



Folate Fast Test Kit (Immunofluorescence Assay)

IF1094 for Getein 1100
IF5094 for Getein 1160
IF3094 for Getein 1180
IF2094 for Getein 1600
IF4094 for Getein 1200

Instructions for use



INTENDED USE

Folate Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of folate in serum samples. This test is mainly used for the auxiliary diagnosis of folate deficiency related diseases. For professional and laboratory use only.

SUMMARY

Folate, a water-soluble B vitamin, serves as an essential coenzyme in cellular metabolism, playing a crucial role particularly in the synthesis of nucleic acids and amino acids. The human body cannot synthesize folate independently, necessitating dietary intake. Serum levels of folate provide an indicator of an individual's folate status, reflecting recent folate consumption. Deficiency of folate has been linked to various health issues, including megaloblastic anemia, fetal neural tube defects, certain cardiovascular diseases, and potential cognitive impairments^[1-4].

Measurement of folate levels aids in evaluating the folate status within the body, particularly important for preconception and prenatal management in women, allowing assessment of neural tube defect risks. Monitoring folate levels plays a critical role in preventing folate deficiency-related diseases, guiding the use of supplements, and assessing nutritional status^[5]. Common detection methods employed in clinical laboratories for folate determination include radioimmunoassay, liquid chromatography-mass spectrometry (LC-MS), and enzyme-linked immunosorbent assay (ELISA).

PRINCIPLE

Folate Fast Test Kit (Immunofluorescence Assay) is a lateral

flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence latex-labelled folate monoclonal antibody binds with the folate in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another folate monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of folate in sample. Fluorescent signals intensity can be analyzed by applicable device thus the folate in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
Folate test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10 tube	25 tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*Folate test card

A test card consists of: Fluorescence latex-labelled folate monoclonal antibody, folate monoclonal antibody.

** Sample diluent

(1)Sample diluent for Getein 1100/Getein 1160/Getein 1180 is 0.2 mL contained in each tube consists of:

-Sample diluent main contains citric acid buffer (50 mmol/L).

(2)Sample diluent for Getein 1200/Getein 1600 is an independent packing box main consists of:

-Citric acid buffer (50 mmol/L) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),

-Box with pipette tips (96 tips/box),

-Mixing plate (1 piece/box).

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

-For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

-For test card of Getein 1200/Getein 1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional and laboratory use only, not for near-patient test and self-testing.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches until performing the test.
5. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
6. Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. Serum can be used as samples in the assay.
2. Due to the high folate content within red blood cells, hemolyzed specimens should not be used.
3. This assay is designed and validated for use with human blood, other specimens or body fluids may not get accurate results.
4. It is recommended to test the sample within 4 hours after

collection. Stable in serum for 7 days at 2~8°C and 6 months at -20°C.

5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

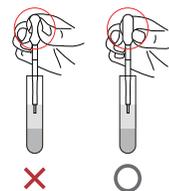
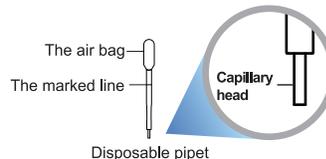
TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

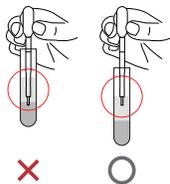
For Getein 1100:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2. Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual analyzer for details).
3. Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4. Use disposable pipet or pipette, deliver 20 µL of sample into one tube of sample diluent, mix thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.

For using the disposable pipet:



Note1: Do not depress the air bag of the disposable pipet with your finger during sampling.



Note 2: The capillary head of the disposable pipet touches the sample level gently and draws the sample automatically.

a. Gently hold the air bag of the disposable pipet and insert the disposable pipet into the sample collection tube until the **scale line** reaches the liquid level. The sample will be sucked into the disposable pipette by capillary action.

b. Insert the disposable pipet into the sample diluent. Squeeze the air bag 8 to 10 times to ensure the sample is fully mixed with the sample diluent.

c. Squeeze the air bag, suck the sample mixed solution to the **marked line** on the disposable pipette.

d. Add all the sucked sample vertically to the sampling area of test card.

5. Reaction time: **15 minutes**. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button or click on "Start" icon. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

1. Confirm SD card lot No. in accordance with test kit lot No..

Perform "SD card" calibration when necessary.

2. Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual analyzer for details).

3. Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.

4. Use disposable pipet or pipette, deliver 20 μ L of sample into one tube of sample diluent, mix thoroughly. Then drop 100 μ L of sample mixture into the sample well on the test card.

5. Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1600/Getein 1200:

1. Each cartridge for Getein 1600/Getein 1200 contains a specific RFID card which can calibrate automatically.

2. Place the sample diluent at the correct position in Getein 1600/Getein 1200.

3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1600/Getein 1200 will do the testing and print the result automatically.

RESULTS

Folate Fast Test Kit (Immunofluorescence Assay) results are reported in ng/mL.

Results in ng/mL may be converted to nmol/L as shown with an example below:

$$\text{ng/mL} \times 2.27 = \text{nmol/L}$$

$$\text{nmol/L} \times 0.44 = \text{ng/mL}$$

Others: Measuring range of the Folate Fast Test Kit is 1.2-40.0 ng/mL or 2.72 -90.8 nmol/L. Samples initially outside the measuring range may be diluted with fetal bovine serum, measuring range can be up to 80.0 ng/mL or 181.6 nmol/L through 2-fold dilution.

LIMITATIONS

1. The test results of this kit are only for clinical reference and cannot be used as the basis for confirming or excluding cases alone. In order to achieve the purpose of diagnosis, this test result should be used in combination with clinical

examination, medical history and other examination results.

2. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Triglyceride	400 mg/dL
Bilirubin	60 mg/dL
Biotin	40 ng/dL
Rheumatoid Factor	1200 IU/mL

EXPECTED VALUE

The expected normal value for folate was determined by testing samples from 300 apparently healthy individuals. The reference range of folate is 3.89 ng/mL~26.8 ng/mL (8.83 nmol/L~60.8 nmol/L) calculated by using normal distribution methods giving a level of confidence of approximately 95%.

It is recommended that each laboratory determine the applicability of the reference ranges through experimentation and establish their own laboratory-specific reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Measuring Range 1.2-40.0 ng/mL (2.72 -90.8 nmol/L)

Limit of Detection \leq 1.2 ng/mL(2.72 nmol/L)

Within-Run Precision \leq 10%

Between-Lot Precision \leq 15%

REFERENCES

- Nazki FH, Sameer AS, Ganaie BA. Folate: metabolism, genes, polymorphisms and the associated diseases. Gene 2014; 533 (1):11-20.
- Scaglione F, Panzavolta G. Folate, folic acid and 5-methyltetrahydrofolate are not the same thing. Xenobiotica 2014; 44(5):480-488.
- Dunn RT, Foster LB. Radioassay of serum Folate. Clin Chem 1973(10):1101-1105.
- Rothenberg SP, DaCosta M, Rosenberg Z. A radioassay for serum folate: use of a two-phase sequential-incubation, ligand-binding system. N Engl J Med. 1972; 286(25):1335-1339.
- Reynolds EH. The neurology of folic acid deficiency. Handb

Clin Neurol. 2014; 120:927-943.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Folate Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		

Thank you for using Folate Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

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