DIRUI 迪瑞

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_贫血试剂_叶酸测定试剂盒 Folate_说明书		
库存编码	1060240	版本号	20201104
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			

Folic Acid Detection Kit (Chemiluminescence Immunoassay) Instructions

【Product Name】

Folic Acid 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 folic acid content in human serum, plasma or whole blood.

Folic acid (folate) is a kind of compound, also known as vitamin B9. Folic acid is an essential nutrient for human body. It has important physiological function for human body and is coenzyme of many biochemical reactions. Folic acid is obtained from daily diet such as fruit, green leafy vegetables, yeast and organ flesh, and then absorbed by small intestine and stored in liver. Folic acid is mainly used in the clinical diagnosis of megaloblastic anemia. Serum folic acid measurement can provide an early indicator of folic acid status in vivo. However, since folic acid concentration in red blood cells is much higher than that in serum, folic acid measurement in red blood cells will more closely reflect the amount of folic acid accumulation in tissues.

【Test Principle】

The folic acid 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 folic acid antibody labeled with acridinium ester, R3 is the folic acid derivative labeled with biotin, R4 and R5 are the sample pretreatment reagents; the folic acid derivative labeled with biotin competes with folic acid in treated samples, and combines with the folic acid antibody labeled with acridinium ester. Immune complex binds to magnetic particles through the reaction between biotin and streptavidin. The folic acid 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℃;
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	folic acid antibodies labeled with acridinium ester	⩾10ng/mL
	R3	folic acid derivatives labeled with biotin	⩾5ng/mL
	R4	dithiothreitol	⩾5g/L
	R5	sodium hydroxide	⩾20g/L
calibrator (high, low)		protein components supplemented with folic acid	see the label
control (level 1, level 2)		protein components supplemented with folic acid	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: required materials for testing whole blood samples but not provided: RBC Folate Releasing Agent.

Note 5: calibrators are traced back to the reference material.

【Storage Conditions & Shelf Life】

1. The reagent kit should be stored at 2℃-8℃, 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℃. The calibrator and control can be stable for 28 days after opened if sealed and stored at 2℃-8℃.

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

【Applicable Instrument】

CM Series Chemiluminescence Immunoassay Analyzer and CSM Series Integrated System

【Sample Requirements】

1. It is recommended to use serum or plasma samples collected from blood vessels of heparin anticoagulants.
2. It is recommended to use whole blood samples collected from blood vessels of EDTA anticoagulants.
3. Adopt correct medical technology to collect samples.
4. Serious hemolysis, lipemia and turbid samples cannot be used for tests.
5. The hematocrit of samples should be measured for the calculation of folic acid in red blood cells.
6. The serum or plasma sample can be stored at 2℃-8℃ for 24 hours; if the test is not finished within 24 hours, the sample should be stored at -20℃ and can be stable for 30 days.
7. The whole blood sample can be stored at 2℃-8℃ for 4 hours; if the test is not finished within 4 hours, the sample should be stored at -20℃ and can be stable for 15 days.
8. Human serum, plasma or whole blood samples for folic acid detection should be kept away from sunlight.
9. 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 all ready-to-use reagents, which can be used directly. Mix the reagents before loading them into the system. Visual inspection of 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, balance them to room temperature and 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 Folate item and scan the calibration information registration card (manual input registration is supported). By measuring low and high 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 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 ng/mL.

Unit conversion: ng/mL × 2.265=nmol/L, nmol/L x 0.44=ng/mL

【Reference Range】

Folic acid in serum or plasma:＞3.1ng/mL

Folic acid in red blood cells of whole blood sample: ＞126ng/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 0.4ng/mL-20ng/mL. Values below the minimum detection limit are reported that＜0.4ng/mL and values exceed the detection limit are reported that＞20ng/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 folic acid's measurement is different in test methods, site identification, specificity and interfering factors. Thus, folic acid 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.

5. Calculation concentration of folic acid in red blood cells Multiply system test results by the dilution ratio required in the preparation of hemolysis samples in red blood cells and the result is the folic acid detection concentration of hemolysis samples in blood cells. Then calculate the concentration of folic acid in red blood cells according to the following calculation formula:

The concentration of folic acid: Folic acid in red blood cells=folic acid concentration of hemolysis sample in red blood cells/%hematocrit×100

Give an example: Folic acid concentration of hemolysis sample in red blood cells=62ng/mL, %hematocrit=40

Folic acid in red blood cells=62ng/mL/40×100=155ng/mL

6. Calculation of corrected concentration of folic acid in red blood cells Generally, the folic acid concentration in red blood cells is much higher than that in serum or plasma, but sometimes the folic acid concentration in serum or plasma is within or higher than the reference range, while the folic acid concentration in red blood cells is lower than the reference range. In this case, the folic acid concentration in red blood cells needs to be corrected according to the following formula:

Corrected concentration of folic acid in red blood cells=

Folic acid concentration in red blood cells-{folic acid concentration in serum or plasma×(100-%hematocrit)/%hematocrit}

Give an example: Folic acid concentration of hemolysis sample in red blood cells=155ng/mL, %hematocrit=40, Folic acid in serum=13.5ng/mL

Corrected concentration of folic acid in red blood cells=

155ng/mL-{13.5ng/mL×(100-40)/40)}=134.75ng/mL

【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. Bilirubin, triglyceride, IgG and IgA in a sample may have an impact on 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. Limit of detection: should be no more than 0.64ng/mL.

3. Linearity: linear range is 0.64ng/mL-20ng/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】

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2. Zemlin A E , Essack Y , Rensburg M , et al. Stability of red blood cells Folate in Whole Blood and Haemolysate[J]. Clinical laboratory, 2010, 56(9-10):391-396.

3. Shi Dan, Jia Yunhong, Bao Yihong. Research Status and Development Trend of Folic Acid Detection Method[J]. China Dairy Industry, 2009(3):42-45.

4. Wang Xu, Xue Jinglun. Research Process of rhe Relationship Between Folic Acid Metabolism and the Stability of Human Genome[J]. Foreign Medicine. Genetics Section, 2005, 28(5):257-261.

5. EP05-A3,Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition [S].2014.

【Instruction Approved & Modified Date】 11/2020

Symbol Explanation

Temperature limit	LOT Batch code	Keep away from sunlight	Consult instructions for use	R22 S28 Danger level	EC REP Authorised Representative	REF Catalogue Number	
IVD In vitro diagnostic medical device	Use-by date	This Way Up	Biological Risk	Manufacturer	CE Comply with In Vitro Diagnostic Devices Directive (98/79/EC)		

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CE IVD

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