



Folate Rapid Test Kit



Instructions for use



For in vitro diagnostic use only.



A02080002



25 Tests

【Product Name】

Folate Rapid Test Kit

【Intended Use】

The Folate Rapid Test Kit along with Anbio FIA Meter is a fluorescence immunoassay for quantitative measurement of Folate in human serum or plasma. The test is used for the auxiliary diagnosis of Folate deficiency related diseases.



For professional use only.

【Summary】

Folic acid is a derivative of pteridine, which was first isolated from the liver and later found to be abundant in the green leaves of plants, therefore it is called folic acid. Folate, with vitamin B12, is essential for DNA synthesis, which is required for normal red blood cell maturation. Humans obtain folate from dietary sources including fruits, green and leafy vegetables, yeast, and organ meats. Folate is absorbed through the small intestine and stored in the liver. Low folate intake, malabsorption as a result of gastrointestinal diseases, pregnancy, and drugs such as phenytoin are causes of folate deficiency. Folate deficiency is also associated with chronic alcoholism. Folate and vitamin B12 deficiency impair DNA synthesis, causing macrocytic anemias. These anemias are characterized by abnormal maturation of red blood cell precursors in the bone marrow, the presence of megaloblasts, and decreased red blood cell survival. Since both folate and vitamin B12 deficiency can cause macrocytic anemia, appropriate treatment depends on the differential diagnosis of the deficiency.

【Test Principle】

The Anbio Folate Rapid Test Kit is based on fluorescence immunoassay technology. The Anbio Folate Rapid Test Kit uses a sandwich immuno detection method. When sample is added to the sample well of the test, the fluorescence-labeled detector Folate antibody binds to Folate antigen in the sample. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and Folate are captured to Folate antibody that has been immobilized on test strip. Thus the more Folate antigen is in the sample, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of Folate captured and Anbio FIA Meter shows Folate concentration in the sample.

【Main Components】

The following components are included in the Folate Rapid Test Kit:

Supplied Materials:

Specification	25 Tests	Main Ingredients
Component		
Test Cartridge	25	1) T line: Mouse anti-Folate monoclonal antibody (coated) 2) C line: Goat anti-rabbit IgG polyclonal antibody 3) Binding pad: Fluorescent microsphere-labeled mouse anti-Folate monoclonal antibody (labeled) and fluorescent microsphere-labeled rabbit IgG polyclonal antibody
IC Card	1	/
Sample Diluent	25	10mmol/L PBS
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Materials Required but not Provided:

1. Transfer Pipette Set
2. Sample Collection Containers
3. Centrifuge
4. Timer
5. Anbio FIA Meter (model number: AF-100, AF-100s, AF-1200, AF-100C)

【Storage Conditions and Shelf Life】

Component	Storage- Temperature limitation	Stability
Test Cartridge		The shelf life is up to 24 months. Please refer to use-by date on the label. Test Cartridge should be used within 1 hour after opening the pack.
IC Card		/
Sample Diluent		The diluent is stable up to 24 months. Please refer to use-by date on the label.



【Warnings and Precautions】

1. This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use Test Cartridge if its lot # does not match with IC Card # that is inserted onto the equipment.
5. The Anbio Folate Rapid Test Kit is only operational in the Anbio FIA Meter.
6. Do not use the Test Cartridge if the pouch is punctured or not well sealed.
7. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and sample diluent tubes for different samples.
9. The sample, used Test Cartridges, pipette tips and sample diluent tubes should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

【Sample Collection and Preparation】

The test can be performed with serum or plasma. The plasma sample is recommended to use EDTA or sodium citrate for anticoagulation. Other body fluids and samples may not get accurate results.

For Serum and Plasma :

1. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
2. Test should be performed immediately after the specimens have been collected. Do not leave the sample at room temperature for prolonged periods. Sample may be stored at 2°C ~ 8°C for up to 48 hours. For long-term storage, the sample can be stable below -20°C for 7 days. Protect from light, freeze only once.

【Test Procedure】

Refer to Anbio FIA Meter Operation Manual (attached to Anbio FIA Meter) for the complete instructions on use of the Test.

Step1:Preparation

Check/ Swipe the IC Card information to the equipment.

