DIRUI 迪瑞

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_性激素试剂_游离β人绒毛膜促性腺激素 F-β-HCG_说明书		
库存编码	1061437	版本号	20201010
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 Beta-Human Chorionic Gonadotropin Detection Kit (Chemiluminescence Immunoassay)

【Product Name】

Free Beta-Human Chorionic Gonadotropin 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
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 free beta-human chorionic gonadotropin content in human serum or plasma.

Human chorionic gonadotropin (HCG) is a glycoprotein hormone secreted by placental syncytiotrophoblast during pregnancy. The relative molecular weight of HCG is 39.5kda, which consists of α and β subunits connected by noncovalent bonds. In vivo, free β subunit (F-β-HCG) accounts for about 0.3%-4% of HCG. At present, the free human chorionic gonadotropin β subunit (F-β-HCG) is widely used in the screening of trisomy 21 and trisomy 18. The median concentration of F-β-HCG in the serum of pregnant women with Down's syndrome (DS) is higher than that of normal pregnant women. 90% of Down's syndrome can be detected by F-β-HCG combined with PAPP-A screening, combined with the age of pregnant women and the thickness of fetal neck translucency (NT).

【Test Principle】

The free beta-human chorionic gonadotropin detection kit is detected by the double antibody 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 free β-HCG antibody labeled with acridinium ester and R3 is the free β-HCG antibody labeled with biotin; the free β-HCG antibody labeled with acridinium ester and the free β-HCG antibody labeled with biotin react immunologically with the free beta-human chorionic gonadotropin in the samples to form the antigen-antibody complex, which binds to magnetic particles through the reaction between biotin and streptavidin. The free beta-human chorionic gonadotropin content in samples in directly proportional to the relative light units (RLUs) detected by system.

The system automatically performs the following steps:

1. Place the sample and reagent into the cuvette and incubate at 37°C;
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	free β-HCG antibodies labeled with acridinium ester	⩾0.5μg/mL
	R3	free β-HCG antibodies labeled with biotin	⩾1μg/mL
calibrator (high, low)		protein components supplemented with free β-HCG	See the label
control (level 1, level 2)		protein components supplemented with free β-HCG	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 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 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, the sample should be stored at -20℃ and can be stable for 12 months.
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 the reagent's bottom ensures that all magnetic particles have been dispersed and re-suspended to avoid bubbles.

Calibrators and controls are ready-to-use reagents, which can be used directly. Mix calibrators and controls well and balance them to room temperature for use.

2. Test procedure

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

3. Calibration

When using new batches of reagents, recalibrate the F-β-HCG item and scan the calibration information registration card (manual input registration is supported). By measuring high and low 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 ng/mL.
Unit conversion: ng/mL×1=mIU/mL, mIU/mL=IU/L

【Reference Range】
1.Health and not pregnant < 0.4ng/mL.
2.Test 1560 serum samples of normal pregnant women, and the median value of F-β-HCG in serum samples of pregnant women in different gestational weeks is shown in the table below:

Pregnant Women	Median Value (ng/mL)	Pregnant Women	Median Value (ng/mL)
8	69.29	15	17.01
9	73.99	16	13.60
10	56.15	17	11.29
11	41.94	18	9.72
12	33.81	19	8.59
13	28.91	20	7.69
14	21.99		

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 0.2ng/mL-200ng/mL. Values below the minimum detection limit are reported that＜0.2ng/mL and values exceed the upper detection limit are reported that＞200ng/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 F-β-HCG's measurement is different in test methods, site identification, specificity and interfering factors. Thus, F-β-HCG 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 ＞1g/dL, triglyceride ＞1500mg/dL and bilirubin＞25mg/dL in the samples may affect test results.
3. Samples containing rheumatoid factors(RF) may result in false positive or false negative results.
4. High-dose biotin treatment may affect test results.
5. Test results should be less than 1.25ng/mL when testing the thyroid stimulating hormone sample with the concentration of no lower than 200μIU/mL.
6. Test results should be less than 1.25ng/mL when testing the follicle stimulating hormone with the concentration of no lower than 200mIU/mL.
7. Test results should be less than 1.25ng/mL when testing the luteinizing hormone sample with the concentration of no lower than 200mIU/mL.
8. Test results should be less than 2.50ng/mL when testing the human chorionic gonadotropin sample with the concentration of no lower than 1000mIU/mL.

【Product Performance Indices】
1. Accuracy: the relative deviation should be no more than ±10%.
2. Limit of blank: should be no more than 0.2ng/mL.
3. Linearity: linear range is 0.4ng/mL-200ng/mL; linear correlation coefficient r≥0.9900.
4. Repeatability: CV≤8.0%.
5. Between-batch difference: CV≤15.0%.
Note: for other performance indexes, refer to the technical requirements.

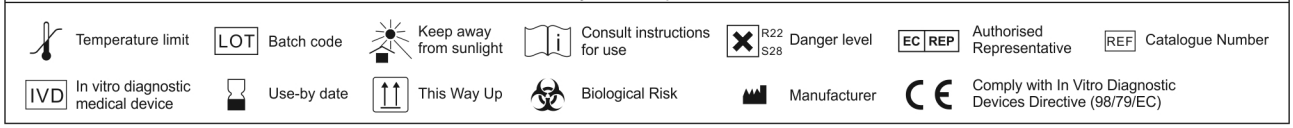
【Matters Needing Attention】
1. This product is only used for in vitro diagnosis.
2. Considering the possible evaporation effect, samples, calibrators and controls on board should be analyzed/measured within 2 hours.
3. Please treat samples as dangerous substances that may be infected with HIV, HBV, HCV, 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. Shiefa S, Amargandhi M, Bhupendra J, Moulali S, Kristine T. First Trimester Maternal Serum Screening Using Biochemical Markers PAPP-A and Free β-HCG for Down Syndrome, Patau Syndrome and Edward Syndrome[J].Indian J Clin Biochem, 2013 , 28(1):3-12.
2. Natasha T, Kevin S, Penelope N, Christin C, Kypros N. Screening for Trisomy 18 by Fetal Nuchal Translucency and Maternal Serum Free β-HCG and PAPP-A at 10–14 Weeks of Gestation[J]. Prenatal Diagnosis,1999, 19:1035-1042.
3. Ekelund C, Wright D et, al. Prospective Study Evaluating Performance of First-trimester Combined Screening for Trisomy 21 Using Repeat Sampling of Maternal Serum Markers PAPP-A and Free β-HCG[J].Ultrasound Obstet Gynecol, 2012 , 40(3):276-81.
4. Spencer K, Crossley J, Aitken D, et al. Temporal Changes in Maternal Serum Biochemical Markers of Trisomy 21 Across the First and Second Trimester of Pregnancy[J]. Annals of Clinical Biochemistry: An International Journal of Biochemistry and Laboratory Medicine, 2002, 39(6):567-576.
5. SImona C, Renu B, Georglos R et.al Integrated ultrasound and biochemical screening for trisomy 21 using fetal nuchal translucency, absent fetal nasal bone, free β-HCG and PAPP-A at 11 to 14 weeks[J]. Prenatal Diagnosis ,2003, 23:306-310.

【Instruction Approved & Modified Date】06/2020

Symbol Explanation



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