PDM签审页

PDM版本：

PDM编码：

产品名称	出口_性激素试剂_黄体生成素测定试剂盒 LH_说明书_英文		
库存编码	1041537	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			

Luteinizing Hormone Detection Kit (Chemiluminescence Immunoassay)

【Product Name】

Luteinizing Hormone 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 luteinizing hormone (LH) in human serum or plasma in vitro.

Luteinizing hormone is a glycoprotein-like gonadotropin secreted by the basophilic cells in the anterior pituitary gland. It contains 219 amino acids and has a molecular weight of about 30,000Da. It consists of a non-specific alpha subunit and a specific beta subunit. LH secretion by the hypothalamus secretion of gonadotropin releasing hormone under strict control, with the menstrual cycle of women and cyclical changes by stimulating ovarian synthesis of steroids and promote ovulation and luteal generation, and promote luteal secretion of estrogen and progesterone; Men promote testicular
stromal cell proliferation, secretion of androgen. Physiological studies on the detection of ovulation, climacteric syndrome, polycystic ovary syndrome, primary infertility, menstrual disorders, endometriosis, hypogonadism and other reproductive systems by detecting LH content, disease diagnosis and treatment, follow-up It is of great significance.

【Test Principle】

The luteinizing hormone detection kit is tested by the double antibody sandwich method based on chemiluminescence immunoassay. The reagent consisits three parts: R1, R2 and R3, R1 is magnetic particle coated with luteinizing hormone antibody, R2 is acridinium ester labeled luteinizing hormone antibody, R3 is a PBS buffer, The acridinium ester labeled luteinizing hormone antibody, luteinizing hormone antibody-coated magnetic particles immunologically react with the luteinizing hormone in the sample to be tested to form an antigen-antibody complex. The content of luteinizing hormone in the sample is proportional to the relative light unit (RLU) detected by the system.

The system automatically performs the following steps:

♦ Put sample and reagent into the cuvette, incubate at 37℃;

♦ Separate the magnetic particles, and then add Washing Buffer to wash them;

♦ Add acid trigger reagent and alkaline trigger reagent to stimulate chemiluminiscence reaction.

【Main Components】

Composition		Main Components	Content
Reagent	R1	Luteinizing hormone antibody -coated magnetic particles	0.01%
	R2	Acridinium ester-labeled luteinizing hormone antibody	0.2μg/mL
	R3	PBS Buffer	20mmol/L
Calibrator (High, Low)		Bovine serum added luteinizing hormone	/
Control (Level 1, Level 2)		Bovine serum added luteinizing hormone	/

Note 1: The components in different batches of kits are not interchangeable.

Note 2: Calibrator and Control contents are different in different batches. For the Calibrator fixed value and Control target value refer to the bottle label.

Note 3: Essential unprovided materials: Acid Trigger Reagent, Alkaline Trigger Reagent, Washing Buffer/Concentrated Washing Buffer. Perform the test according to the instrument user manual or reagent instructions for use.

Note 4: Calibrator can be traced to the enterprise inner reference measurement procedure.

【Storage Conditions & Shelf Life】

1. The reagent kit shall be sealed, stored upright in a dry and dark place at 2℃～8℃, and for the shelf life refer to the label.
2. After being used for the first time, it can be stable for 28 days if stored on the instrument or at 2℃～8℃. The calibrator and control after being opened for the first time can be stable for 28 days 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. Specimens for tests are serum or plasma.
2. Adopt correct medical technology to collect samples.
3. Serious hemolysis, lipemia and turbid samples cannot be used for tests.
4. Samples can be stable for 48h at 2℃～8℃. If a test is not finished within 48h, freeze samples at -20℃ or lower temperature.
5. Samples can only be frozen once. Mix well after thawing.
6. Before putting a ample in the system, ensure that the sample is without fibrous protein or other particles, and bubbles.

【Test Method】

1. Reagent preparing

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 the bottom of the kit ensures that all magnetic particles have been dispersed and re-suspended to avoid bubbles.

Calibrators and Controls are of the freeze-drying type. Add 1.0mL of purified water to reconstitute Calibrators and Controls, let them stand still for 20 minutes and mix upside down to ensure that all dry powder materials are fully dissolved and used. Fresh reconstituted calibrators and controls can be packed and stored at -20℃ for reserve.

2. Test procedure

Before loading reagents on the system, mix all reagents. Visually inspect the reagent bottle bottom to guarantee magnetic particles are divided or resuspended. For detailed operation steps refer to the instrument user manual.

3. Calibration

When using new batches of reagents, the luteinizing hormone determination item needs to be re-calibrated and the calibration information registration card scanned (support manual input registration). By measuring high and low Calibrators, each calibration

point on the pre-input main calibration curve is adjusted to a new calibration curve.
Re-calibrate when the following situations happen:
- Use the reagent kit of a new batch number.
- Replace with new batch trigger reagent.
- Control repeat results are not within the regulated range.

4. QC
1) Test two levels of control on the day of testing samples.
2) Control must be tested when performing calibration. All calibrators and controls should be disposed of regarding as samples.
3) Take the following measures when control results are not within the lab regulated acceptable range.
- Ensure the reagent used has not expired.
- Ensure required maintenance is executed.
- Ensure test procedures are performed strictly following the instructions.
- Use new control to re-test.
- Use new calibrator to re-calibrate.
- Ask local technicians or distributor for help if necessary.

5. Calculation on test results
The instrument can calculate each sample concentration automatically, the unit is mIU/mL.

【Reference Range】

Male	20 ~ 70 years old	1.5mIU/mL ~ 9.3mIU/mL
	> 70 years old	3.1mIU/mL ~ 34.6mIU/mL
Female	Follicular phase	1.9mIU/mL ~ 12.5mIU/mL
	Middle of cycle	8.7mIU/mL ~ 76.3mIU/mL
	Luteal phase	1mIU/mL ~ 16.9mIU/mL
	Pregnancy	< 1.5mIU/mL
	Postmenopause	15.9mIU/mL ~ 54.0mIU/mL
Children		< 6mIU/mL

The lab should study the above reference range. The lab is suggested to set its own reference range due to geographical, patient dietary habit and environmental factors.

【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. There is no direct comparability between sample's luteinizing hormone concentration test by other ways and product test results.
3. Test results outside the reagent kit linear range should be tested again after diluting samples to linear range.
4. When luteinizing hormone concentration up to 18000mIU/mL, there is no high dose hook effect.
5. Luteinizing hormone measurement is different in test method, site identification, specificity and interfering factors, thus, LH 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 between 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 and 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 > 3000mg/dL, bilirubin > 20mg/dL, in a sample may have an impact on the test results.
3. Rheumatoid factor (RF) in samples may lead to false positive or false negative results.

【Product Performance Indices】
1. Accuracy: The recovery rate is in the range of 85% ~ 115%.
2. Minimum detection limit: < 0.2mIU/mL.
3. Linearity: linear range is 0.2mIU/mL ~ 200mIU/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, the samples, calibrators and controls on board should be analyzed/measured within 2 hours.
3. Please treat the samples as dangerous substances that may be infected with HIV, HBV, HCV, etc. To avoid or reduce the risk of infection, disposable gloves and eye/face protective items should be worn.
4. If the reagent enters the eye or 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 and industrial wastes.
6. Clinical samples should be treated as infectious samples, and operate according to the relevant laboratory specifications and requirements promulgated by the Health and Planning Commission, the Ministry of Science and Technology, and National Medical Products Administration and other relevant departments.
7. Avoid freezing the reagents.

【References】

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【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)

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