DIRUI 迪瑞

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_性激素试剂_孕酮测定试剂盒（三试剂）P_说明书		
库存编码	1041540	版本号	20200330
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			

Progesterone Detection Kit (Chemiluminescence Immunoassay) Instructions

【Product Name】

Progesterone Detection Kit (Chemiluminescence Immunoassay)

【Package Specification】

Package Specification	Reagent Kit Composition
1×50 Tests/kit	1×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
1×50 Tests/kit (without Calibrator and Control)	1×Reagent
2×50 Tests/kit	2×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
2×50 Tests/kit (without Calibrator and Control)	2×Reagent
1×100 Tests/kit	1×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
1×100 Tests/kit (without Calibrator and Control)	1×Reagent
2×100 Tests/kit	2×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
2×100 Tests/kit (without Calibrator and Control)	2×Reagent
4×100 Tests/kit	4×Reagent, 2×Calibrator (High), 2×Calibrator (Low), 2×Control (Level 1), 2×Control (Level 2)
4×100 Tests/kit (without Calibrator and Control)	4×Reagent
1×200 Tests/kit	1×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
1×200 Tests/kit (without Calibrator and Control)	1×Reagent
2×200 Tests/kit	2×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
2×200 Tests/kit (without Calibrator and Control)	2×Reagent

【Intended Use】

For quantitative determination of progesterone in human serum or plasma in vitro.

Progesterone (P) is a steroid hormone, mainly produced by the ovarian corpus luteum, and a small part of it can be synthesized by the adrenal cortex. The main function of progesterone is to prepare the uterus for the implantation of fertilized eggs and to maintain pregnancy. Clinical studies have shown that progesterone plays a role in promoting ovulation and maintaining the normal function of corpus luteum in non-pregnant women. If progesterone produced by corpus luteum is insufficient, it may indicate that corpus luteum function is insufficient, and corpus luteum function insufficiency is related to infertility and early abortion. Progesterone is mainly used for auxiliary diagnosis of threatened abortion clinically.

【Test Principle】

The progesterone detection kit is detected by the competitive method based on chemiluminescence immunoassay. The reagent consists of three parts: R1, R2 and R3. R1 is the streptavidin magnetic particles, R2 is the progesterone antibody labeled with acridinium ester and R3 is the progesterone labeled with biotin; the progesterone labeled with biotin and the progesterone in the samples compete with the progesterone antibody labeled with acridinium ester, and immune complexes bind to magnetic particles by reaction between biotin and streptavidin. The content of progesterone in the samples is inversely proportional to the relative light units (RLUs) detected by the system.

The system automatically performs the following steps:

1. Place the sample and reagent into the cuvette and incubate at 37℃;
2. Separate the magnetic particles and then wash them with washing buffer;
3. Add Acid Trigger Reagent and Alkaline Trigger Reagent to stimulate the chemiluminiscence reaction.

【Main Components】

Composition		Main Components	Content
reagent	R1	streptavidin magnetic particle	≥0.03%
	R2	progesterone antibodies labeled with acridinium ester	≥0.05μg/mL
	R3	Progesterone labeled with biotin	≥0.01μg/mL
calibrator (high, low)		protein components supplemented with progesterone	See the label
control (level 1, level 2)		protein components supplemented with progesterone	See the label

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 the calibration and control information registration card.

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 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. 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℃.

【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 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 24 hours; if the test is not finished within 24 hours, freeze the sample at -20℃ or lower.
5. Before putting the sample in 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 separated 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 separated or re-suspended. For detailed operation steps refer to the instrument user manual.

3. Calibration

When using new batches of reagents, recalibrate the P 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 prescribed 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 new a control to re-test.
♦ Use new a 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: ng/mL×3.18=nmol/L
nmol/L×0.314=ng/mL

【Reference Range】

Male		< 1.4ng/mL
Female	Follicular phase	< 1.5ng/mL
	Period of ovulation	0.3ng/mL ~ 12.0ng/mL
	Luteal phase	1.7ng/mL ~ 27ng/mL
	Post-menopause	< 0.8ng/mL
	1st trimester of pregnancy	11ng/mL ~ 44.3ng/mL
	2nd trimester of pregnancy	25.4ng/mL ~ 83.3ng/mL
	3rd trimester of pregnancy	58.7ng/mL ~ 214ng/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 0.1ng/mL~60ng/mL. Values below the detection limit are reported that < 0.1ng/mL and values exceed the detection limit are reported that>60ng/mL.
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. The progesterone's measurement is different in test methods, site identification, specificity and interfering factors. Thus, progesterone 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.
2. Hemoglobin>500mg/dL, triglyceride>250mg/dL and bilirubin>20mg/dLin a sample may have an impact on the test results.
3. 11-deoxycorticosterone>1000ng/mL, pregnenolone>1000ng/mL, cortisol >1000ng/mL, corticosterone>1000ng/mL, testosterone >1000ng/mL, aldosterone >1000ng/mL, 17a-hydroxyprogesterone>1000ng/mL, 11-deoxycortisol>1000ng/mL, 17β-estradiol >1000ng/mL, estrone>100ng/mL, estriol>100ng/mL, danazol>10000ng/mL, prednisolone >1000ng/mL and clomiphene >1000ng/mL in a sample may have an impact on the test results.
4. Samples containing rheumatoid factors (RF) may result in false positive or false negative results.
5. High-dose biotin treatment may affect test results.

【Product Performance Indices】
1. Accuracy: the relative deviation should be within ±15% of the nominal value.
2. Limit of detection: < 0.2ng/mL.
3. Linearity: linear range is 0.2ng/mL~60ng/mL; linear correlation coefficient r≥0.9900.
4. Repeatability: CV≤8.0%.
5. Between-batch difference: CV≤15.0%.

【Matters Needing Attention】
1. This product is only used 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 substances 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 by mistake, 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 the reagents.
8. Samples can only be frozen once. Mix well after thawing.

【References】
1. MojdehSalehnia, SaeedZavareh S. The Effects of Progesterone on Oocyte Maturation and Embryo Development[J]. International Journal of Fertility & Sterility, 2013, 7(2):74-81.
2. David M Haas, Patrick S Ramsey.Progestogen for preventing miscarriage[J]. Cochrane database of systematic reviews (Online), 2008, 10(2):CD003511.
3. LijunDuan, Denglu Yan, WeiyueZeng, et al. Predictive power progesterone combined with beta human chorionic gonadotropin measurements in the outcome of threatened miscarriage[J]. Archives of Gynecology & Obstetrics, 2011, 283(3):431-435.
4. VanessaM.Givens,Gary H.Lipscomb.Diagnosis of Ectopic Pregnancy[J]. Clinical Obstetrics and Gynecology, 2012, 55(2):387-394.
5. EP7-A2,Interference Testing in Clinical Chemistry;Approved Guideline-Second Edition[S].2005.Vol.25, No.27.

【Instruction Approved & Modified Date】03/2020

Symbol Explanation

Temperature limit | LOT 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)

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