DIRUI 迪瑞

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_肿瘤试剂_游离前列腺特异性抗原测定试剂盒 f-PSA_说明书		
库存编码	1041560	版本号	20200723
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			

Free Prostate Specific Antigen Detection Kit
(Chemiluminescence Immunoassay) Instructions

【Product Name】

Free Prostate Specific Antigen 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 free prostate specific antigen (f-PSA) in human serum in vitro.

PSA has some errors in differentiating benign and malignant prostatic diseases. Studies have shown that f-PSA/t-PSA ratio is more accurate than total PSA in the diagnosis of prostate cancer. The reagent kit can determine whether men over 50 years of age have prostate cancer by measuring the concentration of free prostate specific antigen in human serum and assisting rectal digital examination (DRE). The kit can be further used to monitor the condition of prostate cancer patients.

【Test Principle】

The f-PSA detection kit is detected by the double antibody sandwich method based on chemiluminescence immunoassay.

The regent consists of two parts: R1 and R2. R1 is the magnetic particles coated with antibody and R2 is the antibody labeled with acridinium ester; The PSA antibody labeled with acridinium ester and the magnetic particles coated with f-PSA antibody react immunologically with f-PSA in the samples to form antigen-antibody complex. The content of f-PSA 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	magnetic particles coated with f-PSA antibodies	0.01%
R2	f-PSA antibodies labeled with acridinium ester	0.1μg/mL
calibrator (high, low)	serum matrix supplemented with f-PSA	/
control (level 1, level 2)	serum matrix supplemented with f-PSA	/

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 can be traced to the national standard material.

【Storage Condition & 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 test.
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 and R2 are 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 f-PSA 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

【Positive Judgment Value】

＜0.93ng/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 f-PSA 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 f-PSA concentration is up to 15000ng/mL.
5. The f-PSA measurement is different in test method, site identification, specificity and interfering factors. Thus, f-PSA 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. Minimum detection limit: ＜0.01ng/mL.
2. Linearity: linear range is 0.01ng/mL～50ng/mL; linear correlation coefficient r≥0.9900.
3. Accuracy: the ratio of the measured value to the theoretical value should be between 0.85~1.15 when the national (or international) calibrators are tested within the measurement range prescribed by the detection kit.
4. Repeatability: CV≤8.0%。
5. Between-batch difference: CV≤15.0%.
6. Anti-interference, specificity: in the sample, when hemoglobin ≤ 1000 mg/dL, triglyceride≤1500mg/dL, and bilirubin≤40mg/dL, 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】

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2. M.Mack,B.Ivankovic,R.Schlett.Liaison® free PSA, development of an automated chemiluminescence immunoassay for the determination of free prostate specific antigen (f- PSA). Angiogenesis and tumour markers 1997;9: 49.
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4. Zhao LX, Sun L, Chu XG. Chemiluminescence immunoassay. Trends in Analytical Chemistry. 2009;28:404-415.
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【Instruction Approved & Modified Date】07/2020

Symbol Explanation

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