DIRUI 迪瑞

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_性激素试剂_泌乳素测定试剂盒 PRL_说明书_英文		
库存编码	1041539	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			

Prolactin Detection Kit (Chemiluminescence Immunoassay)

【Product Name】
Prolactin 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 prolactin (PRL) in human serum or plasma in vitro.
Prolactin is a protein hormone secreted by lactating cells located in the posterior pituitary gland, a single chain protein consisting of 199amino acid residues. Prolactin has to promote breast milk secretion of physiological activity. Under normal circumstances, large numbers of breast-feeding women secrete prolactin to promote breast milk secretion. Prolactin plays an important role in the human endocrine system, mainly affecting gonadal function. Low doses of prolactin on female ovarian estrogen and progesterone synthesis to promote the role of male, in the presence of testosterone, prolactin can promote prostate and seminal vesicle growth, but also enhance the effect of luteinizing hormone on stromal cells The role of testosterone synthesis increased; however, a large number of prolactin secretion is inhibited. Under normal circumstances, prolactin levels within a certain range to play its function, but if the abnormal secretion, it will cause a variety of diseases.

【Test Principle】
The prolactin detection kit is tested by the double antibody sandwich method based on Chemiluminescence immunoassay. The reagent consists of three parts: R1, R2 and R3. R1 is streptavidin magnetic particles, R2 is acridinum ester labelled prolactin antibodies, and R3 is biotin labelled prolactin antibodies. Acridinum ester labelled prolactin antibodies and biotin labelled prolactin antibodies react with prolactin in the sample, forming antigen-antibody complexes and binding to magnetic particles through the reaction between biotin and streptavidin. The content of follicle stimulating 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, and incubate at 37℃;
♦ Separate the magnetic particles, and then add Washing Buffer to wash them;
♦ Chemiluminescence reaction is stimulated by adding Acid Trigger Reagent and Alkaline Trigger Reagent.

【Main Components】

Composition		Main Components	Content
Reagent	R1	Streptavidin magnetic particles	0.01%
	R2	Acridinium ester labelled prolactin antibody	0.1μg/mL
	R3	Biotin labelled prolactin antibody	0.2μg/mL
Calibrator (High, Low)		Bovine serum added prolactin	/
Control (Level 1, Level 2)		Bovine serum added prolactin	/

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 the 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 sample 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.
Calibrator and control are ready-to-use and can be used directly. Before use, mix calibrator and control, balance them to room temperature and use them.
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 prolactin 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 for 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 ng/mL.
Unit conversion: 1ng/mL=21.19μIU/mL.

【Reference Range】

Male		2.1ng/mL ~ 17.7ng/mL
Female	Non-pregnancy	2.8ng/mL ~ 29.2ng/mL
	Pregnancy	9.7ng/mL ~ 200ng/mL
	Postmenopause	1.8ng/mL ~ 20.3ng/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' prolactin 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 the linear range.
4. When prolactin concentration up to 25000ng/mL, there is no high dose hook effect.
5. Prolactin measurement is different in test method, site identification, specificity and interfering factors, thus, PRL 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 > 1000mg/dL, bilirubin > 20mg/dL, in a sample may have an impact on the test results.
3. The experimental results showed that in the sample, the cross-reactivity rate of thyrotropin1000μIU/mL is 21.19%, the cross-reactivity rate of luteinizing hormone 250mIU/mL is 1.69%, the cross-reactivity rate of human chorionic gonadotropin 200000mIU/mL is 0%, the cross-reactivity rate of follicle stimulating hormone 250mIU/mL is 0.31%, the cross-reactivity rate of human growth hormone 500ng/mL is 1.6%.
4. 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: <0.3ng/mL.
3. Linearity: linear range is 0.3ng/mL ~ 200ng/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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4. Centers for Disease Control. 1988. Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. MMWR, 37:377-82, 387-8.
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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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