

CERTIFICATE OF ANALYSIS	C4 at
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REF	3171005	1 x 50 mL	X	3171080	X	CT31500 2x40 mL	X	KR31710 2x30 mL	X
				3171085	X	CT31502 6x40 mL	X	KR31712 8x30 mL	X

LOT 31045
 2-8°C
 2019-06
IVD

PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
C4 at	APPEARANCE	Colourless liquid. Clear and transparent.	ACCEPTED
	pH	8.2 +/- 0.2	ACCEPTED

(ACCEPTED / N/A)

FUNCTIONALITY

REAGENT	TEST	SPECIFICATIONS	RESULTS
C4 at	ANALYTICAL SENSITIVITY, Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM)	$\Delta A_{340\text{ nm}}$: 9.34 mA·dL/mg Depends on the instrument used	ACCEPTED
	LINEARITY RANGE	0.5 – 100 mg/dL Depends on the C3 concentration of the Plasma Protein Calibrator	ACCEPTED
	PROZONE	> 200 mg/dL	ACCEPTED
	ACCURACY Against two C4 Control Sera (Low and High)	Within values interval	ACCEPTED

(ACCEPTED / N/A)

STABILITY TEST

REAGENT	Days at 37°C	TOLERANCE	RESULT
C4 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 2017-06-07 Quality Control Department
	(APPROVED / NOT APPROVED)	

