

<b>CERTIFICATE OF ANALYSIS</b>	<b>ASLO-Turbidimetric Calibrador</b>
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<b>REF</b>	3110025	1 x 50 mL	3110080 (R1)	3931105	1x1 mL	X	3110010-25	
	3110030	2 x 50 mL	3110081 (R2)	3931120	30 x 1 mL	X	3110015-30	
	3110035	2 x 200 mL	3110085 (R1)	3931180	1 x 100 mL	x	3110020-35	
	CT31117	4 x 50 mL	3110082 (R2)					

<b>Cont</b>	<b>Diluent (R1)</b>	
	<b>Latex (R2)</b>	
	<b>Calibrator</b>	<b>X</b>

**LOT** 39570  
 2-8°C

2020-05  
**IVD**

**PHYSICAL AND CHEMICAL CHARACTERISTICS**

REAGENT	TEST	SPECIFICATIONS	RESULTS
DILUENT (R1)	APPEARANCE	Liquid. Clear and transparent.	N/A
	pH	8.2 +/- 0.1	N/A
LATEX (R2)	APPEARANCE	Liquid. Homogeneous suspension free of macroscopic or flaky particles.	N/A
	pH	9.8 – 10.2	N/A
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	N/A
	LINEARITY RATE	Up to 800 IU/mL This value depends on the instrument used	N/A
	PROZONE	$\Delta A_{540\text{ nm}}, 2000 \text{ IU}/\text{mL} > \Delta A_{540\text{ nm}}, 800 \text{ IU}/\text{mL}$	N/A
	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	N/A
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	N/A
LATEX (R2)			
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	<b>APPROVED</b>	<b>Signed</b> <b>Date of Manufacture:</b> Aina Iglesias 2018-05-02 Quality Control Department
	(APPROVED / NOT APPROVED)	

