

EN • 25-(OH) VD

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

Cod. A02019012 25-(OH) VD Rapid Test Kit: 1 box containing n. 25 test cartridges; n.1 IC card; n. 25 whole blood diluent; n. 25 disposable pipettes with 10 µL capillaries; n. 25 50 µL disposable pipettes; instruction for use.

Manufacturer

Anbio Biotechnology Co., Ltd.

Distributor

Callegari S.r.l.

Intended Use

For the quantitative measurement of 25-hydroxyvitamin D (25-(OH) VD) 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-25-(OH) VD monoclonal antibody 2) Goat anti-rabbit IgG polyclonal antibody 3) Fluorescent microsphere-labeled mouse anti-25-(OH) VD 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

Limit of Detection

5.0 ng/mL

Limit of Quantification

10.0 ng/mL

Measuring Range

10.0 - 100.0 ng/mL

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)

ng/mL	Intra-batch						Inter-batch	
	Batch 1		Batch 2		Batch 3			
	SD	CV %	SD	CV %	SD	CV %	SD	CV %
29.71	2.58	8.71	2.37	8.04	2.47	8.25	2.40	8.07

80.04	7.77	9.79	6.08	7.67	6.76	8.31	6.74	8.42
-------	------	------	------	------	------	------	------	------

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

ng/mL	Repeatability		Intra laboratory precision		Inter laboratory precision	
	SD	CV %	SD	CV %	SD	CV %
29.96	2.30	7.68	2.31	7.71	2.31	7.71
79.43	6.31	7.94	6.31	7.94	6.57	2.27