Instruction For Use

【Product Name】

Insulin (Electrochemiluminescence Immunoassay)

【Order Information】

REF NO.	Package Size
695024	50T
695025	2×50T
695026	100T
695027	2×100T

【Intended Use】

Immunoassay for the in vitro quantitative determination of insulin in human serum and plasma. Determination of insulin is used for evaluation of pancreatic islet function.

Determination of insulin is mainly used in the clinical diagnosis and classification of diabetes, and it can be used to determine whether diabetes patients are type I patients or type II patients. It's mainly suitable for patients without insulin treatment. Blood can be drawn in the fasting and 2 hours after meals for measurement. Under normal circumstances, the fasting insulin level should be 5 ~ 30 IU/mL, and the post-meal level should be 4 ~ 5 times higher than the fasting level. If insulin levels drop significantly, it's called absolute deficiency, which is seen in type 1 diabetes. If there is no significant reduction but instead an increase in blood sugar, it is called a relative deficiency because of a malfunction in the way insulin works, which is common in type 2 diabetes, which is resistant to insulin. In addition, the detection of insulin is of great significance for the treatment of diabetes, the diagnosis of hypoglycemia syndrome and other related diseases.

【Test Principle】

Sandwich principle. Total duration of assay: 18 minutes.

1st incubation: 30 µL of sample, biotinylated monoclonal insulin-specific antibody and monoclonal insulin-specific antibody labeled by ruthenium trisbipyidyl NHS ester form a sandwich compound by immunoreaction.

2nd incubation: After addition of streptavidin-coated micro magnetic beads, the compounds bind to the micro beads via interaction of biotin and streptavidin.

Measurement: The reaction mixture is aspirated into the measuring cell where the micro beads and immuno-compounds are magnetically captured onto the surface of the electrode.

Unbound substances are then removed by Buffer. Application of a voltage to the electrode then induces emission of luminescence 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 (2×50T)	Volume (50T)	Volume (100T)	Volume (2×100T)
MB	Streptavidin-coated micro magnetic beads; preservative	2×1.8 mL	1×1.8 mL	1×3.5 mL	2×3.5 mL
RB	Anti-Insulin-Ab~biotin: 50 mM MES; preservative	2×3.3 mL	1×3.3 mL	1×6.5 mL	2×6.5 mL
RA	Anti-Insulin-Ab~Ru(bpy)$_3^{2+}$: 50 mM MES; preservative	2×3.3 mL	1×3.3 mL	1×6.5 mL	2×6.5 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			

The calibration process of this kit is traceable to WHO insulin international reference substance (83/500).

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 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, 12×2×105

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

- 0320501801, Auffer, 2×2 L, or 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
Stored 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	90 days (freeze-thawed only once)

【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, Sodium heparin, EDTA-3K and EDTA-2K 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. Samples would better to be tested in 8 hours after collection, otherwise, should be stored 2~8ºC for no more than 24 hours or -25~-15ºC, 90 days. 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 Insulin test according to the operational manual.

Put the Insulin reagent pack into the correct analyzer slot to automatically suspend magnetic beads at least 30 minutes before testing.

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

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 -15°C or lower than -15°C.

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 28 days;

(3) Quality control findings outside the defined limits.

Quality control

For quality control, use Insulin control materials.

In addition, other suitable control material can be used.

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

Calculation

The system software automatically calculates the analyte concentration using particular algorithm, and the result unit is µIU/mL or pmol/L.

1 µIU/mL=6.945 pmol/L or 1 pmol/L=0.144 µIU/mL

【Biological reference interval】

According to serum test results of 381 healthy human serum samples (males 196 and females 185, aged between 13 and 64), the percentile 5 to percentile 95 give

reference range 2.44~24.45 μIU/mL.
Due to differences in the region, race, gender and age, laboratories are recommended to set up their own reference ranges.

【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.

When the sample has bilirubin ≤ 90 mg/dL, hemoglobin ≤ 200 mg/dL, triglyceride ≤ 1800 mg/dL, biotin ≤ 30 ng/mL, HAMA ≤ 120 ng/mL, the interference deviation of the measurement results is within ±10%.Rheumatoid factor ≤ 1500 IU/mL,the relative recovery was between 90% and 110%.

【Measuring Range】

The measuring range of the kit is 0.2~1000 μIU/mL. For samples with Insulin content below the lower detection limit, the results are reported as < 0.2 μIU/mL; If the insulin content is above the upper detection limit, the results are reported as > 1000 μIU/mL.

【Analytical Performance】

Lower limits of measurement

Lower detection limit is 0.2 μIU/mL.

Accuracy

The ratio of the measured value of national standard to the theoretical value is between 0.900~1.100. Or measure the accuracy control products traceable to standardization, the ratio of the measured value to the labeled value is between 0.900~1.100.

Linearity

The correlation coefficient (Pearson's r) is not less than 0.9900 in the interval of 0.2~1000 μIU/mL.

Within-run precision (repeatability)

The coefficient of variation (CV) is less than 8.0%.

Between-lot precision

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

Analytical specificity

Test results of blank samples spiked with analogs below:

Analog	Concentration	Result
Proinsulin	10 ng/mL	≤3.0 μIU/mL
c-peptide	20 ng/mL	≤3.0 μIU/mL
Porcine Insulin	48 ng/mL	≤200 μIU/mL
Bovine insulin	100 ng/mL	≤600 μIU/mL
Insulin-like growth factor I	50 ng/mL	≤0.2 μIU/mL
Somatostatin	100 pg/mL	≤0.2 μIU/mL
Glucagon	1000 pg/mL	≤0.2 μIU/mL

Homogeneity of calibrators and control materials

Within-bottle homogeneity: The coefficient of variation (CV) is less than 10.0%.
Between-bottle homogeneity: The coefficient of variation (CV) is less than 10.0%.

Method comparison

A comparison of the Lifotronic Insulin assay (y) with the Roche Elecsys Insulin Method (x) using clinical samples gave the following correlations:
Number of serum samples measured: 218
Linear regression:
Y=0.9822X-1.9472
r = 0.996
The sample concentrations were between approx 0.352 and 944.7 ng/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.
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 limitation		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】

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【Version and Revision】

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