Instruction For Use

【Product Name】

hGH (eCLIA)

【Order Information】

REF NO.	Package Size
0320509601	50 T
0320509602	2×50 T
0320509603	100 T
0320509604	2×100 T

【Intended Use】

Immunoassay for in vitro quantitative determination of human growth hormone (hGH) in human serum or plasma. The results can be used for auxiliary evaluation of the abnormal growth hormone levels caused by pituitary function and non-pituitary disease.

【Summary】

Human growth hormone (hGH) is a single chain polypeptide hormone synthesized and secreted by growth hormone cells in the anterior pituitary gland. In human body, hGH manifests in two different molecular forms with molecular weights of 22KDa and 20KDa respectively. More than 90% of hGH is 22KDa isotype, composed of 191 amino acids. The other 10% is 20KDa isotype, which is the product of selective splicing of pituitary hGH gene and lacks amino acid residue at position 32-46[1]. The level of hGH in human body has important physiological significance. HGH deficiency can lead to growth retardation in children and decreased muscle strength, bone mass, insulin sensitivity, and cardiovascular risk factors in adults[2-3]. Overproduction of hGH often leads to gigantism and acromegaly[4]. HGH deficiency or excess can be evaluated according to clinical development standards and pituitary NMR imaging, and changes in serum hGH concentration can be measured by stimulation or inhibition test to confirm whether the evaluation results are correct[5-6]. The screening level of hGH deficiency varies according to the type of stimulation test and is affected by body mass index (BMI)[7-8]. Therefore, the screening level should be judged by referring to authoritative literature as a guiding document.

【Principles of the testing method】

Sandwich principle. Total duration of assay: 18 minutes.

30 µL of sample, biotinylated monoclonal hGH antibodies, and monoclonal hGH antibodies labeled with 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), and different components and reagents of lot numbers should not be used interchangeably.

Components	Ingredients	Volume (2×50T)	Volume (50T)	Volume (100T)	Volume (2×100T)
(MB)	Streptavidin coated magnetic particles, 0.45 mg/mL, 0.1M PBS, ProClin300	2×1.8mL	1×1.8mL	1×3.5mL	2×3.5mL
(RB)	Biotinylated monoclonal hGH antibodies,1.0 mg/L, 50 mM HEPES, ProClin300	2×3.0mL	1×3.0mL	1×6.0mL	2×6.0mL
(RA)	Monoclonal hGH antibodies labeled with ruthenium, 0.8 mg/L 50 mM HEPES, ProClin300	2×3.0mL	1×3.0mL	1×6.0mL	2×6.0mL
Calibrators	hGH antigen, 0.05M PBS, ProClin300	High: 1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	hGH antigen, 0.05M PBS, ProClin300	High: 1×1.0 mL Low: 1×1.0 mL			

Traceability:This method has been standardized against the international standard substances NIBSC 98/574.

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

【Instruments and Materials Required but Not Provided】

Additional materials for Automated ECL Immunoassay Analyzers 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 0320501904, Buffer, 2×1 L, or REF 0320501905, Buffer, 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 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

【Applicable Instrument】

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

【Storage and Shelf Life】

Store at 2-8℃.

Do not freeze.

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

Damaged, expired or contaminated reagents should be discarded.

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

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

Stability of the calibrators and control materials	
Unopened at 2~8℃	18 months
Store at 2~8℃ after opening	8 weeks
Stored at 18℃~28℃ after opening	8 hours

Store calibrators and control materials upright in order to prevent the calibrator and control materials solution from adhering to the cap of the vial.

【Specimen collection, handling and storage】

It is recommended to use human serum samples or plasma samples collected with EDTA-K2, EDTA-K3, heparin lithium blood collection tubes.

Blood samples should be collected in accordance with the standard operation of venipuncture. After the sample is completely coagulated, centrifugation should be performed to remove residual cellular substances. The sample should be free of air bubbles during testing. Lipid layer covering the sample after centrifugation should be removed. It is not recommended to use hemolyzed samples.

Samples can be stored for 8 hours at room temperature (18~28℃), 24 hours at 2~8℃, and 1 months at -15℃ or below. Freezing and thawing can be performed once.

【Testing Procedure】

Testing procedures and precautions

Before testing, the system operation manual of the measuring instrument should be carefully read, so as to obtain relevant information such as system operating procedures, sample management, safety precautions and maintenance, and materials required for testing should be prepared. hGH testing procedures should be called and set up in accordance with the system operating procedures.

Before using the reagent, put it into the analyzer 30 minutes in advance to automatically stir the magnetic bead particles and keep them in suspension.

Recommended environment temperature for testing: 10~30℃, relative humidity: ≤80%.

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 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 4 weeks;

(3) Quality control findings outside the defined limits.

(4)The Buffer of different lots are used.

Quality Control

For quality control, use hGH 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.

