PDM签审页

PDM版本：

PDM编码：

产品名称	出口_肿瘤试剂_甲胎蛋白测定试剂盒_AFP_说明书		
库存编码	1041558	版本号	20200929
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			

Alpha-fetoprotein Detection Kit
(Chemiluminescence Immunoassay) Instructions

【Product Name】

Alpha-fetoprotein Detection Kit (Chemiluminescence Immunoassay)

【Packaging Specification】

1×50 Tests/Kit; 1×50 Tests/Kit (without Calibrator and Control);
2×50 Tests/Kit; 2×50 Tests/Kit (without Calibrator and Control);
1×100 Tests/Kit; 1×100 Tests/Kit (without Calibrator and Control);
2×100 Tests/Kit; 2×100 Tests/Kit (without Calibrator and Control);
4×100 Tests/Kit; 4×100 Tests/Kit (without Calibrator and Control);
1×200 Tests/Kit; 1×200 Tests/Kit (without Calibrator and Control);
2×200 Tests/Kit; 2×200 Tests/Kit (without Calibrator and Control).

【Intended Use】

For quantitative determination of Alpha-fetoprotein (AFP) in human serum in vitro.

AFP is a single-chain glycoprotein similar to albumin and its molecular weight is about 70,000 Daltons. It is mainly synthesized by immature cells of embryos and yolk sacs. In fetal serum, AFP in pregnancy around 13 weeks can reach the peak value, and then decreases gradually during pregnancy. AFP synthesis is inhibited after birth. AFP concentration in infants at the end of one year is close to that of normal adults.

AFP has certain significance in the early diagnosis of hepatocellular carcinoma. About 80% of the samples of patients with hepatocellular carcinoma have higher AFP concentration. The positive rate of AFP in germ cell carcinoma is about 50%. In other gastrointestinal tract tumors, pancreatic cancer and liver cirrhosis, the positive rate of AFP increased to different degrees.

During pregnancy, AFP concentration increases in women. AFP in maternal amniotic fluid or maternal serum can be used for fetal prenatal detection, such as neural tube defects, spina bifida, anencephalus, etc. AFP may enter amniotic fluid from an open nerve tube, leading to a marked increase in AFP in amniotic fluid; fetal death in uterine cavity, teratoma and other congenital defects may also have an increase in AFP in amniotic fluid. AFP can enter maternal blood circulation through amniotic fluid. In 85% of mothers with spina bifida and anencephalus, high alpha-fetoprotein can be seen around 16-18 weeks of gestation, which is of diagnostic value. However, AFP must be used in combination with relevant fetal examination and clinical experience to assist in the detection of neural tube defects and other diseases in order to avoid false positive errors.

In addition, AFP test is an effective adjunct to the treatment of testicular cancer of non-seminoma. There is no AFP in pure seminoma, but in testicular cancer of non-seminoma, AFP level will rise. AFP concentration can be tracked to monitor the development of cancer.

【Test Principle】

The AFP detection kit is detected by the double antibody sandwich method based on chemiluminescence immunoassay. The reagent consists of three parts: R1, R2 and R3. R1 is the magnetic particles coated with AFP antibody, R2 is the antibody labeled with acridinium ester and R3 is the PBS buffer; the AFP antibody labeled with acridinium ester and the magnetic particles coated with AFP antibody react immunologically with the AFP antigen in the samples to form the antigen-antibody complex.

The content of AFP in the samples is directly proportional to the relative light units (RLUs) detected by the system.

The system automatically performs the following steps:

◆Place the sample and reagent into the cuvette, incubate at 37℃ and rinse;

◆Separate the magnetic particles and then wash them with washing buffer;

◆Add Acid Trigger Reagent and Alkaline Trigger Reagent to stimulate the chemiluminescence reaction.

【Main Components】

Composition	Main Components	Content
R1	magnetic particles coated with alpha-fetoprotein antibodies	0.01%
R2	alpha-fetoprotein antibodies labeled with acridinium ester	0.2μg/mL
R3	PBS buffer	20mmol/L
calibrator (high, low)	serum matrix supplemented with alpha-fetoprotein	/
control (level 1, level 2)	serum matrix supplemented with alpha-fetoprotein	/

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 bottle labels.

