Instruction For Use

【Product Name】

Follicle-stimulating Hormone (Electrochemiluminescence Immunoassay)

【Order Information】

REF NO.	Package Size
697019	50T
697020	2×50T
697025	100T
697026	2×100T

【Intended Use】

Immunoassay for in vitro quantitative determination of follicle-stimulating hormone (FSH) in human serum and plasma. The results mainly used to evaluate pituitary endocrine function.

【Test Principle】

Sandwich principle. Total duration of assay: 18 minutes.

40 µL of sample, Biotinylated anti-FSH antibody, and anti-FSH antibody 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). Different batch of reagent components should not be used interchangeably.

Components	Ingredients	Volume (50T)	Volume (2×50T)	Volume (100T)	Volume (2×100T)
Magnetic Beads (MB)	Magnetic particles coated with streptavidin, 0.75mg/mL; 0.05% ProClin™300	1×3.0 mL	2×3.0 mL	1×5.0 mL	2×5.0 mL
Reagent B (RB)	Anti-FSH-Ab~biotin, 1.0µg/mL; 50mM Tris; 0.05% ProClin™300	1×5.8 mL	2×5.8 mL	1×9.5 mL	2×9.5 mL
Reagent A (RA)	Anti-FSH-Ab~Ru(bpy)$_3^{2+}$, 50mM Tris; 0.05% ProClin™300	1×4.5 mL	2×4.5 mL	1×7.0 mL	2×7.0 mL
Calibrators	50mM Tris; 0.05% ProClin™300	High: 1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	50mM Tris; 0.05% ProClin™300	High: 1×1.0 mL Low: 1×1.0 mL			

Traceability: This method has been standardized against the international standard substances NIBSC 83/575.

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, 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, o 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 opening	8 weeks

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】

It is recommended to use serum samples or plasma samples collected from EDTA-2K, EDTA-3K, heparin lithium, heparin sodium and heparin ammonium blood collection tubes.

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 would better to be tested in 8 hours after collection, otherwise, should be stored 2~8ºC for no more than 14 days or -25~-15ºC, 90 days. Freezing and thawing cycle is permitted only once.

【Assay Procedure】

Testing procedures and precautions

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

Set up FSH test according to the operational manual.

Put the FSH rackpack into the correct 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 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) As required: if the control material results exceed the specified limit.

Quality control

For quality control, use FSH 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 mIU/mL or IU/L.

Specimen dilution

Wide detection range, no need to dilute.

【Biological reference interval】

According to serum test results of 898 healthy people in the hospital (including 210 males, 177 females in follicular stage, 120 females in ovulation stage, 243 females

in luteal stage and 148 females in postmenopausal stage) were tested and analyzed. The test results are as follows:

The crowd	Age	Number	FSH (mIU/mL)		
			Percentile		
			50th	5th	95th
Male	15-64	210	4.5	1.4	12.2
Female					
Follicular stage	16-61	177	6.7	3.4	12.4
Ovulation stage	16-53	120	12.2	4.5	21.3
Luteal stage	15-58	243	3.7	1.6	7.5
Postmenopausal stagestage	37-73	148	67.1	25.5	134.5

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.

The measuring range of the kit is 0.10~200 mIU/mL. Values below the limit of blank are reported as < 0.10 mIU/mL. Values above the measuring range are reported as > 200 mIU/mL.

There is no high-dose hook effect at FSH concentrations 2000 mIU/mL.

When the sample containing bilirubin ≤ 100 mg/dL, hemoglobin ≤ 250 mg/dL, triglyceride ≤ 2000 mg/dL, total protein ≤ 10 g/dL, and biotin concentration ≤ 22.5 ng/mL, HAMA ≤ 210 ng/mL, interference deviation to the test result lies within ±10%. When the rheumatoid factor reached 2310 IU/mL, the relative recovery of the test results is between 90% and 110%.

Detect analogs 200 mIU/mL Luteinizing Hormone (LH), 200 mIU/L Thyroid Stimulating Hormone (TSH), 1000 mIU/mL Human chorionic gonadotropin (hCG), 350 mIU/L Human growth hormone (hGH), 12.5 mg/L Human placental prolactin (hPL), and the determination results are not higher than 0.10 mIU/mL.

【Analytical Performance】

Lower Limits of measurement

Lower detection limit is 0.10 mIU /mL.

Accuracy

When measuring the International standard, the ratio between resulting value and theoretical value lies between 0.900 and 1.100.

When measuring the metrologically traceable accuracy control materials, the ratio between resulting value and target value lies between 0.900 and 1.100.

Linearity

The correlation coefficient (Pearson's r) is not less than 0.9900 in the interval of 0.10~200 mIU/mL.

Within-run imprecision (repeatability)

The coefficient of variation (CV) ≤ 6%.

Between-lot imprecision

The coefficient of variation (CV) ≤ 10%.

Homogeneity of calibrators and control materials

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

Method comparison

A comparison of the Lifotronic FSH assay (y) with the Roche Elecsys FSH Method (x) using clinical samples gave the following correlations:
Linear regression:
y=0.9741x+0.518
r = 0.992
Number of samples measured: 218
The sample concentrations were between approx 0.123 mIU/mL and 176.3 mIU/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		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		

【Manufacturer】

Shenzhen Lifotronic Technology Co., Ltd.
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【Version and Revision】

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