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15-3测定试剂盒 CA15-3_说明书		
库存编码	1041555	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			

Cancer Antigen 15-3 Detection Kit
(Chemiluminescence Immunoassay) Instructions

【Product Name】
Cancer Antigen 15-3 Detection Kit (Chemiluminescence Immunoassay)

【Packaging Specification】
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 15-3 (CA15-3) in human serum in vitro.
CA15-3 is a high concentration of polypeptide protein, a gene product of MUC-1, and the related antigen of metastatic breast cancer. The detection of CA15-3 is not only suitable for monitoring the disease and the course of treatment in patients with metastatic breast cancer, but also for monitoring the recurrence of diseases in patients with previously-treated lymph nodes with stage 2 or stage 3 breast cancer who have more than two positive lymph nodes. With CA15-3, the direct relationship between treatment response and predictive disease status can be monitored and disease progression and treatment response monitored by continuous assays. Among known and metastatic patients, a decrease in CA15-3 indicates that the treatment is effective. On the contrary, horizontal height indicates that the treatment has no effect and the disease is progressing, which requires further monitoring.

【Test Principle】
This reagent is detected by the double antibody sandwich method based on chemiluminescence immunoassay.
CA15-3 antigen in the sample combines with the CA 15-3 antibody labeled with biotin and the streptavidin magnetic particles. Incubate and wash away superfluous immune complex. Add the CA 15-3 antibody labeled with acridinium ester, incubate and rewash. The content of CA15-3 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 chemiluminiscence reaction.

【Main Components】

Composition	Main Components	Content
R1	streptavidin magnetic particles	0.01%
R2	CA15-3 antibodies labeled with acridinium ester	0.25μg/mL
R3	CA15-3 antibodies labeled with biotin	1μg/mL
Calibrator (high, low)	serum matrix supplemented with CA15-3 antigen	/
control (negative)	serum matrix supplemented with CA15-3 antigen	/

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 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 after being used for the first time 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, frozen 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 reagent bottle bottom to guarantee magnetic particles 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 15-3 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 U/mL.

【Positive Judgment Value】
＜32.4U/mL
The lab should study the above reference range and is suggested to set its own reference range due to geography, diet and environment factors, etc.

【Interpretation of Test Results】
1. Test results are not the only one as diagnosis index of clinical applications. Clinical significance is analyzed specifically combined with other test indices and clinical manifestation.
2. There is no direct comparability between the sample's CA15-3 concentration tested by other ways and test results of the product.
3. The CA15-3 measurement is different in test method, site identification, specificity and interfering factors. Thus, CA 15-3 test results are different for 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: ＜1.0U/mL.
2. Linearity: linear range is 1U/mL～200U/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: in the sample, when homoglobin≤1000mg/dL, triglyceride≤900mg/dL, bilirubin≤25mg/dL and total protein≤6.5g/dL, there is no effect on test results.

【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 the National Health Commission, Ministry of Science and Technology, and National Medical Product Administration and other relevant departments.
7. Avoid freezing the reagents.

【References】
1. Gao JJ, Zhang QY, Xu JJ, et al. Clinical significance of serum miR-21 in breast cancer compared with CA153 and CEA. Chin J Cancer Res 2013;25(6):743-748.
2. Álvaro R, Pablo A, María CDR, et al. CA15.3 Serum Concentrations in Older Women with Infiltrating Ductal Carcinomas of the Breast. Int. J. Mol. Sci. 2014, 15, 19870-19876.
3. Elisabetta M, Antonio DG, Francesco F, et al. CA 15-3 cell lines and tissue expression in canine mammary cancer and the correlation between serum levels and tumour histological grade. Manuali et al. BMC Veterinary Research 2012, 8:86.
4. Mariarosaria I, Peppino M, Onofrio C, et al. CA15-3 is a useful serum tumor marker for diagnostic integration of hybrid positron emission tomography with integrated computed tomography during follow-up of breast cancer patients. Incoronato et al. BMC Cancer 2014, 14:356.
5. Wang GP, Qin Y, Zhang JX, et al. Nipple Discharge of CA15-3, CA125, CEA and TSGF as a New Biomarker Panel for Breast Cancer. Int. J. Mol. Sci. 2014, 15, 9546-9565.

【Instruction Approved & Modified Date】09/2020

Symbol Explanation

Temperature limit	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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