Calculation

The system software automatically calculates the analyte concentration using particular algorithm, and the result unit is ng/mL, pg/mL, mIU/L.

Conversion factors: ng/mL x 1000= pg/mL

pg/mL x 0.001 = ng/mL

ng/mL x 3.0 =mIU/L

mIU/L x 0.333 =ng/mL

Specimen dilution

hGH concentration in the sample higher than the upper limit of detection can be

The recommended dilution ratio is 1:2. The results are reported by multiplying the measured values by the dilution ratio.

【Biological reference interval】

By analyzing the serum samples of healthy population from Guangdong province, the calculation of reference interval is shown in the table below :

Gender	Age	Percentiles	hGH（ng/mL）
Female	0～10	2.5%-97.5%	0.121～7.792
	11～17	2.5%-97.5%	0.125～8.053
	adult	2.5%-97.5%	0.126～9.884
Male	0～10	2.5%-97.5%	0.093～6.294
	11～17	2.5%-97.5%	0.078～10.81
	adult	97.5%	2.473

Due to the differences in geography, race, gender and age, it is recommended that each laboratory determine the applicability of reference range through tests, and establish the reference range of this laboratory if necessary.

【Interpretation of results】

When interpreting the test results, it is necessary to refer to the patient's overall clinical situation, including: symptoms, medical history as well as other corresponding data and information.

【Limitations】

The test results are only for clinical reference and cannot be used alone as the basis for diagnosis or exclusion of cases.

The detection range of the kit is 0.02 ng/mL～50 ng/mL. If the hGH concentration in the sample is lower than the lower limit of detection, the result is reported as less than this value (for example, <0.02 ng/mL), if the hGH concentration in the sample is higher than the upper limit of detection, the result is reported as greater than this value (for example, >50 ng/mL), or the sample is manually diluted with sample diluent at the dilution ratio of 1:2, and the result is reported with the measured value multiplied by the dilution ratio.

When jaundice (bilirubin) is ≤25 mg/dL, hemolysis (hemoglobin) is ≤0.5 g/dL, lipemia (triglyceride) is ≤1500 mg/dL, biotin is ≤30 ng/mL, in the sample, the interference deviation of the measured results is within ±10%. When the concentration of rheumatoid factor in the sample is less than or equal to 600 IU/mL, the relative recovery of the test results is between 90% and 110%.

When the hGH concentration reaches 2000 ng/mL, there is no high-dose Hook effect.

【Analytical Performance】

Lower limit of measurement

Limit of Blank = 0.02 ng/mL

Limit of Detection = 0.03 ng/mL.

Accuracy

The relative deviation shall not exceed ±10%.

Linearity

The correlation coefficient is not less than 0.9900 in the interval of 0.03 ~ 50 ng/mL.

Within-run precision (repeatability)

The coefficient of variation (CV) is less than or equal to 5.0%.

Between-lot precision

The coefficient of variation (CV) is less than or equal to 10.0%.

Homogeneity of calibrators and control materials

Within-bottle homogeneity: The coefficient of variation (CV) is less than or equal to 5.0%.

Analytical specificity

When testing specific samples containing 2000 mIU/L prolactin (PRL), the test result should be≤0.5 ng/mL.

Accuracy of calibrators

The relative deviation shall not exceed ±10%.

Measured values of control materials

The measured results of supporting assigned quality control of the kit should be within the quality control range.

Method comparison

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

Number of serum samples measured: 119

Linear regression:

y=1.0168x+0.1703

r = 0.996

The sample concentrations were between 75.53 and 46987 pg/mL.

【Precaution and Warning】

The kit is only used for in vitro diagnostics.

Exercise the normal precautions required for handling all laboratory reagents.

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

Disposal of all waste material should be in accordance with local guidelines.

Safety data sheet available for professional user on request.

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.

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 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 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.

【Literature References】

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2. Hans D B , Geert-Jan B , Van d V E A . Clinical aspects of growth hormone deficiency in adults.[J]. Endocrine Reviews, 1995;(1):63-86.
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4. Fulya Akin, Emrah Yerlikaya. Acromegaly and gigantism.[J]. Practitioner, 1980;26(9):149-151.
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7. Laursen T, Jorgensen JOL, Christiansen JS. The management of adult growth hormone deficiency syndrome. Expert Opin Pharmacother 2008;9:2435-2450.
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【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		

【Manufacturer】

Shenzhen Lifotronic Technology Co., Ltd.
Lifotronic Tower, No.8, Qiuzhi East Road, Guancheng Community, Guanhu Street, Longhua, 518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
E-mail: inter-service@lifotronic.com

【European Representative】

Umedwings Netherlands B.V.
Treubstraat 1, 2288EG, Rijswijk, The Netherlands
Tel: +31(0) 642758955
E-mail: ar@umedwings.eu

【Version and Revision】

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