Instruction For Use

【Product Name】

Testosterone (Electrochemiluminescence Immunoassay)

【Order Information】

REF NO.	Package Size
697035	50T
697036	2×50T
697037	100T
697038	2×100T

【Intended Use】

Immunoassay for in vitro quantitative determination of testosterone in human serum and plasma. Clinically used for the auxiliary diagnosis of diseases with abnormal level of testosterone.

【Test Principle】

Competitive principle. Total duration of assay: 18 minutes.

20 µL of sample and the ruthenium (Ru) complex-labeled testoterone derivative compete to bind biotin-labeled testosterone antibody,an immune response occurs to form an antibody-antigen compounds. After addition of streptavidin-coated micro magnetic beads, the compounds bind to the micro beads via interaction of biotin and streptavidin.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 batch of reagent components should not be used interchangeably.

Components	Ingredients	Volume (50T)	Volume (2×50T)	Volume (100T)	Volume (2×100T)
Magnetic Beads (MB)	Streptavidin-coated microparticles,0.75 mg/mL; 100 mM PBS; 0.05% ProClin300	1×1.8 mL	2×1.8 mL	1×3.5 mL	2×3.5 mL
Reagent B (RB)	TESTO-Ab~Biotin: 200ng/mL，0.1M PBS, 0.05 % ProClin™ 300	1×2.8 mL	2×2.8 mL	1×5.5 mL	2×5.5 mL
Reagent A (RA)	TESTO~Ru(bpy)$^{2+}_{3}$:40ng/mL, 0.1M PBS, 0.05 % ProClin™ 300	1×3.8 mL	2×3.8 mL	1×7.5 mL	2×7.5 mL
Calibrators	0.1M PBS, 1.5% BSA, 0.05 % ProClin™ 300	High: 1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	0.1M PBS, 1.5% BSA, 0.05 % ProClin™ 300	High: 1×1.0 mL Low: 1×1.0 mL			

Traceability：This method can be traceable to Roche Elecsys Testosterone II.

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, 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 and heparin lithium anticoagulant blood collection tubes.

Samples should be collected in accordance with the standard operation of Word Health Organization guidelines for blood collection. 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 would better to be tested in 8 hours after collection at room temperature (18~28ºC), otherwise, should be stored 2~8ºC for no more than 7 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 TESTO test according to the operational manual.

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

Recommended test 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

For quality control, use TESTO 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 can be set as ng/mL, ng/dL or nmol/L.

Conversion factors: ng/mL × 3.47 = nmol/L

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ng/mL × 100 = ng/dL
nmol/L × 0.288 =ng/mL

【Biological reference interval】

According to serum test results of 625 healthy human (males 344, females 281), biological reference interval was shown as flow:

Sex	Age	Testosterone (ng/mL)	
		Number	5-95%
Male	Male < 50	221	2.488~8.363
	Male ≥ 50	123	1.930~7.405
Female	Female < 50	161	0.084~0.480
	Female ≥ 50	120	0.029~0.408

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 0.025~15 ng/mL. Values below the lower detection limit are reported as < 0.025 ng/mL. Values above the measuring range are reported as > 15 ng/mL.

When the sample containing bilirubin ≤ 30 mg/dL, triglyceride ≤ 1000 mg/dL, hemoglobin ≤ 0.6 g/dL, biotin ≤ 30 ng/mL, interference deviation to the test result lies within ±10%. When the RF concentration in the sample is ≤ 1000 IU/mL, the relative recovery of the test results is between 90% and 110%.

【Analytical Performance】

Lower Limits of measurement

Lower detection limit is 0.025 ng/mL .

Accuracy

When measuring the appropriate concentration of the added sample, the recovery rate should be in the range of 90% to 110%. Or the ratio between resulting value and target value lies between 0.900 and 1.100 by measuring the metrologically traceable trueness control materials.

Linearity

The correlation coefficient (Pearson's r) is not less than 0.9900 in the interval of 0.025~15 ng/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

Following cross-reactivities to analogues were found:

Analog	Concentration (ng/mL)	Cross-reactivity
Dehydroepiandrosterone	100000	≤ 0.1%
Androsterone	1000	≤ 0.01%
Hydrocotisone	1000	≤ 0.01%
Estradiol	1000	≤ 1.0%
Estrone	1000	≤ 0.01%
Progesterone	100	≤ 0.01%
5-α-Dihrdrotestosteronesterone	100	≤ 5.0%
Danazol	1000	≤ 1.0%
Dexamethasone	1000	≤ 0.01%
17α-Methyltestosteronesterone	1000	≤ 5.0%
Norethindrone	5	≤ 5.0%
Androstendione	500	≤ 5.0%
D-5-Androstene-3β,17β-diol	1000	≤ 5. 0%
Cortisone	1000	≤ 0.01%
Estriol	100	≤ 0.1%
11-Deoxycortisol	1000	≤ 0.1%

Calibrator , control material uniformity

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

Method comparison

A comparison of the Lifotronic TESTO assay (y) with the Roche Elecsys testosterone II Method (x) using clinical samples gave the following correlations:
Number of paired values: 219
Linear regression:
y=0.982x+ 0.0082
r = 0.9961
The sample concentrations were between approx 0.03 and 14.23 ng/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. Nieschlag E, Behre HM. Testosterone Action, Deficiency, Substitution. Cambridge University Press, 2004. ISBN 0 521 83390 9.
2. Rosner W, Auchus RJ, Azziz R et al. Utility, Limitations, and Pitfalls in Measuring Testosterone: An Endocrine Society Position Statement. J Clin Endocrinol Metab 2007; 92: 405-413.
3. Vermeulen A, Verdonck L, Kaufman JM. A critical evaluation of simple methods for the estimation of free testosterone in serum. J Clin Endocrinol Metab 1999;84:3666-3672.

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