PDM签审页

PDM版本：

PDM编码：

产品名称	出口_肿瘤试剂_癌胚抗原测定试剂盒 CEA（三试剂）说明书		
库存编码	1060026	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			

Carcinoembryonic Antigen Detection Kit
(Chemiluminescence Immunoassay) Instructions

【Product Name】
Carcinoembryonic Antigen Detection Kit (Chemiluminescence Immunoassay)

【Packaging Specification】
1×50 Tests/Kit; 1×50 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 the carcinoembryonic antigen (CEA) in human serum or plasma in vitro. It is mainly used for dynamic monitoring of patients with malignant tumors to assist in judging the disease process or treatment effect. It can not be used as the basis for early diagnosis of malignant tumors, and it is not used for tumor screening of general population.
Carcinoembryonic antigen is originally found in adult colon cancer tissue, first reported by Gold in 1965. CEA is a complex structure of soluble glycoprotein with a molecular weight of about 200kD. It is mainly found in the gastrointestinal tract, pancreas and liver of the fetus in the embryonic stage, and the content of the tissue after birth is very low. Increased CEA is seen in gastrointestinal malignancies and is also elevated in samples from patients with breast, lung, and other malignancies. Therefore, CEA is a kind of broad-spectrum tumor marker. Although it cannot be used as a specific marker in the diagnosis of a malignant tumor, CEA still has important clinical value in the differential diagnosis of malignant tumor, condition monitoring and curative evaluation.

【Test Principle】
The carcioembryonic antigen 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 streptavidin magnetic particles, R2 is the CEA antibody labeled with acridinium ester and R3 is the CEA antibody labeled with biotin; the CEA antibody labeled with acridinium ester and the CEA antibody labeled with biotin react immunologically with CEA in the samples to form the antigen-antibody complex and bind to magnetic particles by reaction between biotin and streptavidin. The content of CEA 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	⩾0.03%
R2	CEA antibodies labeled with acridinium ester	⩾0.1μg/mL
R3	CEA antibodies labeled with biotin	⩾0.5μg/mL
Calibrator (high, low)	protein components supplemented with CEA	/
control (level 1, level 2)	protein components supplemented with CEA	/

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 values 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, 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 reference material (national standard material: NIBSC 73/601).

【Storage Conditions & Shelf Life】
1. The reagent kit should be stored at 2℃-8℃, away from sunlight, kept airtight and upright. Avoid freezing the reagents. 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 stored at 2℃-8℃. The calibrator and control can be stable for 28 days after opened if sealed and stored at 2℃-8℃.
3. Date of manufacture and 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℃ for 48 hours; if the test is not finished within 48 hours, freeze the sample at -20℃ or lower.
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 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.
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 CEA 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) 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.

【Reference Range】

≤5.0ng/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 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 0.2ng/mL-1000ng/mL. Values below the minimum detection limit are reported that < 0.2ng/mL and values exceed the detection limit are reported that > 1000ng/mL.
3. The CEA measurement is different in test method, site identification, specificity and interfering factors, thus, CEA 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.
3. Bilirubin, triglyceride and hemoglobin with high concentration in a sample may have an impact on the test results.
4. High-dose biotin treatment may affect test results.

【Product Performance Indices】

1. Minimum detection limit: should be no more than 0.2ng/mL.
2. Linearity: linear range is 0.4ng/mL-1000ng/mL; linear correlation coefficient r≥0.9900.
3. Accuracy: test with the reference material, the relative deviation of the measurement results should be within ±10%.
4. Repeatability: CV≤8.0%.
5. Between-batch difference: CV≤15.0%.
6. Methodological comparison:

The results of linear regression analysis of Dirui Carcioembryonic Antigen Detection Kit (Chemiluminescence Immunoassay) in clinical samples measured by Dirui chemiluminescence immunoassay analyzer and a commercial integrated system are as follows:

Concentration of Sample (ng/mL)	Slope	Intercept	r^2	Number of Samples
0.8-1000	1.003	-1.086	0.993	210

7. Specificity: AFP≤1000ng/mL, CA125≤1000U/mL, CA15-3≤100U/mL, CA19-9≤1000U/mL, ANA and HAMA antibody positive samples have no significant effect on the test results.
8. Anti-interference: in the sample, hemoglobin≥500mg/dL, triglyceride≥1000 mg/dL, bilirubin≥20mg/dL, RF≥500IU/mL, biotin ≥20ng/mL, cisplatin≥1.50μg/mL, tamoxifen≥133μg/mL, cyclophosphamide≥3300μg/mL, adriamycin≥100μg/mL, mitomycin C≥60μg/mL, methotrexate≥4500μg/mL, bleomycin≥1300μg/mL, human albumin ≥1.8g/dL and 5-fluorouracil≥360μg/mL may have an impact on the tests results.
9. Hook effect: when the concentration of the CEA antigen reaches 100000ng/mL, there is no hook effect.

【Matters Needing Attention】

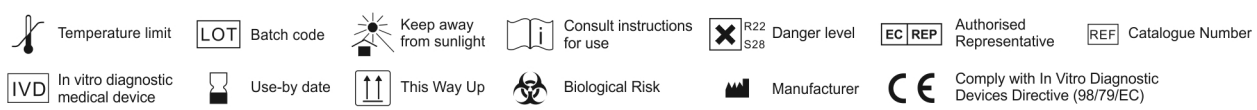
1. This product is only for in vitro diagnosis.
2. Considering the possible evaporation effect, samples, calibrators and controls on board should be analyzed/measured within 2 hours.
3. Please treat samples as dangerous substance that may be infected with HIV, HBV, HCV, etc. To avoid or reduce the risk of infection, disposable gloves and eyes/face protective items should be worn.
4. If the reagent enters eyes or the mouth, 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 the National Health Commission, the Ministry of Science and Technology, and National Medical Product Administration and other relevant departments.
7. Avoid freezing and thawing the calibrators and controls.
8. Samples can only be frozen once. Mix well after thawing.

【References】

1. Chen Jianhua, Ouyang Yulin, Zhu Wenbiao, etc. Detection of Carcinoembryonic Antigen as a Tumor Marker in the Diagnosis and Treatment of non-small Cell Lung Cancer[J]. Modern oncology, 2005, 13(2):199-200.
2. Kuroki M, Haruno M, Arakawa F, et al. Reaction profiles of seven enzyme immunoassay kits for carcinoembryonic antigen (CEA) analyzed with purified preparations of CEA and related normal antigens[J]. Clinical Biochemistry, 1992, 25(1):29-35.
3. Zhu hui, Song Yong, Xie Jiamei. Significance of Combined Detection of Serum CA125, CA19-9 and CEA in Ovarian Diagnosis[J], Huaihai Medicine,2014, 32(4):379-370.
4. Yang X, Guo Y, Wang A. Luminol/antibody labeled gold nanoparticles for chemiluminescence immunoassay of carcinoembryonic antigen[J]. Analytica Chimica Acta, 2010, 666(1):91-96.
5. EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition [S]. 2014.

【Instruction Approved & Modified Date】 09/2020

Symbol Explanation



DIRUI®

DIRUI INDUSTRIAL CO.,LTD.
95 Yunhe Street, New &High Tech.
Development Zone Changchun, Jilin 130012 P.R.China

Tel: +86 431 85100409
Fax: +86 431 85172581
E-mail: dirui@dirui.com.cn
http: //www.dirui.com.cn

CE IVD
EC REP
EMERGO EUROPE Prinsessegracht 20
2514 AP The Hague The Netherlands