Instruction For Use

【Product Name】

Prolactin (Electrochemiluminescence immunoassay)

【Package】

50T, 1×100T, 2×100T

【Intended Use】

Immunoassay for in vitro quantitative determination of Prolactin (PRL) in human serum and plasma. It is mainly used to evaluate the endocrine function of pituitary in clinic, and can not be used for the auxiliary diagnosis of hypophysoma.

Prolactin is a kind of protein hormone synthesized and secreted by the anterior pituitary gland, which is widely distributed in many organelles outside the pituitary. The hormone has 198 amino acids and molecular weight is about 22-23kd. There are three forms of prolactin in serum, among which the most active monomer ("small") is prolactin (about 80%), 5-20% is dimer ("large") form without biological activity, and 0.5-5% is tetramer ("large large") form 1 with lower biological activity. In mammals, prolactin can regulate breast development, promote milk production, activate and maintain lactation by autocrine and paracrine as a cytokine. Prolactin also plays a role in the periodic growth of hair follicles. Prolactin also has an effect on human ovary, which is manifested in stimulating the formation of luteal receptor in follicle and allowing the biosynthesis of ovarian hormone

【Test Principle】

Prolactin (Electrochemiluminescence immunoassay) was detected by double site sandwiched Electrochemiluminescence Method. The biotinylated PRL monoclonal antibody, ruthenium (RU) complex labeled PRL monoclonal antibody and the antigen in the sample formed antigen antibody sandwich complex. After binding with the magnetic particles coated with streptavidin, the composite was transferred to the measuring cell and fixed to the electrode surface, and the unbound material was washed away. After the electrode is electrified, the electrochemiluminescence reaction takes place. The optical signal is detected by photomultiplier tube and converted into electrical signal. After the instrument processing, the concentration of prolactin in the sample is calculated from the calibration curve.

【Main Component】

The reagent pack consists of MB, RA, RB, calibrator and quality control, different lots cannot be used at the same time or mixed up together.

Component	Ingredients	Volume (50T)	Volume (1×100T)	Volume (2×100T)
(MB)	Streptavidin-coated microparticles, 0.75 mg/mL: 0.1M PBS; 0.05% ProClin™ 300	1×3.5 mL	1×5.0 mL	2×5.0 mL
(RB)	Biotin labeled PRL mouse monoclonal antibody, 0.5 μg/mL; 50 mM MES; 0.05% ProClin™ 300	1×5.5 mL	1×9.0 mL	2×9.0mL
(RA)	Ruthenium complex labeled PRL mouse monoclonal antibody, 0.3μg/mL;50 mM MES; 0.05% ProClin™ 300	1×5.5mL	1×9.0mL	2×9.0 mL
Calibrator (High)	equinum serum product, ProClin™ 300	1×1.0 mL	1×1.0 mL	1×1.0 mL
Calibrator (Low)	equinum serum product, ProClin™ 300	1×1.0 mL	1×1.0 mL	1×1.0 mL
Quality control (High)	equinum serum product, ProClin™ 300	1×1.0 mL	1×1.0 mL	1×1.0 mL
Quality control (Low)	equinum serum product, ProClin™ 300	1×1.0 mL	1×1.0 mL	1×1.0 mL

The PRL calibrator's value complies strictly with GB/T21415, and can be traced back to WHO reference material 84/500.

Calibrators and quality controls of PRL are lyophilized, which were completely dissolved within 20 minutes after adding deionized water and other complex solvents.

Materials and instruments required but not provided:

- Auffer
- Buffer
- Concentrated Washing Buffer
- Series Automated ECL Immunoassay Analyzer
- Assay cup

【Storage and Shelf Life】

Unopened reagent rackpack, Calibrator and quality control should be placed at 2~8ºC and will be valid until expiration date.

The reagents, auxiliary calibration products and quality control products should be taken out and sealed in time after the opening/on-machine test, and stored at 2~8ºC for 28 days.

The production and expiration date are printed on the box and bottle label.

【Applicable Instrument】

Automated ECL Immunoassay Analyzer: eCL8000.

【Specimen collection, handling and storage】

Serum samples or anticoagulants such as heparin lithium, heparin sodium and edta-k2 are recommended for blood vessel collection of plasma samples.

