DIRUI 迪瑞

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_肿瘤试剂_癌抗原125测定试剂盒 CA125_说明书		
库存编码	1041556	版本号	20200928
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			

Cancer Antigen 125 Detection Kit
(Chemiluminescence Immunoassay) Instructions

【Product Name】

Cancer Antigen 125 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 cancer antigen 125 (CA 125) content in human serum in vitro.
CA125 is a glycoprotein with a relative molecular mass of 200KD, originating from fetal epithelial tissue. CA125 exists as a group in the sample and is commonly distributed in the mesothelium of the pleura, pericardium, peritoneum, endometrium, genital tract and amniotic membrane cell surface. When these parts become malignant or are stimulated by inflammation, the level of CA125 in the sample will be significantly increased.
Ovarian cancer cells can raise the level of human monoclonal antibody CA125, and its characteristic antigen glycoprotein is named as cancer antigen 125. CA125 is a commonly used indicator for screening ovarian cancer, but not a diagnostic marker for ovarian cancer. Simple serosal cavitation is sufficient to elevate CA125, and may be used as a surveillance indicator only when women are diagnosed with ovarian cancer. Therefore, the elevation of CA125 level should take into account various etiologies. For patients with ovarian cancer, it should also be noted that the elevation of CA125 should take into account a variety of other factors.

【Test Principle】

This reagent 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 streptavidin magnetic particles, R2 is the antibody labeled with acridinium ester and R3 is the antibody labeled with biotin; the CA125 antibody labeled with acridinium ester and biotin, and streptavidin magnetic particles react immunologically with the CA 125 in the samples to form the antigen-antibody complex. The content of CA125 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 and incubate at 37℃;
◆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	Streptavidin magnetic particles	0.01%
R2	CA125 antibodies labeled with acridinium ester	0.25μg/mL
R3	CA125 antibodies labeled with biotin	0.5μg/mL
Calibrator (high, low)	serum matrix supplemented with	/
control (negative)	serum matrix supplemented with	/

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: calibrator can be traced to the company's internal reference measurement procedure.

【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 preparing
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 CA 125 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 on test results

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

【Positive Judgment Value】

＜35U/mL

The lab should study the above reference range and is suggested to set its own reference rangedue 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. There is no direct comparability between the sample's CA 125 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 CA125 concentration is up to 70000U/mL.
5. The CA125 measurement is different in test method, site identification, specificity and interfering factors. Thus, CA125 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. 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.
2. Accuracy of test results depends on the calibration of the instrument, temperature measurement and time control.

【Product Performance Indices】

1. Minimum detection limit: ＜2U/mL.
2. Linearity: linear range is 2～1000U/mL; linear correlation coefficient r≥0.9900.
3. Accuracy: recovery rate should be within 85%～115%.
4. Repeatability: CV≤8.0%.
5. Between-batch difference: CV≤15.0%.
6. Anti-interference, specificity: in the sample, when bilirubin≤20mg/dL, triglyceride≤900mg/dL, hemoglobin≤1000mg/dL, 5-fluorouracil≤1μg/mL, cisplatin≤175μg/mL, cyclophosphamide≤800μg/mL, diethylstilbestrol≤25μg/mL, doxorubicin≤50μg/mL, Fluamide≤10μg/mL, Megestrol Acetate≤10μg/mL and mitomycin≤75μg/mL, there is no effect on test results.

【Matters Needing Attention】

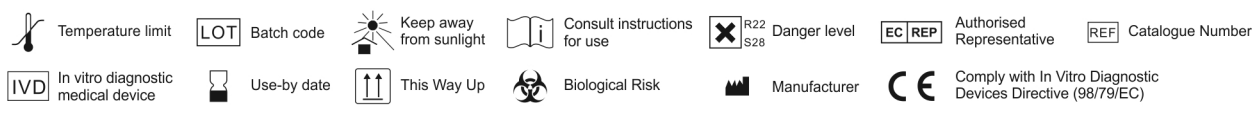
1. The product is only used for in vitro diagnosis.
2. Please treat samples as dangerous substance that may be infected with HIV, HBV, HCV, etc. To avoid or reduce the risk of infection, disposable gloves and eyes/face protective items should be worn.
3. If the reagent enters eyes or the mouth, or touches 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. Lavin PT, Knapp RC, Malkasian G, et al. CA 125 for the monitoring of ovarian carcinoma during primary therapy. Obstet Gynecol 1987; 69(2): 223–7.
2. O'Brien TJ, Hardin JW, Bannon GA, et al. CA 125 antigen in human amniotic fluid and fetal membranes. Am J Obstet Gynecol 1986; 155(1): 50–5.
3. Klug TL, Bast RC Jr, Niloff JM, Knapp RC, Zurawski VR Jr. Monoclonal antibody immunoradiometric assay for an antigenic determinant (CA 125) associated with human epithelial ovarian carcinomas. Cancer Res 1984; 44: 1048-1053.
4. Pittaway DE, Fayez JA, Douglas JW. Serum CA-125 in the Evaluation of Benign Adnexal Cysts. Am J Obstet Gynecol 1987; 157: 1426-8.
5. Pittaway DE, Fayez JA. Serum CA-125 Antigen Levels Increase During Menses. Am J Obstet Gynecol 1987; 156: 75-6.
6. Yang JJ, Sa M, Huang M, et al. The reference intervals for HE4, CA125 and ROMA in healthy female with electrochemiluminescence immunoassay. Clinical Biochemistry. 2013;46:1705-1708.
7. 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



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