

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

Cod. A02008012 D-Dimer Rapid Test Kit: 1 box containing n. 25 test cartridges; n.1 IC card; n. 25 sample diluent; 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 D-Dimer 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-D-Dimer monoclonal antibody 2) Goat anti-rabbit IgG polyclonal antibody 3) Fluorescent microsphere-labeled mouse anti-D-Dimer 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

0.05 mg/L FEU

Limit of Quantification

0.1 mg/L FEU

Measuring Range

0.1 – 10 mg/L FEU

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 %
0.498	0.0377	7.16	0.0446	8.88	0.0440	8.36	0.0424	8.18

5.003	0.4945	10.23	0.3490	6.67	0.4456	9.00	0.4517	9.02
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(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 %
0.498	0.0394	7.82	0.0394	7.82	0.0394	7.82
5.003	0.4552	9.00	0.4552	9.00	0.4556	9.01