

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

Cod. A02025012 β -HCG Rapid Test Kit: 1 box containing n. 25 test cartridges; n.1 IC card; n. 25 sample diluent; n. 25 disposable pipettes with 50 μ L capillaries; instructions for use.

Manufacturer

Anbio Biotechnology Co., Ltd.

Distributor

Callegari S.r.l.

Intended Use

For the quantitative measurement of human chorionic gonadotropin (β -HCG) 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- β -HCG monoclonal antibody 2) Goat anti-rabbit IgG polyclonal antibody 3) Fluorescent microsphere-labeled mouse anti- β -HCG 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

2.00 mIU/mL

Limit of Quantification

2.00 mIU/mL

Measuring Range

2 - 200,000.00 mIU/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)

mIU/mL	Intra-batch						Inter-batch	
	Batch 1		Batch 2		Batch 3			
	SD	CV %	SD	CV %	SD	CV %	SD	CV %
9.99	0.886	8.69	1.100	11.07	0.905	9.22	0.948	9.49

495.45	48.502	9.92	60.036	11.90	51.552	10.46	52.121	10.52
9922.76	804.029	8.32	1070.991	10.70	1103.467	10.94	984.414	9.92

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

mIU/mL	Repeatability		Intra laboratory precision		Inter laboratory precision	
	SD	CV %	SD	CV %	SD	CV %
10.11	0.96	9.50	0.96	9.50	0.972	9.61
501.97	40.472	8.06	41.42	8.25	41.42	8.25
10067.05	933.504	9.27	933.504	9.27	933.504	9.27