Instruction For Use

【Product Name】

Prolactin (Electrochemiluminescence Immunoassay)

【Order Information】

REF NO.	Package Size
697027	50T
697028	2×50T
697029	100T
697030	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.

Prolactin is a single chain peptide hormone secreted by the adenohypophysis of vertebrates. It has more than 300 different biological functions and is an essential growth factor for the growth and development of animals[2]. It has a direct effect on the division and proliferation of somatic cells, and its forms of action are circulating hormone and cytokine[3]. When the animal body has a stress response, the concentration of prolactin in the blood also increases. It is one of the three hormones secreted by the adenohypophysis in the stress response, along with adrenocorticotropic hormone and growth hormone. In mammals, prolactin acts as a cytokine that regulates mammary gland development, promotes milk production, and initiates and maintains lactation through autocrine and paracrine functions[4]. Prolactin also plays a role in the periodic growth of hair follicles. Prolactin also has an effect on the human ovary, which is manifested in stimulating the production of follicular luteal receptors and allowing the biosynthesis of ovarian hormones[5].

【Test Principle】

Sandwich principle. Total duration of assay: 18 minutes.

10 µL of sample, biotinylated PRL antibody and PRL antibody labeled with a ruthenium complex react to form a sandwich complex. After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. 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 system reagent. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Results are determined via a calibration curve which is instrument specifically generated by 2-point calibration and a master curve provided via the RFID.

【Main Components】

The reagent pack consists of MB, RA, RB, calibrators and control materials (Optional). Different batch of reagent components should not be used interchangeably.

Components	Ingredients	Volume (50T)	Volume (2×50T)	Volume (1×100T)	Volume (2×100T)
Magnetic Beads (MB)	Streptavidin-coated microparticles,0.75 mg/mL:0.1M PBS; 0.05% ProClin™ 300	1×3.0 mL	2×3.0 mL	1×5.0 mL	2×5.0 mL
Reagent B (RB)	Biotin labeled PRL mouse monoclonal antibody, 0.5 µg/mL; 50 mM MES; 0.05% ProClin™ 300	1×5.8 mL	2×5.8 mL	1×9.5 mL	2×9.5 mL
Reagent A (RA)	Ruthenium complex labeled PRL mouse monoclonal antibody, 0.3µg/mL; 50 mM MES; 0.05% ProClin™ 300	1×5.8 mL	2×5.8 mL	1×9.5 mL	2×9.5 mL
Calibrators	99.95%equinum serum, 0.05%ProClin™ 300; lyophilized	High: 1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	99.95%equinum serum, 0.05%ProClin™ 300; lyophilized	High: 1×1.0 mL Low: 1×1.0 mL			

The PRL calibrator value can be traced back to WHO reference material 84/500.

See the control material value sheet for the target values and ranges of control materials.

Supporting instruments and materials required but not provided in this pack (provided by Lifotronic):

Additional materials for Automated ECL Immunoassay Analyzer eCL8000, eCL8000i, eCL8000p, eCL8000x:

- REF 679005, Auffer, 480 mL, or REF 679004, Auffer, 6×480 mL
- REF 679007, Buffer, 480 mL, or REF 679006, Buffer, 6×480 mL
- REF 679009, Concentrated Washing Buffer, 1 L, or REF 679008, Concentrated Washing Buffer, 6×1 L
- REF 679011, Assay Cup, 300 T, or REF 679012, Assay Cup, 3000 T

Additional materials for Automated ECL Immunoassay Analyzer eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p:

- REF 0320501804, Auffer, 2×1 L, or REF 0320501805, Auffer, 4×1 L
- REF 0320507502, PreClean, 2×800 mL, or REF 0320507503, PreClean, 4×800 mL
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 032120111, Assay Cup/Assay Tip, 12×2×105

Additional materials for Automated ECL Immunoassay Analyzer eCL9000, eCL9600, eCL9900, eCL9900i:

- REF 0320501801, Auffer, 2×2 L, or REF 0320501806, Auffer, 4×2 L
- REF 0320501901, Buffer, 2×2 L, or REF 0320501906, Buffer, 4×2 L
- REF 0320507501, PreClean, 2×2 L, or REF 0320507504, PreClean, 4×2 L
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 0320510002, Assay Cup/Assay Tip, 1×6×105

【Storage and Shelf Life】

Store at 2ºC-8ºC.

