

EN • CK-MB/cTnI/Myo

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

Cod. A02002012 CK-MB/cTnI/Myo Rapid Test Kit: 1 box containing n. 25 test cartridges; n.1 IC card; n. 25 whole blood buffer; n. 25 disposable pipettes with 50 µL capillaries; instructions for use.

Manufacturer

Anbio Biotechnology Co., Ltd.

Distributor

Callegari S.r.l.

Intended Use

For the quantitative measurement of creatine kinase (CK-MB), troponin I (cTnI) and myoglobin (Myo) in whole blood, serum or plasma, using the AF-100C analyzer. The test is intended for professional use.

Composition

Tube - Buffer Reagent
Phosphate buffered saline (PBS) 10 mmol/L
Test Cartridge
1) Mouse anti-CK-MB monoclonal antibody 2) Goat anti-cTnI polyclonal antibody 3) Mouse anti-Myo monoclonal antibody 4) Goat anti-rabbit IgG polyclonal antibody 5) Fluorescent microsphere-labeled mouse anti-CK-MB/cTnI/Myo 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 tube buffer reagent is stable until the expiry date stated on the package.

Performance Characteristics

Detection Limit

CK-MB: 1.0 ng/mL; cTnI: 0.07 ng/mL; Myo: 10.0 ng/mL.

Linear Range

CK-MB: 2.0 - 100.0 ng/mL; cTnI: 0.1 - 50.0 ng/mL; Myo: 10.0 - 400.0 ng/mL.

Linear correlation coefficient $R \geq 0.990$.

Precision

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

Accuracy

SD $\pm 15\%$