Blood samples shall be collected in accordance with standard procedures for venipuncture: after the samples have been completely coagulated, centrifugation shall be performed to remove the remaining celllike substances. If the sample is covered with lipid layer after centrifugation, try to remove it. The use of samples with severe hemolysis is not recommended;

The samples can be stored at room temperature (18-28ºC) for 8 hours, 2-8ºC for 14 days, and -15~-25ºC for 6 months. The samples can only be frozen and thawed to take into account the possible influence of evaporation factors. The on-machine test of the samples' calibration and quality control products can be completed within 2 hours as far as possible.

【Assay Procedure】

Testing procedures and precautions

Previous to operation, the system operation manual of the analytical instrument should be carefully read to obtain the system operation procedures, sample management, safety precautions, maintenance and maintenance and other relevant information, then prepare the required materials for the test. Set up PRL determination procedure according to the system operating procedure.

Put the PRL reagent bottle into the analyzer slot to automatically suspend magnetic beads at least 30 min before testing.

The total test time is 18 minutes, and the principle is as follows

- 1st incubation: add the sample (10 μL) and the biotinylated PRL monoclonal antibody (75μl) and ruthenium (RU) complex labeled PRL monoclonal antibody (75μl), incubate at 37ºC for 9 min, immuno-complexes are formed.
- 2nd incubation: add 35ul of streptavidin coated magnetic particles and incubate at 37ºC for 9min, so that the immune complex formed above can be bound to the magnetic particles through the reaction between the substance and streptavidin.
- Measurement: The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with Buffer. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Results are automatically detected by the instrument from the standard curve (the curve is obtained by calibration of the original standard curve obtained by the instrument through two-point calibration).

Calibration

Calibration should be performed using lot-matching reagent and calibrators.

Before calibration, the reagent and main curve information on the RFID card (inductive electronic chip card or proximity card) should be imported into the system. The analyzer adjusts the main curve to produce working curve according to the calibrator results, and identifies validity of the working curve automatically.

The calibration target value has been written into the RFID card.

Recalibration is recommended as follows

(1) the reagents of different lot are used;

(2) the same lot of reagents were used on the analyzer beyond 28 days;

(3) quality control misses the target.

Quality control

In order to ensure the reliability of test results, it's recommended to test the Quality control every 24 hours. After each calibration, reagent lot change, maintenance or failure repairment,quality control is recommended.The quality control results should fall within the scope of local regulations. If beyond, the analyzer status, reagents, calibration and other factors should be checked.

The target value and range of quality control products are batch specific. The target value and range are shown in the quality control card.

Pre-treatment of lyophilized calibrators and quality controls:

Add 1 mL de-ionized water accurately and put them vertically for 10~20 minutes at room temperature (18~28ºC) to dissolve the material in the bottle. Mix the calibrators and quality controls thoroughly and avoid producing bubbles then subpackaged and labeled. The subpackaged calibrators and quality controls need to be transferred rapidly to -15~-25ºC if not performed immediately.

Calculation

The system software automatically calculates the analyte concentration using particular algorithm, and the result unit is ng/mL or μIU/mL : 21.2 μIU/mL = 1 ng/mL.

【Biological reference interval】

According to serum test results of 308 asymptomatic human (120 male, 188 non-pregnant female) in Guangdong Province, P. R. China, The reference range of PRL kit was calculated from the 2.5th percentile to the 97.5th percentile by statistical method.

Gender	Number	The reference range (μIU/mL)	The reference range (ng/mL)
male	120	86-324	4.06-15.3
non-pregnant female	188	102-496	4.81-23.4

Due to the differences in geography, race, gender and year, it is suggested that each laboratory should determine the applicability of the reference range through experiments, and establish the reference range of this laboratory if necessary.

【Result Interpretation】

For explaining the result, the patient's overall clinical manifestation should be referred to, including symptoms, medical history and other relevant data and

information.

【Limitations】

Test results are used only for clinical reference and cannot be used as the basis for diagnosis or rule-out of diseases alone.

The measuring range of the kit is 1.0~10600 μIU/mL. Values below the limit of blank are reported as < 1.0 μIU/mL. Values above the measuring range are reported as >10600 μIU/mL.

