



Chuangxingwell

Folic Acid & Vitamin B12 & Ferritin (FA/VB12/Ferr) Rapid Test Kit
(Immunofluorescence Assay)

Package Insert

For in vitro diagnostic use only. For professional use only.

INTENDED USE

The Folic Acid & Vitamin B12 & Ferritin (FA/VB12/Ferr) Rapid Test Kit is intended for *in vitro* quantitative determination of Folic Acid, Vitamin B12 and Ferritin in human whole blood, serum or plasma along with Fluorescence Immunoassay Analyzer (FIA).

SUMMARY

Iron is an essential mineral that carries oxygen throughout the body in red blood cells. Ferritin is a protein that stores iron for future use when the body needs it most. While an iron test gives the current amount of iron in your blood, this test measures body's overall iron storage and determines if human have a healthy amount of iron in the body.

When iron levels drop too low, the body cannot make enough hemoglobin to produce the red blood cells it needs. As a result, human may become anemic, which may cause people to feel tired, dizzy, or short of breath. If left untreated, anemia may worsen and lead to additional symptoms. If iron levels get too high, your body absorbs more than is needed, which may be a sign of additional health problems like liver disease, heart problems and diabetes.^[1,2]

Vitamin B12 participates in the development of bone marrow red blood cells in the human body, promotes the growth of red blood cells in the human body, prevents malignant anemia, and can effectively reduce the adverse symptoms caused by anemia. Vitamin B12 can also exist in the form of auxiliary enzymes to increase the utilization of folic acid, promote the digestion and metabolism of carbohydrates, proteins and sugars, and effectively promote the metabolism in the human body.^[3]

Folic acid is a compound composed of pterinidine, p-aminobenzoic acid and glutamic acid. It is a water-soluble B vitamin. When folic acid is deficient, the forms of deoxythymidylate, purine nucleotides and amino acid interconversion are blocked, DNA synthesis in cells is reduced, cell division and maturation are hindered, and megaloblastic anemia occurs.^[4]

PRINCIPLE

The kit is based on fluorescence immunoassay (FIA) technology. It uses a sandwich immunodetection method.

The test uses mixed FA/VB12/Ferr monoclonal antibody I conjugated with fluorescence coated on the fibreglass bonding mat and another set of FA/VB12/Ferr monoclonal antibody II coated on different test lines of nitrocellulose membrane, respectively. When sample is added to the sample well of the test Cassette, the fluorescence-labeled FA/VB12/Ferr monoclonal antibody I will bind with the FA/VB12/Ferr in blood specimen respectively and form marked complexes. These complexes move to the test detection zone (T) by capillary action. Then marked complexes will be captured on different test lines (T) by FA/VB12/Ferr monoclonal antibody II, respectively.

The more FA/VB12/Ferr is in blood specimen, the more complexes are accumulated on test strip. The fluorescence intensity of test line increases in proportion to the amount of FA/VB12/Ferr in sample. The test area is scanned by a FIA Analyzer to obtain the corresponding optical signal, and then the signal is converted to the concentration of FA/VB12/Ferr through the built-in standard curve.

Regardless of whether FA/VB12/Ferr is present in the sample, a fluorescent band will appear in the quality control area (C). The fluorescent band displayed in the quality control area (C) is a standard for judging whether there are enough samples and whether the chromatographic process is normal, and also serves as an internal control standard for the detection reagents.

KIT COMPONENTS

Materials Supplied



- Test Cassettes
- ID Card for calibration
- Sample Buffer and empty tube for sample dilution.
- Package Insert

a) A test cassette consists of:

A plastic shell and a reagent strip. The reagent strip is composed of a sample pad, nitrocellulose membrane (the conjunction of sample pad and nitrocellulose membrane is coated with fluorescence labelled FA/VB12/Ferr monoclonal antibody I), nitrocellulose membrane (test lines are coated with FA/VB12/Ferr monoclonal antibody II respectively. The control line C is coated with sheep anti-rabbit antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

b) The sample buffer consists of:

sodium chloride (NaCl), PB buffer, surfactant tween-20 and proclin300.

MATERIALS REQUIRED BUT NOT PROVIDED

- Transfer Pipette
- Specimen Collection Containers
- Sterile Lancets (for fingerstick whole blood only)
- capillary tubes and dispensing bulb (for fingerstick whole blood only)
- Centrifuge ((for Plasma/Serum only))
- Timer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 18 months. Do not use the kit beyond the expiration date.

