Instruction For Use

【Product Name】

PROG STAT (eCLIA)

【Order Information】

REF NO.	Package Size
0320510601	50 T
0320510602	2×50 T
0320510603	100 T
0320510604	2×100 T

【Intended Use】

Immunoassay for the in vitro quantitative determination of progesterone (PROG) in human serum and plasma. Determination of PROG is used for auxiliary diagnosis of threatened abortion in clinical practice.

【Summary】

Progesterone is a steroidal hormone with a molecular weight of 314.5 Da, which is mainly formed in luteal cells and in the placenta during pregnancy. The secretion of progesterone changes periodically. During the follicular phase of the menstrual periods, progesterone is at low levels. An increase in progesterone levels can be observed the day before ovulation. In the post-ovulatory luteal phase, the progesterone produced by the corpus luteum rises rapidly and peaks 4 to 7 days after ovulation. After 4 to 6 days of maintenance, it falls to baseline levels, including menstrual periods[1-2]. Clinical studies have demonstrated that progesterone plays a role in promoting ovulation and maintaining the normal function of the luteum in non-pregnant women. If the luteum produces insufficient progesterone, it may indicate the presence of luteal insufficiency (LPD), suggesting infertility and early miscarriage[3-4]. During the first ten weeks of pregnancy, the level of progesterone in the serum is maintained at a relatively peak level, and after 10 weeks of pregnancy, the level of progesterone slowly rises until the full term of pregnancy. Clinically, progesterone values can be used as an indicator of early miscarriage and as a monitoring indicator of progesterone supplementation during miscarriage treatment. Decreased levels of progesterone in early pregnancy suggest luteal insufficiency or abnormal embryonic development, or both.

【Test Principle】

Competitive principle. Total duration of assay: 9 minutes.

20 µL sample was incubated with biotinylated monoclonal PROG antibody. The binding sites of the labeled antibody become occupied by the sample analyte (depending on its concentration). After addition of streptavidin-coated microparticles and PROG antigen labeled with ruthenium, 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 lots cannot be used at the same time or mixed up together.

Components	Ingredients	Volume (2×50T)	Volume (50T)	Volume (100T)	Volume (2×100T)
Magnetic Beads (MB)	Streptavidin-coated microparticles, 0.3mg/mL; ProClin300	2×1.5 mL	1×1.5 mL	1×3.0 mL	2×3.0 mL
Reagent B (RB)	Biotinylated monoclonal PROG antibody; 25 mM PBS; ProClin300	2×3.5 mL	1×3.5 mL	1×7.0 mL	2×7.0 mL
Reagent A (RA)	PROG antigen labeled with ruthenium;25 mM PBS; ProClin300	2×2.5 mL	1×2.5 mL	1×5.0 mL	2×5.0 mL
Calibrators	PROG antigen; 25 mM PBS; ProClin300	High: 1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	PROG antigen; 25 mM PBS; ProClin300	High: 1×1.0 mL Low: 1×1.0 mL			

The calibration process of this kit can be traced to manufacturer's selected measurement procedures.

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.

Damaged, expired or contaminated reagents should be discarded.

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

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

Stability of the calibrators and control materials	
Unopened at 2~8ºC	18 months
Store at 2~8ºC after opening	8 weeks

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

【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 human serum samples or plasma samples collected with EDTA-K3, EDTA-K2, Heparin lithium, Heparin sodium 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 24 hours at room temperature (18~28ºC), 5 days at 2~8ºC, and 6 months at -15ºC or below. Freezing and thawing can be performed 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 PROG STAT test according to the operational manual.

Put the PROG STAT reagent pack into the correct analyzer slot to automatically suspend magnetic beads at least 30 min before testing.

Recommended ambient temperature: 10ºC~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 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.

(4) The Buffer of different lots are used.

Quality control

For quality control, use PROG STAT 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 nmol/L, ng/mL, μg/L.

Conversion factors: nmol/L ×0.314 = ng/mL (μg/L)
ng/mL × 3.18 = nmol/L

Specimen dilution

Samples exceeding the measuring range would be manually diluted with sample dilution. It is recommended to dilute at 1:10 (by instrumental automatic dilution or manual dilution). If diluted manually, the result need to multiply dilution ratio. If diluted automatically, the instrument will calculate the result.

【Biological Reference Interval】

A reference interval of 5%-95% was calculated by testing 1048 healthy humans (men 128; non-pregnant women 526; pregnant women 394) :

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

Subject		Number	PROG (ng/mL) 5%~95% confidence interval
Healthy men		128	0.212～1.290
Healthy non-pregnant women	Follicular phase	126	0.213～1.456
	Ovulation phase	145	0.843～2.736
	Luteal phase	131	1.726～24.65
	Postmenopause	124	0.122～0.725
Healthy pregnant women	1st trimester	146	12.46～41.55
	2nd trimester	125	24.05～79.15
	3rd trimester	123	61.85～198.5

【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 blank limit of the kit is 0.02 ng/mL, and the detection range is 0.02~60 ng/mL. If the PROG concentration in the sample is lower than the lower limit of detection, the result is reported as 0.02 ng/mL. If the PROG concentration in the sample is higher than the upper limit of detection, the result is reported as ＞60 ng/mL.
When jaundice (bilirubin) is ≤ 54 mg/dL, hemolysis (hemoglobin) is ≤ 1 g/dL, lipemia (triglyceride) is ≤ 720 mg/dL, biotin is ≤ 30 ng/mL, albumin is ≤ 10 mg/mL, the interference deviation of the measured results is within ±10%. When the concentration of rheumatoid factor in the sample is ≤ 1200 IU/mL, the relative recovery of the test results is between 90% and 110%.
Cortisol (10 ng/mL) and 17α-hydroxyprogesterone (10 ng/mL) are added to the sample containing the target concentration of 20 ng/mL (allowable relative deviation of ±15%) progesterone, respectively. The mean measurement results of each sample should be within the range of the mean (M) ±2 standard deviation (SD) of the target concentration.

【Analytical Performance】

Lower Limits of Measurement

Limit of Blank = 0.02 ng/mL.
Limit of Detection is 0.1 ng/mL.

Accuracy

The relative deviation shall not exceed ±10%.

Linearity

The correlation coefficient is not less than 0.9900 in the interval of 0.1 ~ 60 ng/mL.

Within-run precision (repeatability)

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

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 8.0%.

Accuracy of calibrators

The relative deviation shall not exceed ±10%.

Measured values of quality control

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 PROG STAT assay (y) with the Lifotronic PROG reagent kit (x) using clinical samples gave the following correlations:
Number of plasma samples measured: 178
Linear regression:
y=1.0189x-0.0241
r = 0.991
The sample concentrations were between 0.00 and 58.98 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.

【Literature References】

1. Chattoraj SC, Watts NB. Endocrinology. In: Tietz NW, editor. Fundamentals of clinical chemistry. Philadelphia: WB Saunders 1987;P:575.
2. Filicori M, Butler JP, Crowley WF Jr. Neuroendocrine regulation of the corpus luteum in the human. J Clin Invest 1984;73:1638−47.
3. Goldstein D, Zuckerman H, Harpaz S, et al. Correlation between estradiol and progesterone in cycles with luteal phase deficiency. Fertil Steril 1982;37(3):348−54.
4. Mais V, Cetel NS, Muse KN, et al. Hormonal dynamics during luteal-follicular transition. J Clin Endocrinol Metab 1987;64:1109−14.

【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】

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【Version and Revision】

Version: 2.0
Issue Date: 2025-03-04