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 alpha-fetoprotein national standard 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. Open vial stability: after being used for the first time, the reagent can be stable for 28 days if sealed and stored at 2℃~8℃.
3. Instrument-loading stability: stable for 28 days.

【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.
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℃ for 48 hours; If the test is not finished within 48 hours, freeze the sample at -20℃ or lower.
5. Samples can only be frozen once. Mix well after thawing.
6. 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 and R3 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.

2. Test procedure

Before loading reagents on the system, mix all reagents. Visually inspect the reagent bottle bottom to guarantee magnetic particles are separated or re-suspended. For detailed operation steps refer to the instrument user manual.

3. Calibration

When using new batches of reagents, recalibrate the AFP 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 prescribe range.

4. QC
1) Two levels of controls are determined on the day of testing each sample.
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: 1ng/mL =0.83IU/mL.

【Positive Judgment Value】
≤7.0ng/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 Result】
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. There is no direct comparability between the sample's AFP concentration tested by other ways and test results of the product.
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. There is no high dose hook effect When AFP concentration is up to 1000000ng/mL,
5. The AFP measurement is different in test method, site identification, specificity and interfering factors. Thus, AFP 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】
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. Samples containing rheumatoid factors (RF) may result in false positive or false negative results. Although this reagent contains inhibitor that can eliminate the interference, there may be possibility of existing false positive or false negative samples. The test results need to be combined with other information for comprehensive analysis.

【Product Performance Indices】
1. Lower detection limit: ＜1.3ng/mL.
2. Linearity: linear range is 1.3ng/mL～1000ng/mL; linear correlation coefficient r≥0.9900.
3. Accuracy: test with national standard material, the relative deviation of measured results should be within ±10%.
4. Repeatability: CV≤8.0%.
5. Between-batch difference: CV≤15.0%.
6. Anti-interference and specificity: in the sample, when bilirubin≤ 20mg/dL, triglyceride≤1000mg/dL, hemoglobin≤500mg/dL, there is no effect on test results; when aspirin is 10mg/mL, bleomycin is 3000 IU/mL, cisplatin is 1000μg/mL, human chorionic gonadotropin is 1000 IU/mL, r-globulin is 30mg/mL, cyclophosphamide is 330μg/mL, doxorubicin is 10μg/mL, 5-Fluorouracil is 360μg/mL, methotrexate is 13μg/mL and vincristine is 700μg/mL, the interference rate is less than 10%.

【Matters Needing Attention】
1. This product is only for in vitro diagnosis.
2. Please treat samples as dangerous substance 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.
3. If the reagent enters eyes or the mouth, or touches the skin, please rinse it with water quickly and receive medical treatment if necessary.
4. 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.
5. The reagent contains sodium azide, which may react with copper and lead pipes to form explosive metal azides. If it is time to drain reagents into the sewer, flush with plenty of water to prevent the formation of azides.
6. All human-derived materials used in the preparation of this product have been tested. Syphilis, HIV1 & 2 antibodies, HCV antibodies and HBsAg are negative (using approved experimental methods). Since there is currently no definitive test method to ensure that samples tested negative will be free of HBV, HCV, HIV and other infectious viruses, all human-derived substances, particularly 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.

【References】
1. Gitlin D, Perricelli A, Gitlin G. Synthesis of α-fetoprotein by liver, yolk sac and gastrointestinal tract of the human conceptus. Cancer Res 1972; 32:979–82.
2. James T, Linda ,Karen. Serum Alpha Fetoprotein (AFP) Levels in Normal Infants . Pediatr Res 1981; 15: 50-52.
3. Gerald J,Thomas P. Carter, Diane W,Ronald. Measurement of Serum Alpha-Fetoprotein in Early Infancy: Utilization of Dried Blood Specimens .Pediatr Res 1983; 17: 47-50.
4. Ding-Shinn Chen,Juei-Low Sung. Serum Alphafetoprptein in Hepatocellular Carcinoma.Cancer 1977;40:779-783.
5. D. Badera, A. Riskin, O. Vafsi, A. Tamir, B. Peskin, N. Israel, R. Merksamer, H. Dar, M. David. Alpha-fetoprotein in the early neonatal period—a large study and review of the literature. Clinica Chimica Acta 2004;349:15–23.
6. Clinical and Laboratory Standards Institute (formerly NCCLS). Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI EP7-A2.

【Instruction Approved & Modified Date】 09/2020

Symbol Explanation

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

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