Instruction For Use

【Product Name】

Parathyroid Hormone (Electrochemiluminescence Immunoassay)

【Package】

REF NO.	Package Size
693022	50T
693023	2×50T
693019	100T
693020	2×100T

【Intended Use】

It's used for quantitative determination of parathyroid hormone in human serum or plasma in vitro.

Intact Parathyroid Hormone (iPTH) is a basic single-stranded peptide hormone secreted by parathyroid gland's main cells and released into the blood. The intact parathyroid hormone (iPTH) is composed of 84 amino acids with a molecular weight of approximately 9,500 daltons[1]. The biological half-life of the complete and bioactive peptide segments of PTH is only a few minutes. After secreting, rapid proteolysis of PTH results in the generation of various circulating c-terminal segments, and only 10% of the blood retains the original PTH form[2]. The rest were converted into three peptides: the amino terminus, the intermediate terminus and the carboxyl terminus. And finally, filtration and clearance mainly arises in the glomerulus[3]. The detection of parathyroid hormone can be used to evaluate the secretion activity of parathyroid gland.

【Test Principle】

Sandwich principle. Total duration of assay: 18 minutes

- 1st incubation: 50 µL of sample, biotinylated monoclonal PTH antibody and monoclonal PTH antibody labeled with a ruthenium complex react to form a sandwich complex.
- 2nd incubation: After addition of streptavidin-coated microparticles, the complex binds to the solid phase via interaction of biotin 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 determined via calibration and a master curve provided via the reagent barcode.

【Main Components】

The reagent pack consists of MB, RA, RB, calibrators and control materials (Optional). Different lots cannot be used at the same time or mixed up together.

Components	Ingredients	Volume (50T)	Volume (2×50T)	Volume (1×100T)	Volume (2×100T)
Magnetic Beads (MB)	Streptavidin-coated microparticles: preservative	1×1.75mL	2×1.75 mL	1×3.5 mL	2×3.5 mL
Reagent B (RB)	Anti-PTH-Ab~biotin: 0.1M PBS; preservative	1×3.0 mL	2×3.0 mL	1×6.0 mL	2×6.0 mL
Reagent A (RA)	Anti-PTH-Ab~Ru(bpy)$_3^{2+}$: 0.1M PBS; preservative	1×3.0 mL	2×3.0 mL	1×6.0 mL	2×6.0 mL
Calibrators	Bovine serum, preservative; lyophilized	High: 1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	Bovine serum, preservative; lyophilized	High: 1×1.0 mL Low: 1×1.0 mL			

Traceability: This method can be traceable to the NIBSC (National Institute for Biological Standards and Control) 95/646 standard material.

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 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	7 days
Store at -25ºC~-15ºC after reconstituted	3 months (freeze 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】

Human serum and plasma added with heparin lithium, EDTA-K_3 and EDTA-K_2 anti-coagulants are recommended. Blood samples should be collected by standard operation of venous puncture; after complete coagulation, the tangible component should be removed by centrifugation. The sample should avoid bubbling during testing. Lipid layer floating on the upper of the sample should be removed. Samples with severe hemolysis are not recommended.

Serum samples would better to be tested in 7 hours after collection, otherwise, should be stored at 2~8°C for no more than 24 hours or at -25~-15°C for 12 weeks; EDTA-K_3 and EDTA-K_2 plasma samples would better to be tested in 24 hours after collection, otherwise, should be stored at 2~8°C for no more than 48 hours or at -25~-15°C for 24 weeks; heparin lithium plasma samples would better to be tested in 24 hours after collection, otherwise, should be stored at 2~8°C for no more than 48 hours or at -25~-15°C for 12 weeks.

Freezing and thawing cycle is permitted only once.

【Assay Procedure】

Testing procedures and precautions

Previous to operation, one should read the operational manual carefully to obtain system operation procedure, sample processing, security precaution, maintenance and other related information.

Set up PTH test according to the operational manual.

Put the PTH rackpack into the correct analyzer slot to automatically suspend magnetic beads at least 30 min before testing.

