


<b>CERTIFICATE OF ANALYSIS</b>	<b>C3 at</b>
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<b>REF</b>	3170005	1 x 50 mL	X	3170080	X	CT31400 2x40 mL	X	KR31700 2x30 mL	X
				3170085	X	CT31402 6x40 mL	X	KR31702 8x30 mL	X

**LOT** 31078  
2-8°C

 2019-11  
**IVD**

**PHYSICAL AND CHEMICAL CHARACTERISTICS**

REAGENT	TEST	SPECIFICATIONS	RESULTS
C3 at	APPEARANCE	Colourless liquid. Clear and transparent.	ACCEPTED
	pH	8.2 +/- 0.2	ACCEPTED

(ACCEPTED / N/A)

**FUNCTIONALITY**

REAGENT	TEST	SPECIFICATIONS	RESULTS
C3 at	ANALYTICAL SENSITIVITY, Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM)	$\Delta A_{340\text{ nm}}$ : 3.42 mA·dL/mg Depends on the instrument used	ACCEPTED
	LINEARITY RANGE	4.2 – 500 mg/dL Depends on the C3 concentration of the Plasma Protein Calibrator	ACCEPTED
	PROZONE	> 800 mg/dL	ACCEPTED
	ACCURACY Against two C3 Control Sera (Low and High)	Within values interval	ACCEPTED

(ACCEPTED / N/A)

**STABILITY TEST**

REAGENT	Days at 37°C	TOLERANCE	RESULT
C3 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	<b>APPROVED</b>	<b>Signed</b> <b>Date of Manufacture</b> Pilar Montolio 2017-10-17 Quality Control Department
	(APPROVED / NOT APPROVED)	