Do not open pouches until ready to perform the test. Use the test cassette within 1 hour once the foil pouch is opened.

Store the sample diluent at 0~30°C with a valid period of 18 months. Store the sample diluent at 2~8°C for better results.

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 Cassette if its lot # does not match with ID Card # that is inserted onto the equipment.
5. The Test kit is only operational in the matched FIA Analyzer.
6. Do not use the Test Cassette if the pouch is punctured or not well sealed.
7. The Test Cassette and Analyzer should be used away from vibration and magnetic field. During normal usage, the Analyzer itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and detector buffer vials for different specimens.
9. Blood specimens, used Test Cassette s, pipette tips and detector buffer vials 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.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with serum or plasma or whole blood.

1. For Whole Blood Collected by Fingerstick:

Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger. Puncture the skin with a sterile lancet. Wipe away the first sign of blood. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site. Add the Fingerstick Whole Blood specimen to the test by using a capillary tube.

2. For Whole Blood Collected by Venipuncture:

Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (EDTA recommended).

It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2°C ~ 8°C. It's not suitable to test the whole blood samples storing at 2°C ~ 8°C for more than 2 days.

3. For Serum and Plasma:

Separate the serum/plasma from blood as soon as possible to avoid hemolysis.



Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2°C ~ 8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

Note: The frozen samples shall be completely melted, reheated and mixed before being used. Repeated freeze-thaw should be avoided. It is recommended that samples be freeze-thaw not more than once. If there are sediments in thawed samples, centrifuge the samples before testing them.

TEST PROCEDURE

Refer to FIA Analyzer Operation Manual for the complete instructions on use of the Test. The test should be operated in room temperature (15°C-30°C).

Step1: Preparation:

Start the FIA Analyzer and correctly select the corresponding sample type on the instrument.

Take out the ID card, make sure that the batch number of the ID card is consistent with that of the test cassette, and insert the ID card into the ID card port of the instrument.

Step2: Loading

Testing for FA: Dispense 100 µl of sample diluent into the empty sample dilution vial. Add 20µl of the test sample into this sample diluent and mix by rinsing the tip 3 times.

Testing for VB 12: Dispense 200 µl of sample diluent into the empty sample dilution vial. Add 100µl of the test sample into this sample diluent and mix by rinsing the tip 3 times.

Testing for Ferr: Dispense 200 µl of sample diluent into the empty sample dilution vial. Add 5µl of the test sample into this sample diluent and mix by rinsing the tip 3 times. Close the lid of the sample dilution vial, label with sample identity and mix the content of the vial by gently inverting it for 10 times.

Take out the test cassette from the aluminum foil bag and place the test card on a clean horizontal table.

Dispense 100 µl of the above mixture into the sample well of test cassette.

Step3: Testing

Standard test: Insert the Test Cassette onto the Test Cassette Holder of FIA Analyzer and click "timing Test". 15 minutes later, the result will be shown on the screen..

Quick test: Put the Test Cassette on the operation platform. 15 minutes later, insert the Test Cassette onto the Test Cassette Holder of FIA Analyzer and click "Quick Test". The result will be shown on the screen.

Notes: It is required to perform ID card calibration when starting to use one new batch of kit.

INTERPRETATION OF RESULTS

For FA:

1. The folic acid test result is less than 3.10ng/mL, indicating folic acid deficiency.
2. When the concentration of the test sample is higher than 30ng/mL, the test kit will have a more obvious HOOK phenomenon.
3. When the report result is <1.00ng/mL, it means that the content of folic acid in the sample is less than 1.00ng/mL; when the report result is >20.00ng/mL, it means that the content of folic acid in the sample exceeds 20.00ng/mL. If the content of folic acid in the sample exceeds 20.00ng/mL, it should be diluted with the sample diluent before testing. The report result is the measured value multiplied by the dilution factor (the maximum dilution factor does not exceed 2 times).

For VB 12:

1. For samples with VB12 concentration lower than 20.00 pmol/L and higher than 1500.00 pmol/L, the detection results are reported as "<20.00 pmol/L" and ">1500.00 pmol/L", respectively.
2. Unit conversion relationship: 1.355 pg/mL=1pmol/L

For Ferr:

If the test result of the sample is more than 1000ng/ml, the analyzer displays ">1000ng/ml", and if the result is less than 5ng/ml, the analyzer displays "< 5ng/ml". Specific data can be exported through related software as needed.

This reagent is only used for auxiliary detection. If the test results are abnormal, it should be reviewed in time and judged in combination with clinical symptoms.

