PDM签审页

PDM版本：

PDM编码：

产品名称	出口_贫血试剂_维生素B12测定试剂盒 VB12_说明书		
库存编码	1062400	版本号	20210621
成品尺寸	210×297mm	单位	mm
印刷色	单色	允差	±2mm
材质	80g胶版纸，双面印刷		
备注			
设计			
审核			
批准			

Vitamin B12 Detection Kit
(Chemiluminescence Immunoassay) Instructions

【Product Name】
Vitamin B12 Detection Kit(Chemiluminescence Immunoassay)

【Package Specification】

Package Specification	Reagent Kit Composition
1×50 Tests/kit	1×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
1×50 Tests/kit (without Calibrator and Control)	1×Reagent
1×100 Tests/kit	1×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
1×100 Tests/kit (without Calibrator and Control)	1×Reagent
2×100 Tests/kit	2×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
2×100 Tests/kit (without Calibrator and Control)	2×Reagent
4×100 Tests/kit	4×Reagent, 2×Calibrator (High), 2×Calibrator (Low), 2×Control (Level 1), 2×Control (Level 2)
4×100 Tests/kit (without Calibrator and Control)	4×Reagent
1×200 Tests/kit	1×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
1×200 Tests/kit (without Calibrator and Control)	1×Reagent
2×200 Tests/kit	2×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
2×200 Tests/kit (without Calibrator and Control)	2×Reagent

【Intended Use】
For quantitative determination of vitamin B12 content in human serum or plasma in vitro.
Vitamin B12 (VB12), also known as cobalamin, is a type of corrinoid compound containing pyrrole ring. Vitamin B12 cannot be synthesized in the human body. The main sources are meat, fish, eggs and dairy products. Vitamin B12 deficiency can affect the synthesis of red blood cells and can lead to megaloblastic anemia caused by abnormal DNA synthesis. Therefore, it is mainly used clinically for the auxiliary diagnosis of megaloblastic anemia.

【Test Principle】
The vitamin B12 detection kit is detected by the competition method based on chemiluminescence immunoassay. The reagent consists of five parts: R1, R2, R3, R4 and R5. R1 is the streptavidin magnetic particles, R2 is the vitamin B12 antibody labeled with acridinium ester, R3 is the vitamin B12 derivative labeled with biotin, R4 and R5 are the reagents for sample pretreatment. The vitamin B12 derivative labeled with biotin competes with the vitamin B12 in the samples after pretreatment to form the vitamin B12 antibody labeled with acridinium ester. The immune complex binds to the magnetic particles through the reaction between biotin and streptavidin. The vitamin B12 content in samples is inverse proportion to the relative light units(RLUs) detected by the system.
The system automatically performs the following steps:
1. Place the sample and reagent into the cuvette and incubate at 37°C;
2. Separate the magnetic particles and then wash them with washing buffer;
3. Add Acid Trigger Reagent and Alkaline Trigger Reagent to stimulate the chemiluminescence reaction.

【Main Components】

Composition		Main Components	Content
reagent	R1	streptavidin magnetic particles	⩾0.03%
	R2	vitamin B 12 antibodies labeled with acridinium ester	⩾10ng/mL
	R3	vitamin B12 derivatives labeled with biotin	⩾5ng/mL
	R4	dithiothretol	⩾0.5g/L
	R5	sodium hydroxide potassium cyanide	⩾20g/L ⩾10μg/mL
calibrator (high, low)		protein components supplemented with vitamin B12	See the label
control (level 1, level 2)		protein components supplemented with vitamin B12	See the label

Note 1: components in different batches of reagent kits are not interchangeable.
Note 2: do not use calibrators and controls mixed from different lots. Fixed values of calibrators and target value range of controls are detailed in the calibration and control information registration card.
Note 3: required materials not provided are Acid Trigger Reagent, Alkaline Trigger Reagent and Washing Buffer/Concentrated Washing Buffer. Operate according to the instrument user manual and instructions of the above reagents.
Note 4: calibrators are traced back to the company's internal reference measurement procedure.

【Storage Conditions & Shelf Life】
1. The reagent kit should be stored at 2-8°C, away from sunlight, kept airtight and upright. For the shelf life refer to the label.
2. After being used for the first time, the reagent can be stable for 28 days if stored at 2-8°C. The calibrator and control can be stable for 28 days after opened if sealed and stored at 2-8°C.

【Date of Manufacture& Expiry Date】 See the label.

【Applicable Instrument】
CM Series Chemiluminescence Immunoassay Analyzer and CSM Series Integrated System

【Sample Requirements】
1. The sample type for tests is serum or plasma.
2. Adopt correct medical technology to collect samples.
3. Serious hemolysis, lipemia and turbid samples cannot be used for tests.
4. The sample can be stored at 2-8°C for 24 hours; if the test is not finished within 24 hours, the sample should be stored at -20°C and can be stable for 60 days.
5. Before putting the sample into the system, ensure that the sample is without fibrous protein or other particles and bubbles.

【Test Method】
1. Reagent preparation
R1, R2, R3, R4 and R5 are ready-to-use reagents, which can be used directly. Mix the reagents before loading them into the system. Visual inspection of the reagent's bottom ensures that all magnetic particles have been dispersed and re-suspended to avoid bubbles.
Calibrators and controls are ready-to-use reagents, which can be used directly. Mix calibrators and controls well and balance them to room temperature for use.
2. Test procedure
Before loading reagents on the system, mix all reagents. Visually inspect the reagent bottle bottom to guarantee magnetic particles are dispersed or re-suspended. For detailed operation steps refer to the instrument user manual.
3. Calibration

When using new batches of reagents, recalibrate the vitamin B12 item and scan the calibration information registration card(manual input registration is supported). By measuring high and low calibrators, each calibration point on the pre-input main calibration curve is adjusted to a new calibrated curve.

