

CERTIFICATE OF ANALYSIS	IgM at
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REF	3167510	1 x 50 mL	X	3167580	X	CT31900 2x40 mL	X	KR31670 2x30 mL	X
				3167585	X	CT31902 6x40 mL	X	KR31672 8x30 mL	X

LOT 31110 2020-02
 2-8°C **IVD**

PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
IgM at	APPEARANCE	Colourless liquid. Clear and transparent.	ACCEPTED
	pH	8.2 +/- 0.2	ACCEPTED

(ACCEPTED / N/A)

FUNCTIONALITY

REAGENT	TEST	SPECIFICATIONS	RESULTS
IgM at	ANALYTICAL SENSITIVITY, Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM)	$\Delta A_{340\text{ nm}}$, 1.2 mA·dL/mg Depends on the instrument used	ACCEPTED
	LINEARITY RANGE	3 – 500 mg/dL Depends on the IgM concentration of the Plasma Protein Calibrator	ACCEPTED
	PROZONE	> 1000 mg/dL	ACCEPTED
	ACCURACY Against two IgM Control Sera (Low and High)	Within values interval	ACCEPTED

(ACCEPTED / N/A)

STABILITY TEST

REAGENT	Days at 37°C	TOLERANCE	RESULT
IgM at	12	After a stability study, the specifications remain unchanged	ACCEPTED

(ACCEPTED / N/A)

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 Pilar Montolio 2018-01-23 Quality Control Department
	(APPROVED / NOT APPROVED)	