EXPECTED VALUE

For FA:

Through the test of 120 normal people, the statistical analysis of 95% reference value range shows that the normal reference range is 3.10~19.90ng/mL.

For VB 12:

The following reference intervals were derived from a 95% confidence interval statistical analysis of serum and plasma VB 12 levels in 196 healthy individuals: the reference value is 197-771 pg/mL.

For Ferr:

Through the determination of Human Ferr content in the whole blood, serum and plasma samples of 180 healthy people, the following reference interval was obtained after the statistical analysis of 95% distribution range.

Male: 16-220 ng/mL

Female: 10-125 ng/mL

Note: Note: Due to geographical, ethnic, gender and age differences, it is recommended that each laboratory establish its own reference range.

PRODUCT PERFORMANCE

For FA:

● **Minimum detection limit**

The minimum detection limit should not be higher than 1.00ng/mL.

● **Intra-assay precision**

Intra-assay precision CV (%) should not be higher than 15.0%.

● **Inter-assay precision**

Inter-assay precision CV (%) is not higher than 15.0%.

● **Linear range**

Within the range of 1.00ng/mL~20.00ng/mL, the linear correlation coefficient should not be less than 0.990.

● **Accuracy**

The absolute value of the relative deviation should not be higher than 15.0%.

For VB 12:

● **Limits of detection:**

No higher than 20.00 pmol/L.

● **Precision**

The within and between assay coefficient of variations are within 15%.

● **Linear range**

Within the linear range (20.00 ~ 1500.00) pmol/L, the linear correlation coefficient R≥0.990.

● **Accuracy**

The relative deviation from the target value is within ±15%.

● **Hook Test**

No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of measuring range, and the detection result was greater than the upper limit of detection.

For Ferr:

● **Minimum detection limit**

The minimum detection limit should not be higher than 1.00ng/mL.

● **Precision**

Precision: within batch C.V. is ≤ 15%; between batches C.V. is ≤ 15%;

● **Linear range**

Within the range of 1.0ng/mL~1000.0ng/mL, Linear correlation coefficient R ≥ 0.990;

● **Accuracy**

The relative deviation is within the range of ±15%.

● **Hook Test**

No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of measuring range, and the detection result was greater than the upper limit of detection.

PRECAUTIONS

1. Only for In vitro diagnostic use.

2. Do not mix components from different kit lots.

3. The reagents with damaged inner package and beyond the validity period cannot be used.

4. The test kit, sample diluent and the buffer tube are disposable and cannot be reused.

5. Do not test samples with severe hemolysis, severe lipemia, and jaundice.

6. The test kit must not be frozen. Bring all reagents and samples to room temperature before use.

7. After the test cassette is removed from the sealed pouch, it should be tested within 1 hour to avoid excessive time in the air, resulting in dampness.

8. The test kit should be used only in conjunction with matched FIA analyzer for accurate and reliable results.

9. The Test Cassette and Analyzer should be used away from vibration and magnetic field. During normal usage, the Analyzer itself may cause vibration, which should be regarded as normal.

10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

11. The used kits should be treated as potential infectious substances, and all samples, reagents and potential pollutants should be disinfected and treated according to the relevant local regulations.

LIMITATION

1. This kit is only for human whole blood, serum and plasma.

2. The test result of this kit are only one of the diagnostic aids for the clinicians. But the results cannot be used as the only basis for clinical diagnosis, but should be evaluated with all the existing clinical and experimental data.

3. Samples containing interfering substances can affect test results. The maximum allowable concentration is: hemoglobin 3 mg/ mL bilirubin 0.25 mg/ mL and triglyceride 10 mg/ mL.

4. The false positive results may come from cross-reactions with some similar antibodies in blood; and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.

REFERENCES

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[3]. Stabler SP. Vitamin B12 deficiency [J]. N Engl J Med, 2013, 3(1):54-55.

[4] Clarke R, Smith A D, Jobst K A , et al. Folate, Vitamin B12, and Serum Total Homocysteine Levels in Confirmed Alzheimer Disease[J]. JAMA Neurology, 1998, 55(11):1449-1455.

SYMBOLS

	Caution		In Vitro Diagnostic Medical Device
	Manufacturer		Date of Manufacture
	CE Marking		Do Not Re-use
	Keep Dry		Keep Away From Sunlight
	Batch Code		Do Not Use if Package is Damaged
	Catalogue Number		Contains Sufficient for <n> Tests
	Use-By Date		Temperature Limit
	Authorized representative in the European Community		



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