Make sure the sample diluent is at the bottom of the tube by tapping or flicking before using.

Step2:Sampling

Draw 10 µL of serum/plasma with a transfer pipette and add it to the diluent tube.

Step3: Mixing

Close the lid of diluent tube and mix the sample by shaking or tapping 6-8 times, until the sample completely mixed. Let it incubate at room temperature for 10 minutes.

Step4: Loading

Take 50µL of sample mixture with a transfer pipette and load it into the sample well of the Test Cartridge.

Step5:Testing

Timing test: Insert the Test Cartridge onto the Test Cartridge Holder and click "Timing Test". 15 minutes later, the result will show in the display and print out when click "Print".

Quick test: Put the Test Cartridge on the operation platform. 15 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click "Quick Test". The result will show in the display and print out when click "Print".

【Limitations of Procedure】

1. This test has been developed for testing human serum and plasma sample.
2. The results of Anbio Folate Rapid Test Kit should be evaluated with all clinical and laboratory data available. If Folate test results do not agree with the clinical evaluation, additional tests should be performed.
3. Incorrect results can be caused by interference from some similar substance in the sample.
4. Other factors may interfere with Anbio Folate Rapid Test Kit and may cause erroneous results. These include technical or procedural errors, as well as additional substances in the sample.

【Quality Control】

Internal procedural controls are included in the test. When testing, the quality control line (C line) will show a

certain luminescence intensity, which is an internal procedural control. It confirms that a sufficient volume of samples has been added and that the correct procedure has been performed.

【Interpretation of Results】

The Anbio FIA Meter calculate the test result automatically and displays Folate concentration of the test sample in terms of ng/mL.

1. Conversion factor:

1 ng/mL = 2.265 nmol/L.

2.The reference value

≥ 3.5 ng/mL (≥ 7.9275 nmol/L)

Note: Individual reference range is suggested to be established for each laboratory.

【Performance Characteristics】

Limits and Range

Limit of Detection: 0.6 ng/mL ;

Limit of Quantitation: 1.0 ng/mL;

Measuring range: 1.0-30.0 ng/mL

Precision

Precision was determined with Anbio test kits, samples, and controls 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		
3.52	0.33	9.41%	0.30	8.15%	0.24	6.99%	0.29	8.27%
25.12	1.84	7.25%	1.56	6.33%	1.83	7.27%	1.72	6.84%

(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
3.51	0.266	7.57%	0.266	7.57%	0.266	7.57%
25.23	1.696	6.72%	1.821	7.22%	1.821	7.22%

Limitations-Interference

Detection of the effects of the following endogenous substances on assay performance. Interfering substances detected in the listed concentration range had no effect on the results.

Compound	Concentration
Bilirubin	350 μmol/L
Triglycerides	40 mmol/L
Hemoglobin	2 g/L
RF	1500 IU/mL
HAMA	1000 ng/mL
Antinuclear antibody	1:640

Limitations-Cross-Reactivity

















The following substances do not interfere with the Folate test results at the indicated concentrations.

Cross material	Concentration (ng/mL)
Amethopterin	500
Aminopterin	500
Folic acid	500

【Bibliography of Suggested Reading】

1. Appling DR. Compartmentation of folate-mediated one-carbon metabolism in eukaryotes FASEB J 1991; 5(12): 2645-51
2. Reynolds E H .The neurology of folic acid deficiency[J].Handbook of Clinical Neurology, 2014, 120:927-943.DOI:10.1016/B978-0-7020-4087-0.00061-9.
3. Pfeiffer C M , Johnson C L , Jain R B ,et al.Trends in blood folate and vitamin B-12 concentrations in the United States, 1988 2004[J].The American journal of clinical nutrition, 2007, 86(3):718-27.DOI:10.1093/ajcn/86.3.718.

【Index of Symbols】

	In vitro diagnostic medical device		Do not re-use
	Authorized representative in the European Community/ European Union		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
	Temperature limit		Batch code
	Use-by date		Keep dry
	Keep away from sunlight		Catalog number
	Date of manufacture		Contains sufficient for <n> tests
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Do not use if package is damaged and consult instructions for use

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