Lifotronic

CE

Instruction For Use

【Product Name】

Estradiol (Electrochemiluminescence Immunoassay)

【Order Information】

REF NO.	Package Size
697031	50T
697032	2×50T
697033	100T
697034	2×100T

【Intended Use】

Immunoassay for in vitro quantitative determination of 17β-estradiol (E2) in human serum and plasma, which is clinically used for auxiliary diagnosis of ovarian diseases.

Estradiol (E2) is a natural female with a molecular weight of 272.3 Dalton. Most of the circulating estradiol binds to proteins. It's estimated that only 1~3% of estradiol is free. Estradiol promotes secondary sexual characteristics and sexual organ maturation in adolescent females. In addition to maintaining secondary sexual characteristics for adult women, it can also be in the hypothalamic-pituitary system feedback regulation, so that the endometrium produces a series of changes, contribute to the menstrual cycle. It can also enhance uterine activity, improve the sensitivity of uterine smooth muscle to oxytocin, promote vaginal epithelial hyperplasia and keratinization of surface cells.In addition, estrogen can also promote or inhibit the release of gonadotropin through is feedback effect on pituitary gland and hypothalamus, and indirectly affect the morphology and function of ovary. E2 is important hormone index to evaluate ovarian function.

【Test Principle】

Competition principle. Total duration of assay: 18 minutes.

1st incubation: Antigen in the sample and the ruthenium (Ru) complex-labeled 17β-estradiol derivative compete to bind biotin-labeled 17β-estradiol antibody,an immune response occurs to form an antibody-antigen compounds.

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. Different lots cannot be used at the same time or mixed up together.

Components	Ingredients	Volume (50T)	Volume (2×50T)	Volume (100T)	Volume (2×100T)
(MB)	Streptavidin-coated micro magnetic beads: perservative	1×1.8 mL	2×1.8 mL	1×3.5 mL	2×3.5 mL
(RB)	Anti-E2-Ab~biotin: 0.05M HEPES; perservative	1×3.8 mL	2×3.8 mL	1×7.5 mL	2×7.5 mL
(RA)	E2~Ru(bpy)$_3^{2+}$: 0.05M HEPES; perservative	1×3.8 mL	2×3.8 mL	1×7.5 mL	2×7.5 mL
Calibrator (High)	0.1M PB, 0.05 % ProClin™ 300	1×1.0 mL	2×1.0 mL	1×1.0 mL	1×1.0 mL
Calibrator (Low)	0.1M PB, 0.05 % ProClin™ 300	1×1.0 mL	2×1.0 mL	1×1.0 mL	1×1.0 mL
Control Material (High)	0.1M PB, 0.05 % ProClin™ 300	1×1.0 mL	2×1.0 mL	1×1.0 mL	1×1.0 mL
Control Material (Low)	0.1M PB, 0.05 % ProClin™ 300	1×1.0 mL	2×1.0 mL	1×1.0 mL	1×1.0 mL

The assignment of calibrators value complies strictly with ISO 17511:2020, and this method can be traceable to Roche Elecsys Estradiol III.

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:

- Auffer, 480 mL, 6×480 mL
- Buffer, 480 mL, 6×480 mL
- Concentrated Washing Buffer
- Assay Cup

Additional materials for Automated ECL Immunoassay Analyzer eCL9000, eCL9000i, eCL9600, eCL9900, eCL9900i:

- Auffer, 2 L
- Buffer, 2 L
- Concentrated Washing Buffer
- Assay Cup, reaction cup
- Disposable Sampling Tips, pipette tips
- PreClean, system wash solution
- Waste Bags, litter bags

【Storage and Shelf Life】

Unopened reagent rackpack, calibrators and control materials should be placed at 2~8ºC and will be valid for 12 months.

The reagent can be stored in the machine (4~15ºC) for 28 days.

Opened reagents, calibrators and control matirials should be used and stored at 2~8ºC in 28 days, otherwise trashed.

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

Damaged, expired or contaminated reagents should be discarded.

【Applicable Instrument】

Automated ECL Immunoassay Analyzer: eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL9000, eCL9000i, eCL9600, eCL9900, eCL9900i.

【Specimen collection, handling and storage】

Human serum and plasma added with heparin lithium and EDTA-2K, EDTA-3K, 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 would better to be tested in 12 hours after collection, otherwise, should be stored 2~8ºC for no more than 2 days or -25~-15ºC, 180 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 E2 test according to the operational manual.

