PDM签审页

PDM版本：

PDM编码：

产品名称	出口_性激素试剂_17α-羟孕酮测定试剂盒 17α-OHP_说明书			
库存编码	1056139	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				

17α-Hydroxyprogesterone Detection Kit
(Chemiluminescence Immunoassay) Instructions

【Product Name】
17α-Hydroxyprogesterone 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 17α-hydroxyprogesterone in human serum or plasma in vitro.
17α-hydroxyprogesterone (17α-OHP) is a C-21 endogenous progesterone produced in the process of synthesizing glucocorticoids and sex steroids. It is mainly produced in the adrenal cortex, part of it is produced in the gonad, and the newborn mainly comes from the adrenal cortex. 17α-OHP in serum mainly works with sex hormones to promote the development of individual organs. The level of 17α-OHP was lower in follicular period or menopause, and higher in luteal period and pregnancy. 17α-OHP can be used to assess progesterone levels during pregnancy, as well as to analyze common acne, male baldness and some unexplained infertility in men and women. Masculinity occurs in childhood or adolescence. In boys, pubic hair appears early, sexual precocity, growth acceleration and bone age advance; in girls, menarche delay, primary amenorrhea and hirsutism appear. In addition, the content of 17α - OHP in serum is one of the clinical diagnosis indexes of congenital adrenal hyperplasia (CAH). The concentration of 17α-OHP in serum of CAH patients caused by 21 hydroxylase deficiency is significantly increased. 17α-hydroxyprogesterone is mainly used in the auxiliary diagnosis of adrenocortical diseases.

【Test Principle】
The 17α-hydroxyprogesterone 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 17α-hydroxyprogesterone antibody labeled with acridinium ester and R3 is the 17α-hydroxyprogesterone analogue labeled with biotin; the 17α-hydroxyprogesterone analogue labeled with biotin competes with the 17α-hydroxyprogesteronein the samples to form the 17α-hydroxyprogesterone antibody labeled with acridinium ester, and binds to the magnetic particles by reaction between biotin and streptavidin. The content of 17α-hydroxyprogesterone 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 chemiluminescence reaction.

【Main Components】

Composition		Main Components	Content
reagent	R1	streptavidin magnetic particles	≥0.03%
	R2	17α-hydroxyprogesterone antibodies labeled with acridinum ester	≥0.025μg/mL
	R3	17α-hydroxyprogesterone analogues labeled with biotin	≥0.005μg/mL
calibrator (high, low)		protein components supplemented with 17α-hydroxyprogesterone	see the label
control (level 1, level 2)		protein components supplemented with 17α-hydroxyprogesterone	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 instrumentuser manual and instructions of the above reagents.
Note 4: calibrators are traced back to the reference 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 28days 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,the sample should be stored at -20℃ and can be stable for 60 days.
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 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 17α-OHP 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 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】

Normal Male		0.31ng/mL ~ 2.01ng/mL
Normal Female	Follicular Phase	0.05ng/mL～1.02ng/mL
	Luteal Phase	0.3ng/mL～2.34ng/mL
	Oviposit Period	0.1ng/mL～1.4ng/mL
	Menopause	＜0.93 ng/mL
	Late pregnancy	2.28 ng/mL～-9.24 ng/mL
1-13 years old children		＜2.32ng/mL
1 month-1 year old infant		0.82 ng/mL～16.63 ng/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 0.05ng/mL ~ 30ng/mL. Values below the minimum detection limit are reported that < 0.05ng/mL and values exceed the detection limit are reported that > 30ng/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 17α-hydroxyprogesterone's measurement is different in test methods, site identification, specificity and interfering factors. Thus, 17α-hydroxyprogesterone 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 > 100mg/dL, triglyceride > 6000mg/dL and bilirubin > 25mg/dL in a sample may have an impact on the test results.

3. Samples containing high concentrations of rheumatoid factors (RF) may result in false positive or false negative results.

4. High-dose biotin treatment may affect test results.

5. Serious hemolysis, lipemia and turbid samples used for tests may cause incorrect results.

【Product Performance Indices】

1. Accuracy: the relative deviation should be within ±15% of the nominal value.

2. Minimum detection limit: should be no more than 0.05ng/mL.

3. Linearity: linear range is 0.1ng/mL~30ng/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 National Health Commission, 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. Víctor R. De Jesús, Simms D A , Schiffer J , et al. Pilot proficiency testing study for second tier congenital adrenal hyperplasia newborn screening[J]. ClinicaChimicaActa, 2010, 411(21-22):1684-1687.

2. John W Honour. 17-Hydroxyprogesterone in children, adolescents and adults[J].The Association for ClinicalBiochemistry & Laboratory Medicine, 2014,51(4):424-440.

3. EP05-A3,Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition[S].2014.

4. CRISTINA, BOTELHO,IVANI NOVATO SILVA,et al. Neonatal screening for congenital adrenal hyperplasia[J].RevAssoc Med Bras 2012, 58(4):459-464.

5. Monique J.M. de Groot, Karijn J. Pijnenburg-Kleizen, Chris M.G. Thomas,et al. Salivary morning androstenedione and 17α-OH progesterone levels in childhood and puberty in patients with classic congenital adrenal hyperplasia[J].ClinChem Lab Med, 2015, 53(3):461-468.

【Instruction Approved & Modified Date】 03/2020

Symbol Explanation

	Temperature limit	LOT Batch code	Keep away from sunlight	i 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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IVD
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