

EN • CRP/SAA

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

Cod. A02064012 CRP/SAA 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) and serum amyloid protein A (SAA) 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) Mouse anti-SAA monoclonal antibody 3) Goat anti-rabbit IgG polyclonal antibody 4) Fluorescent microsphere-labeled mouse anti-CRP/SAA 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 Characteristics

Detection Limit

CRP: 0.5 mg/L; SAA: 3.0 mg/L.

Linear Range:

CRP: 0.5 – 200 mg/L; SAA: 3.0 – 200.0 mg/L.

Linear correlation coefficient $R \geq 0.990$.

Precision:

Within batch CV is $\leq 15\%$; between batches CV is $\leq 20\%$.

Accuracy:

SD $\pm 15\%$