Put the E2 rackpack into the correct analyzer slot to automatically suspend magnetic beads at least 30 min before testing.

The sample volume required for each E2 test is 25 μL.

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) When using a new lot of reagent;

(2) When the same lot of reagents has been used on the analyzer for more than 28 days;

(3) If the quality control result exceeds the defined limit;

(4) When changing the buffers of different lot numbers.

Quality control

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 within 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 pmol/L, pg/mL, ng/L.

Conversion relation: pmol/L × 0.272 = pg/mL (ng/L); pg/mL × 3.67 = pmol/L; pg/mL × 0.00367 = nmol/L

Specimen dilution

Samples with E2 concentrations above the measuring range would be manually diluted with E2-negative serum.

The recommended dilution ratio is 1:10. After manual dilution, multiply the result by the dilution factor.

【Biological reference interval】

According to serum test results of 985 asymptomatic human , the reference range of the E2 assay kit was calculated by using the statistical method from the 2.5th percentile to the 97.5th percentile as shown in the table below.

Population	E2 (pg/mL)				
	number	age	2.5 percentile	median	97.5 percentile
Healthy men	120	17~72	23.8	38.41	60.21
Follicular phase	126	15~40	10.30	59.01	229.88

Oviposit period	121	17~42	40.59	131.54	394.98
Luteal phase	123	19~41	19.64	108.47	337.77
Menopause	130	50~74	<5.0	<5.0	134.49
Early pregnancy	125	24~37	158.7	858.3	3288
Middle pregnancy	120	22~38	1580	7759	21445
Late pregnancy	120	22~35	8583	17968	>30000

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 5~3000 pg/mL. For samples with E2 contents below the lower detection limit, the results are reported in < 5 pg/mL. If the E2 contents is above the upper detection limit, then the sample should be diluted and re-tested. The results are reported after multiplying with the dilution factor.

When the sample containing bilirubin ≤ 66 mg/dL, lipid ≤ 1000 mg/dL, hemoglobin ≤ 100 mg/dL, biotin ≤ 45 ng/mL, total protein concentration ≤10g /dL interference deviation to the test result lies within ± 10%. When the RF concentration in the sample is ≤1200 IU/mL, the relative recovery of the test results is between 90% and 110%.

【Analytical Performance】

Detection Limit

5 pg/mL.

Accuracy

measuring the metrologically traceable accuracy control materials, the relative deviation between the measured value and the theoretical value shall not exceed ±15.0%

Linearity

The correlation coefficient (Pearson's r) is not less than 0.9900 in the interval of 5~2200 pg/mL.

Within-run imprecision (repeatability)

The coefficient of variation (CV) is no more than 7.5%.

Between-lot imprecision

The coefficient of variation (CV) is no more than 10%.

Analytical specificity

Test the following analog-additive blank samples, the cross reactivity is as follows:

Analog	Concentration	Cross-reactivity
Aldosterone	1.0×10^5 pg/mL	≤0.01%
Androstenedione	1.0×10^5 pg/mL	≤0.01%
E3	1.0×10^5 pg/mL	≤1.0%
Pregnenolone	1.0×10^5 pg/mL	≤0.01%
PROG	1.0×10^5 pg/mL	≤0.01%
17α-Hydroxyprogesterone	1.0×10^5 pg/mL	≤0.01%
Hydrocortisone	2.0×10^5 pg/mL	≤0.01%
Cortisone	2.0×10^5 pg/mL	≤0.01%
TESTO	1.0×10^7 pg/mL	≤0.01%
Ethinylestradiol	5.0×10^4 pg/mL	≤0.01%
17α-Estradiol	1.0×10^5 pg/mL	≤0.01%

Calibrator, control material uniformity

In-bottle uniformity: coefficient of variation (CV) ≤ 10%.
Uniformity between-bottle: coefficient of variation (CV) ≤ 10%.

Biosafety

The results of HBsAg, HIV antibody and HCV antibody of calibration and quality control products in the kit should be negative.

【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. The preservative ProClin™ 300 will be harmful if inhalation, contact with skin and/or swallow, and may be toxic to aquatic organisms. Abandoned reagents should be dealed with in compliance with local regulations.

【Symbol】

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

【Manufacturer】

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【Version and Revision】

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