When the sample containing bilirubin ≤ 60 mg/dL, hemoglobin≤ 1500 mg/dL, lipid ≤ 3000 mg/dL, biotin ≤ 80 ng/ml, total protein ≤ 75 mg/mL, interference deviation to the test result lies within ±10%. When HAMA concentration reaches 300 ng/mL and rheumatoid factor reaches 1100U/mL, the interference deviation of the determination results is within 10% range.

【Analytical Performance】

Limit of blank

The limit of blank is not more than 1.0 μIU/mL.

Linearity

The correlation coefficient (Pearson's r) is not less than 0.9900 in the interval of 1.0~10600 μIU/mL.

Intra-run precision (repeatability)

The coefficient of variation (*CV*) is less than 7.5%.

Between-lot precision

The coefficient of variation (*CV*) is less than 10%.

Analytical specificity

Test results of blank samples spiked with analogs below are lower than 10.6 μIU/mL (0.5 ng/mL) .

Analog	Concentration	PRL test concentration (ng/mL)
Follicle stimulating hormone (FSH)	250 mIU/mL	<0.5
Human chorionic gonadotropin (hCG)	200 IU/mL	<0.5
Human growth hormone (hGH)	500 ng/mL	<0.5
Luteinizing hormone (LH)	250 mIU/mL	<0.5
Human placental prolactin (HPL)	12.5 μg/mL	<0.5

Accuracy

The relative deviation of measurement result lies within±10% when measure the international standards (WHO 84/500).

The relative deviation of the measurement result lies within±10% when measure the traced accuracy control product.

The results of quality controls

The quality control test results should fall within the scope of the regulations.

Homogeneity of calibrations and quality controls

Homogeneity in bottle: $CV \leq 10\%$.

Homogeneity between bottles: $CV \leq 10\%$.

【Precaution and Warning】

The kit is only used for in vitro diagnostics.

When using the kit, it's necessary to comply with regulations in the laboratory.

All reagents and samples including specimen, calibrators and Quality control, should avoid foaming before and during test.

Test results of the kit are for clinical reference only, and clinical evaluation of patients should be combined with their symptoms and signs, medical history, other laboratory examination results and treatment responses.

Due to factors such as methodology or antibody specificity, testing identical samples with reagents from different manufacturers may get different results, and the results from different kits should not compare directly, lest cause the wrong medical explanation; It's suggested that laboratorians should point out the characteristics of used reagent in the test report to the clinician. In serial monitoring, if the reagent type is changed, a continuous parallel test should be performed and comparison of the results to the former to determine new baseline value.

This product contains animal-sourced materials and may have potential biological risk. All samples and test wastes should be treated as the source of infection, and all wastes must be disposed according to local regulations. The preservative ProClin™ 300 contains 3% 2-methyl-4-isothiazolin-3-one (MIT) and 5-chloro-2-methyl-4-isothiazolin-3-one (CMIT), will be harmful if inhalation, contact with skin and/or swallow, and may be toxic to aquatic organisms, abandoned reagents should be dealed with in compliance with local regulations.

【Symbol】

Symbol	Title of Symbol
	Manufacturer
	Authorized representative in the European Community
	Use by
	Lot number
	Serial number
	Temperature limitation
	Consult instructions for use
	In vitro diagnostic medical device
	Indicates this device is in compliance with Europe Directive.
	Sufficient for <n> tests
	Biological risks
	This way up

【Reference】

1.Smith CR, Norman MR. Prolactin and growth hormone: molecular heterogeneity and measurement in serum , Ann ClinBiochem 1990; 27: 542-550 .

2.Yu-lee LY, Luo G, Book M L, ct al. Laclogenic hormone signal transduction (J) . Biol Reprod, 1998, 58 (2), 295-301.

3.Tworoger S S. Hankinson S E. Prolactin and breast caner risk[J]. Cancer Letters, 2006. 243 (2), 160-169.

【Manufacturer】

Shenzhen Lifotronic Technology Co., Ltd.

Unit A, 4th Floor, Building 15, Yijing Estate, No.1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R.China

E-mail: inter-service@lifotronic.com

【European Representative】

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

Tel.+49-40-2513175 Fax.+49-40-255726

【Version and Revision】

Version: A0

Revision Date: Mar. 13th, 2020