DIRUI 迪瑞

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_性激素试剂_卵泡刺激素测定试剂盒（三试剂）FSH_说明书		
库存编码	1041538	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			

Follicle Stimulating Hormone Detection Kit (Chemiluminescence Immunoassay) Instructions

【Product Name】

Follicle Stimulating 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 follicle stimulating hormone in human serum or plasma in vitro.

Follicle stimulating hormone (FSH) is a glycoprotein gonadal hormone synthesized and secreted by the basophils of the anterior pituitary. In women, FSH promotes follicular development and maturation, which plays an important role in detecting the dysfunction of pituitary ovarian axis; in men, FSH mainly promotes sperm production and maturation. The detection of FSH level is of great significance to the understanding of pituitary endocrine function, the indirect understanding of the functional state of hypothalamus and ovary, the prediction of ovulation time, infertility, polycystic ovarian syndrome and the diagnosis and treatment of endocrine diseases. FSH is mainly used to evaluate the endocrine function of pituitary.

【Test Principle】

The follicle stimulating hormone detection kit is detected by the double sandwich method based on chemiluminescence immunoassay. The reagent consists of three parts: R1, R2 and R3. R1 is the streptavidin magnetic particles, R2 is the follicle stimulating hormone antibody labeled with acridinium ester and R3 is the follicle stimulating hormone antibody labeled withbiotin; the follicle stimulating hormone antibody labeled with acridinium ester and the follicle stimulating hormone antibody labeled with biotin react immunologically with the follicle stimulating hormone in the samples to form the antigen-antibody complex, and bind to magnetic particles by reaction between biotin and streptavidin. The content of follicle stimulating hormone in the samples is directly 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 particles	⩾0.03%
	R2	follicle stimulating hormone antibodies labeled with acridinium ester	⩾0.2μg/mL
	R3	follicle stimulating hormone antibodies labeled with biotin	⩾0.5μg/mL
calibrator (high, low)		protein components supplemented with follicle stimulating hormone	See the label
control (level 1, level 2)		protein components supplemented with follicle stimulating hormone	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 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 8 hours; if the test is not finished within 8 hours, freeze the sample at -20℃ or lower.
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 FSH 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 mIU/mL or IU/L.

【Reference Range】

Male	/	1.5mIU/mL~12.4mIU/mL
Female	Follicular phase	3.5mIU/mL~12.5mIU/mL
	Period of ovulation	4.7mIU/mL~21.5mIU/mL
	Luteal phase	1.7mIU/mL~7.7mIU/mL
	Post-menopause	25.8mIU/mL~134.8mIU/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 0.1mIU/mL~200mIU/mL. Values below the minimum detection limit are reported that<0.1mIU/mL and values exceed the detection limit are reported that> 200mIU/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 follicle stimulating hormone's measurement is different in test methods, site identification, specificity and interfering factors. Thus, follicle stimulating hormone 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 > 150mg/dL, triglyceride > 1000mg/dL and bilirubin > 20mg/dL in a sample may have an impact on the test results.
3. Samples containing rheumatoid factors (RF) may result in false positive or false negative results.
4. For thyrotropin samples with a concentration of not less than 200mIU/L, and the measurement result should be less than 2.0 IU/L.
5. For human chorionic gonadotropin samples with a concentration of not less than 1000IU/L, and the measurement result should be less than 2.0IU/L.
6. For luteinizing hormone samples with a concentration of not less than 200 IU/L, and the test result should be less than 2.0 IU/L.
7. 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. Minimum detection limit: should be no more than 0.1mIU/mL (equivalent to IU/L).
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, 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. Qing R. Fan, Wayne A. Hendrickson. Structure of human follicle-stimulating hormone in complex with its receptor[J]. Nature, 2005, 433:269-277.
2. William H Walker, Jing Cheng. FSH and testosterone signaling in Sertoli cells[J]. Reproduction, 2005, 130(1):15-28.
3. G.Jurjen E. Oosterhuis , IstvanVermes , Henri W. B. Michgelsen, et al. Follicle stimulating hormone measured in unextracted urine throughout the menstrual cycle correlates with age and ovarian reserve[J]. Human Reproduction, 2002, 17(3):641-646.
4. RetoStricker, Raphael Eberhart,Marie ChristineChevailler, et al. Establishment of detailed reference values for luteinizing hormone, follicle stimulating hormone, estradiol, and progesterone during different phases of the menstrual cycle on the Abbott ARCHITECT analyzer[J]. Clinical Chemical Laboratory Medicine, 2006, 44(7):883-887.
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