

EN • CRP***In vitro* diagnostic medical device – CE mark - In compliance with EC Directive 98/79**

Cod. A02011012 CRP Rapid Test Kit: 1 box containing n. 25 test cartridges; n.1 IC card; n. 25 sample diluent; n. 25 disposable pipettes with 10 µL capillaries; n. 25 50 µL disposable pipettes; instructions for use.

Manufacturer

Anbio Biotechnology Co., Ltd.

Distributor

Callegari S.r.l.

Intended Use

For the quantitative measurement of C-reactive protein (CRP) in whole blood, serum or plasma, using the AF-100C analyzer. The test is intended for professional use.

Composition

Tube - Diluent
Phosphate buffered saline (PBS) 10 mmol/L
Test Cartridge
1) Mouse anti-CRP monoclonal antibody 2) Goat anti-rabbit IgG polyclonal antibody 3) Fluorescent microsphere-labeled mouse anti-CRP monoclonal antibody and fluorescent microsphere-labeled rabbit IgG polyclonal antibody

Preparation and Storage

The kit should be stored in a temperature range of 2-30 °C. The test cartridge must be used within 1 hour of opening the blister. The diluent is stable until the expiry date stated on the package.

Performance CharacteristicsLimit of Detection

0.5 mg/L

Limit of Quantitation

0.5 mg/L

Measuring range:

0.5 – 200 mg/L

Precision

Precision was determined according to the CLSI (Clinical and Laboratory Standards Institute) protocol (EP05-A3):

(1) 3 batches of test kits, repeated 10 times per batch (n=30)

mg/L	Intra-batch						Inter-batch	
	Batch 1		Batch 2		Batch 3			
	SD	CV %	SD	CV %	SD	CV %	SD	CV %
2.97	0.25	8.60	0.26	8.92	0.27	8.51	0.27	9.22

10.01	0.89	9.00	0.88	9.00	0.95	9.11	0.92	9.23
49.94	4.26	8.99	4.59	9.25	4.81	9.11	4.93	9.88

(2) 3 laboratories with duplicate testing 5 times a day for 5 days (n=75)

mg/L	Repeatability		Intra laboratory precision		Inter laboratory precision	
	SD	CV %	SD	CV %	SD	CV %
3.02	0.234	7.76	0.245	8.12	0.246	8.16
10.08	0.987	9.79	0.987	9.79	0.987	9.79
50.19	4.541	9.05	4.541	9.05	4.680	9.32