In the following cases, recalibration is recommended:

- Use the reagent kit with a new batch number.
- Replace trigger reagent with a new batch number.
- When the repeated QC results are not within the prescribed range.

4. QC

1) Regarding the frequency of QC, please follow the regulations or requirements of the government.

2) Controls must also be determined when calibration is performed. All calibrator and control samples are treated equally to patients' samples.

3) If the quality control results are not within the acceptable range prescribed by the laboratory, the following measures can be taken.

- Ensure the reagent used has not expired.
- Ensure required maintenance is executed.
- Ensure test procedures are performed strictly following the instructions.
- Use a new control to re-test.
- Use a new calibrator to re-calibrate.
- Ask local technicians or distributor for help if necessary.

5. Calculation of test results

The instrument will automatically calculate the concentration of each sample in pg/mL.

Unit conversion: pg/mL×0.738=pmol/L

pmol/L × 1.36 = pg/mL

【Reference Range】

197 pg/mL -771pg/mL

The lab should study the above reference range and is suggested to set its own reference range due to geography, diet, environment factors, etc.

【Interpretation of Test Results】

1. Test results are not the only one as diagnosis index of clinical indications. Clinical significance is analyzed specifically combined with other test indices and clinical manifestation.
2. The detection range is 30pg/mL-2000pg/mL. Values below the minimum detection limit are reported that ＜30 pg/mL and values exceed the detection limit are reported that ＞2000 pg/mL.
3. For test results beyond the linear range of the reagent kit, the sample needs to be diluted to the linear range for testing.
4. The vitamin B12's measurement is different in test methods, site identification, specificity and interfering factors. Thus, vitamin B12 test results are different for a specified sample; inspectors should indicate the test method when supplying a laboratory test report to doctors. No direct comparability among test results obtained from different test methods. Direct cross use may lead to misinterpretation of its clinical significance; in the continuous monitoring of the efficacy of patients, before the method can be changed halfway, it is necessary to go through a full parallel experiment between the old and new methods and confirm its feasibility.

【Limitations of Test Method】

1. Patients of frequent exposure to animals, animal serum products and those who have used antibodies for in vivo diagnosis and treatment may contain heterophilic antibodies, which may lead to false positive or false negative.
2. Samples containing bilirubin, hemoglobin, triglyceride and total protein may affect test results.
3. Samples containing high concentrations of rheumatoid factors(RF) may result in false positive or false negative results.
4. High-dose biotin treatment may affect test results.
5. Serious hemolysis, lipemia and turbid samples used for tests may cause incorrect results.

【Product Performance Indices】

1. Accuracy: the relative deviation should be within ±15% of the nominal value.
2. Minimum detection limit: should be no more than 30pg/mL.
3. Linearity: linear range is 50 pg/mL-2000 pg/mL; linear correlation coefficient r≥0.9900.
4. Repeatability: CV≤8.0%
5. Between-batch difference: CV≤15.0%

Note: for other performance indexes, refer to the technical requirements.

【Matters Needing Attention】

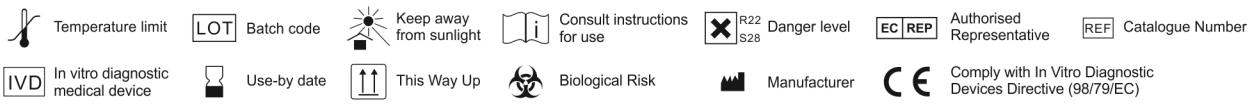
1. This product is only used for in vitro diagnosis.
2. Considering the possible evaporation effect, samples, calibrators and controls on board should be analyzed/measured within 2 hours.
3. Please treat samples as dangerous substances that may be infected with HIV, HBV, HCV, etc. To avoid or reduce the risk of infection, disposable gloves and eyes/face protective items should be worn.
4. If the reagent enters eyes or the mouth by mistake, or touches the skin, please rinse it with water quickly and receive medical treatment if necessary.
5. Samples and waste liquids are potentially biologically contagious. Operators should abide by laboratory safety regulations and treat waste liquids in accordance with local medical wastes, infectious wastes, industrial wastes, etc.
6. Clinical samples should be treated as infectious samples, and operate according to the relevant laboratory specifications and requirements promulgated by National Health Commission, Ministry of Science and Technology, and National Medical Product Administration and other relevant departments.
7. Avoid freezing the reagents.
8. Samples can only be frozen once. Mix well after thawing.

【References】

1. Kumar S S , Chouhan R S , Thakur M S . Enhancement of Chemiluminescence for Vitamin B12 Analysis[J]. Analytical Biochemistry,2009;388(2):312-316.
2. Allen LH. How Common is Vitamin B-12 Deficiency?[J]. Am J ClinNutr,2009;89(2):693S-6S.
3. Lv Yingjian, Huang Junming.Study Progress of Vitamin B12[J]. Chinese Journal of Food Hygiene, 2012;24(4):394-399.
4. Qiu Zhenhua, Gaoyan, Chen Yufeng, etc. Determination of Folic Acid and Vitamin B12 in Serum by CLIA and Its Clinical Application[J]. Experimental Diagnostics in China, 2009;13(7):967-968.
5. EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition [S].2014.

【Instruction Approved & Modified Date】 09/2020

Symbol Explanation



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