Vitamin B12 (VB12) Rapid Quantitative Test（Fluorescence immunoassay)
User manual

【Product name】
Vitamin B12 (VB12) Rapid Quantitative Test（Fluorescence immunoassay)

【Package specification】
25 Tests/kit

【Intended use】
This kit is used for quantitative determination of Vitamin B12 in human whole blood, plasma and serum.
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.

【Test principle】
The reagent adopts the principle of competitive method. Take the sample to be tested, add it into the sample diluent and mix it evenly. Add the mixed sample into the sample adding hole. VB12 in the sample combines with the fluorescent labeled antibody on the binding pad to form a complex. Under the action of chromatography, the complex moves forward along the nitrocellulose membrane, and the fluorescent labeled antibody that does not bind to the test line is captured by VB12-BSA coated on the nitrocellulose membrane detection line. The more VB12 in the sample, the fewer complexes gathered on the detection line, and the signal of fluorescent antibody is inversely proportional to the number of objects to be tested in the sample. The quantitative detection results were obtained by NIR-1000 dry fluoroimmunoassay analyzer.

【Components】

Name	Quantity	Component
Test cards	25	It is composed of nitrocellulose membrane (coated with Goat anti mouse IgG antibody), absorbent paper and backing
Diluent buffer	1（2.50 mL）	Phosphate buffer
VB12 antibody lyophilized powder	25	VB12 antibody (lyophilized)
Fluorescent lyophilized powder	25	Fluorescent labeled VB12 (lyophilized)
ID card	1	With specific stand curve file

The components in different batches of kits cannot be used interchangeably.

【Storage conditions and validity】
The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20% ~ 90% relative humidity.
The production date, batch number and expiration date are shown in the outer package of the product.

【Applicable instruments】
Mod:NIR-1000 Dry Fluoroimmunoassay Analyzer produced by WWHS Biotech.Inc.

【Sample requirements】
1. Plasma, serum can be used as samples. If the serum procedure is used, collect blood in a tube without anticoagulant and allow clotting. Hemolyzed samples should not be used. It is recommended to use serum samples preferentially.
2. Venous blood was collected according to routine laboratory methods to avoid hemolysis.
3. It is highly recommended to use fresh samples instead of keeping the samples at room temperature for a long time. After samples were collected, the detection should be completed within 4 hours at room temperature (15℃~30℃). Plasma and serum samples can be stored at 2℃~ 8℃ for 7 days, -20℃for 30 days.
4. Before testing, the sample should return to room temperature (15℃~30℃). The frozen samples should be completely thawed, rewarming and mixed evenly before use. Repeated freeze-thaw cycles should be avoided.

【Test procedure】
1. Before the test, please read the instructions completely. If the test card and sample are stored in cold storage, they should be balanced at room temperature (15-30)℃ for not less than 30min before use.
2. Start NIR-1000 dry fluoroimmunoassay analyzer and correctly select the corresponding sample type on the instrument.
3. Take out the ID card, make sure that the batch number of the ID card is consistent with that of the test card, and insert the ID card into the ID card port of the instrument.
4. Take out the test card from the aluminum foil bag and use it within 15 minutes.
5. Place the test card on a clean horizontal table and mark it horizontally.
6. Add 100μL diluent buffer to the tube containing VB12 antibody lyophilized powder（white）. One tube is used by one test.
7. Add 20 μL sample to the tube, mix the solution thoroughly and keep incubation for 5 minutes.
8. Apply 100 μL of incubated sample to the tube containing fluorescent lyophilized powder（blue）, mix the solution thoroughly and keep incubation for 5 minutes.
9. Apply 100 μL of incubated sample to the well of the test card.
10. At 15 minutes after addition of incubated sample, insert the test card into dry fluorescent

immunoanalyzer, read and record the results then dispose of used test appropriately.

【Reference interval】

The normal reference value is 150−700 pmol/L in this assay. It is recommended that each laboratory should establish its own normal range based on a representative sampling of the local population.

【Interpretation of results】

1. 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.
2. 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.
3. Unit conversion relationship: 1.355 pg/mL=1pmol/L

【Limitations of methods】

1. Due to the limitations of immunoassay methods of antigen and antibody reaction, the results cannot be used as the only basis for clinical diagnosis, but should be evaluated with all the existing clinical and experimental data.
2. The content of triglyceride in the sample shall not exceed 15mg/ml, the content of hemoglobin shall not exceed 2.0mg/ml, and the content of bilirubin shall not exceed 0.5mg/ml, and the relative deviation of the test results shall not exceed ±15%。
3. When the concentration of VB12 in the sample is less than 200.00 ng/mL, there is no hook effect.
4. HAMA effect was not produced when the concentration of human anti rat in the sample was less than 50ng/ml.
5. When RF concentration in the sample is less than 2000IU/ml, the relative deviation of the test results is within ±15%.

【Performance】

1. Limits of detection

No higher than 20.00 pmol/L.

2. Accuracy

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

3. Precision

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

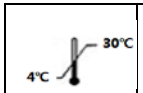
4. Linear range

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

【Precaution】

1. This kit is only used for in vitro diagnosis.
2. The test card and sample diluent are disposable and cannot be reused.
3. Please check the integrity and validity of the kit package before use, and then open the package. When it is stored at low temperature, it should be restored to room temperature (15℃ ~ 30℃) before opening the package for use. The reagents with damaged inner package and beyond the validity period cannot be used.
4. The requirements of specimen collection and storage should be strictly observed. If the specimen is turbid, it should be centrifuged and discarded before use.
5. 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.

【Interpretation of signs】

	Temperature limit		Do not re-use		Use-by date
	Keep away from sunlight	IVD	In vitro diagnostic medical device	LOT	Batch code
	Keep dry		Consult instructions for use	UDI	Unique device identifier
	Manufacturer		Date of manufacture	EC REP	Authorized representative in the European Community

【Reference】

[1] Yajnik C S , Deshpande S S , Jackson A A , et al. Vitamin B12. 2007.

[2] 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.

【Basic Information】

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