

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

Cod. A02024012 TSH 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 thyroid stimulating hormone (TSH) 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-TSH monoclonal antibody 2) Goat anti-rabbit IgG polyclonal antibody 3) Fluorescent microsphere-labeled mouse anti-TSH 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

0.1 mIU/L

Limit of Quantification

0.1 mIU/L

Measuring Range

0.1 - 100 mIU/L

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/L	Intra-batch						Inter-batch	
	Batch 1		Batch 2		Batch 3			
	SD	CV %	SD	CV %	SD	CV %	SD	CV %
0.51	0.043	8.96	0.047	8.87	0.039	7.65	0.046	9.02

5.06	0.414	7.92	0.519	10.59	0.444	8.77	0.465	9.19
50.70	4.694	9.36	4.452	8.69	3.916	7.72	4.236	8.36

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

mIU/L	Repeatability		Intra laboratory precision		Inter laboratory precision	
	SD	CV %	SD	CV %	SD	CV %
0.50	0.046	9.20	0.048	9.60	0.047	9.40
5.05	0.385	7.62	0.444	8.79	0.444	8.79
50.45	4.491	8.90	4.592	9.10	4.592	9.10