Do not freeze.

Store the reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Stability of the reagents	
Unopened store at 2ºC~8ºC	18 months
Store at 2ºC~8ºC after opening	8 weeks
on the analyzers at 2ºC~15ºC	8 weeks

The calibrators and control materials are stable up to the stated expiration date.

Stability of the calibrators and control materials	
Unopened store at 2ºC~8ºC	18 months
Store at 2ºC~8ºC after reconstituted	4 weeks
Store at -25ºC~-15ºC after reconstituted	8 weeks (freeze-thawed only once)

The expiration date is labeled on the box, rackpack and bottles.

Damaged, expired or contaminated reagents should be discarded.

【Applicable Instrument】

Automated ECL Immunoassay Analyzers: eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p, eCL9000, eCL9600, eCL9900, eCL9900i.

【Specimen collection, handling and storage】

Serum samples or anticoagulants such as heparin lithium, heparin sodium and EDTA-2K 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 -25~-15ºC 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.

Recommended ambient temperature:10~30ºC; Relative humidity: ≤ 80%.

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

For quality control, use PRL control materials.

In addition, other suitable control material can be used.

Control materials for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

If necessary, repeat the measurement of the samples concerned.

Follow the applicable government regulations and local guidelines for quality

Please make sure that the correct values are used.

Handing of lyophilized calibrators and control materials:

Carefully dissolve the contents of one bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 10~15 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer aliquots of the reconstituted calibrators or control materials to the additional bottles. After bottles is marked and dispensed. If you do not test immediately, you need to store the aliquots immediately at -25~-15°C.

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 healthy human (120 males, 188 non-pregnant females), 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, Triglyceride≤ 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 1100 IU/mL the interference deviation of the determination results is within 10% range.

There was no hook effect when the concentration of PRL reached 296800 μIU/mL (14000 ng/mL).

【Analytical Performance】

Lower limits of measurement

The lower detection limit 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) ≤ 7.5%.

Between-lot precision

The coefficient of variation (CV) ≤ 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	Result(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)	12.5μg/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 products.

The results of quality controls

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

Homogeneity of Calibrators and Control Materials

Homogeneity in bottle: CV ≤ 10%.

Homogeneity between bottles: CV ≤ 10%.

Method comparison

A comparison of the Lifotronic PRL assay (y) with the Roche Elecsys Prolactin II Method (x) using clinical samples gave the following correlations:

Number of paired values: 108

Linear regression:

y=1.0027x+14.557

r = 0.999

The sample concentrations were between approx 99.65 μIU/mL and 7823 μIU/mL.

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.

Any serious incident that would be occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

The preservative ProClin™300 which contain Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1): May cause an allergic skin reaction. thus, proper personal protection should be adopt while handling the reagent: avoid breathing dust/fume/gas/mist/vapours /spray, wear protective gloves and contaminated work clothing should not be allowed out of the workplace. If skin irritation or rash occurs: get medical advice/attention, take off contaminated clothing and wash it before reuse, and dispose of contents/container to an approved waste disposal plant.

【Symbols Explanation】

Symbol	Title of Symbol	Symbol	Title of Symbol
	Manufacturer		Consult instructions for use
	Use-by date		In vitro diagnostic medical device
	Batch code		Sufficient for <n> tests
	Serial number		Biological risks
	Temperature limit		This way up
	Authorized representative in the European Community		Indicates this device is in compliance with Europe Directive.
	Catalogue number	P/N	Material code
	Warning		Date of manufacture
	Unique device identifier		

【Reference】

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3. Shiu RP，Kelly PA，Friesen HG. Radioreceptor assay for prolactin and other lactogenic hormones. Science, 1973, 180 (89): 968-971.
4. Yu-lee LY, Luo G, Book M L, et al. Laclogenic hormone signal transduction. Biol Reprod, 1998, 58 (2): 295-301.
5. Tworoger S S. Hankinson S E. Prolactin and breast caner risk. Cancer Letters, 2006. 243 (2): 160-169.

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【Version and Revision】

Version: 2.0

Issue Date: 2025-03-04