Calibration

Calibration should be performed using lot-matching reagent and calibrators. Before calibration, the reagent and main curve information should be imported into the analyzer via radio frequency identification (RFID) reagent card (refer to instrument user manual). The analyzer adjusts the main curve to produce working curve according to the calibrator results, and identifies validity of the working curve automatically.

Recalibration is recommended when:

(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.

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 -20°C (± 5°C).

Quality control

For quality control, use PTH 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 control.
Please make sure that the correct values are used.
See the quality control card for the target value and scope of quality control products.

Calculation

The system software automatically calculates the analyte concentration using particular algorithm, and the result unit is pg/mL or pmol/L: pg/mL×0.106 = pmol/L.

Specimen dilution

Wide detection range, without dilution.

【Biological reference interval】

By testing and analyzing the serum samples of 583 cases (including 307 males and 276 females), the 2.5 percentile to 97.5 percentile were selected by statistical method, and the reference range of PTH was 14.9 ~ 56.9 pg/mL.
Due to differences in geography, race, sex and age, it is recommended that each laboratory establish its own reference range.

【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 detection range of the kit was 5 ~ 2500 pg/mL. For samples with PTH content below the detection limit, the results were reported as <5.0 pg/mL.If the sample PTH content is higher than the upper limit, the result will be reported as > 2500 pg/mL.
When the sample has bilirubin ≤ 200 mg/dL, triglyceride ≤2000 mg/dL, biotin ≤10 ng/mL, hemoglobin ≤100 mg/dL, HAMA ≤200 ng/mL, rheumatoid factor ≤800 IU/mL, the interference deviation of the measurement results was within ±10%.
When PTH concentration reached 20000 pg/mL, no hook effect was observed.

【Analytical Performance】

Lower Limits of measurement

Lower detection limit < 5.0 pg/mL

Linearity

The correlation coefficient (r) of the kit was not less than 0.9900 in the range 5.0 ~ 2500 pg/mL.

Within-run imprecision (repeatability)

The coefficient of variation (CV) ≤ 7.5%.

Between-lot imprecision

The coefficient of variation (CV) ≤ 10%.

Analytical specificity

The following analogues were tested and no significant cross-reactions were found:

Analogue	Concentration	Cross-Reactivity
PTH(1-38)	20000pg/mL	≤0.50%
PTH(1-44)	20000pg/mL	≤0.50%
PTH(39-68)	20000pg/mL	≤0.50%
PTH(53-84)	20000pg/mL	≤0.50%
CT	20000pg/mL	≤0.50%
ACTH	200pg/mL	≤1.0%

Accuracy

The ratio of the measured value to the theoretical value of the international standard is between 0.900 and 1.100.The ratio of the measured value to the labeled value is between 0.900 and 1.100.

Homogeneity of calibrators and control materials

Within-bottle homogeneity: coefficient of variation (CV) ≤ 10%.
Between-bottle homogeneity: coefficient of variation (CV) ≤ 10%.

Method comparison

A comparison of the Lifotronic PTH assay (y) with the Roche Elecycs PTH reagent kit (x) using clinical samples gave the following correlations:
Number of plasma samples measured: 108
Passing-Bablok regression:
y=1.008x+0.130
r = 0.9971
The sample concentrations were between 5.68 and 2229 pg/mL.

【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 control materials, 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 a 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	IVD	In vitro diagnostic medical device
LOT	Batch code	Σ	Sufficient for <n> tests
SN	Serial number		Biological risks
	Temperature limit		This way up
EC REP	Authorized representative in the European Community	CE	Indicates this device is in compliance with Europe Directive.
REF	Catalogue number	P/N	Material code
	Warning		Date of manufacture
UDI	Unique device identifier		

【Reference】

1. Armitage EK. Parathyrin(parathyroid hormone): metabolism and population and methods for assay. Clin Chem, 1986, 32: 418-24.
2. Kao PC. Grant CS, Klee GG, Khosla S. Clinical performance of Parathyroid immunometric assays. Mayo Clin Proc, 1992, 67: 637-45.
3. Retention prediction and computer-assisted optimization for the separation of PTH-amino acids in isocratic reversed-phase liquid chromatography. Chromatographia, 1988, Volume 25.

【Manufacturer】

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