV) and its expected value (EV). Rate OV/TV: 0.9 – 1.1 Control Serums: Within interval values	ACCEPTED
CALIBRATOR	TOLERANCE VALUE	290-380 UI/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	10		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 2018-03-21 Quality Control Department
	(APPROVED / NOT APPROVED)	

