Finecare™

Progesterone Rapid Quantitative Test

Catalog No.: W233

INTENDED USE

The Finecare™ Progesterone Rapid Quantitative Test is a fluorescence immunoassay used along with Finecare™ FIA System for quantitative determination of progesterone concentration in human whole blood, serum or plasma specimen. The test is used as an aid to track ovulation, monitor the effect of progesterone therapies and in early pregnancy to help diagnose an ectopic or failing pregnancy.

For in vitro diagnostic use only. For professional use only.

SUMMARY

Progesterone is a female hormone produced by the ovary. It is important for the regulation of ovulation and menstruation of human.
During the follicular phase of the menstrual cycle, progesterone levels remain low. Following the LH surge and ovulation, luteal cells in the ruptured follicle produce progesterone in response to LH thus the progesterone level rises rapidly at day 5-7 following ovulation. During the luteal phase, progesterone transforms the estrogen-primed endometrium from a proliferative to a secretory state. If pregnancy does not occur, progesterone levels decrease during the last four days of the cycle.
If the conception occurs, during the first trimester the ovaries will produce progesterone maintaining at mid-luteal level to help build and maintain the lining of the uterus to allow a fertilized egg to implant until the placenta takes over the function around the 9-10th week of pregnancy.

PRINCIPLE

This test employs a quantitative competitive fluorescence immunoassay technique. A competitive binding assay is based upon the competition of labeled and unlabeled analyte for a limited number of antibody binding sites.
Unbound antibodies and immunocomplexes migrate along the nitrocellulose membrane forward to the Test line. The unbound antibodies are then captured by antigens immobilized on the Test line. The more progesterone in the patient specimen, the more immnocomplexes are formed, thus the less fluorescent-labeled antibodies captured on the test line. The fluorescent signal intensity reflects the amount of progesterone captured and is processed in Finecare™ FIA System. The progesterone concentration is expressed in ng/mL.

PRECAUTIONS

1. This kit is for *in vitro* diagnostic use only. Do not swallow.
2. Lot Number of all the test components (test device, ID chip and buffer) must match each other. Do not mix components from different kit lots.
3. Inspect the packaging and labels before use. Do not use if the pouch is broken, torn or not well sealed, or the vial looks damaged or leaked.
4. Carefully follow the instructions and procedures described in this insert.
5. Do not use the test device beyond the expiration date. The test device must remain in its original sealed pouch until ready to use.
6. A buffer tube should be used for processing one sample only.
7. The operation shall be conducted away from vibration and magnetic field. Finecare™ FIA System may generate minute vibration during use, which should be regarded as normal.
8. One pipette tip should be used for one specimen only.
9. Do not touch the test area of the test device
10. All specimens and used test materials are considered as potentially infectious. The used pipette tips, buffer tubes, test devices and specimens must be handled carefully and disposed of in accordance with local regulations and procedures.

MATERIAL

Materials Provided

Each box contains:
1. 25 individual sealed pouches, each containing:
   - a test Device
   - a desiccant pouch
2. One Test Device ID Chip
3. Instructions for Use
4. 25 tubes of buffer

Materials Required But Not Provided

1. Finecare™ FIA System
2. Transfer Pipette
3. Timer
4. Centrifuge

STORAGE AND STABILITY

1. Store the test kit at 4 ～ 30℃ up to the expiration date.
2. Once the pouch is opened, the test should be performed within an hour.
3. If removed from refrigerator, allow the test for 30 minutes to attain room temperature before testing.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with either serum, plasma or whole blood.

For Whole Blood:

1. Following standard phlebotomy venipuncture procedure, collect whole blood specimen in anticoagulant. Sodium Heparin tubes are recommended.
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2℃～8℃.
3. It' s not suitable to test the whole blood samples which have been stored at 2℃ ～ 8℃ for more than 48 hours.

For Plasma or Serum:

1. Following standard phlebotomy venipuncture procedure, collect whole blood specimen using a blood collection tube.
   If plasma sample will be used, Sodium Heparin tubes are recommended for sample collection. If serum sample will be used, use a serum separator tube.
2. Separate serum or plasma from blood after blood collection. If serum sample will be used, ensure that complete clot formation has taken place prior to centrifuge. If a specimen appears to be severely hemolyzed, another specimen should be obtained and tested.
3. Optimally, the test should be performed immediately after the specimen collection. If the test cannot be performed within 2 hour after blood collection, store the specimen at 2℃～ 8℃ for no longer than 48 hours. For long-term storage, specimens shall be kept below -20℃.

Bring all materials to room temperature before use. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolyzed specimens can be used.

TEST PROCEDURE

Refer to Finecare™ FIA System Operation Manual for complete instructions for use of the Test device.

1. Set a Test Device on a clean, level horizontal place.
2. Make sure that the Test Device lot No. matches with ID Chip No. Insert ID Chip into the meter. Be aware not to touch the insertion tip of the ID chip.
3. Pipette 75μl of prepared sample into the buffer, gently mix well. Vigorous agitation and foaming should be avoided.
4. Pipette 75μl of mixed sample to add into the sample of the test device. Avoid forming bubbles.
5. Please refer to the Operation section in Operation Manual for details.
   a) Quick Test mode: start the timer right after adding the sample mixture to the sample well. Leave the Test Device at room temperature for 15 minutes. Then insert test device immediately onto the holder of the meter and click Test. The instrument will scan the Test Device automatically and show the test result.
   b) Standard Test mode: insert the Test Device into the device holder of the Meter right after adding the sample to the sample well, click Test. The meter will start to countdown and read the test result automatically.
6. Results are displayed on the main screen or be printed by click Print.
7. Discard the used Test Device and other materials according to local regulations and procedures after released from the meter.

Traceability: The Finecare™ Progesterone Rapid Quantitative Test is traceable via ID-GC/MS to the international reference material ERM-DA347.

INTERPRETATION OF RESULTS

1. The Finecare™ FIA System calculates progesterone test results automatically and displays the concentration of progesterone on the screen right after correctly adding the sample to the sample well for 15 minutes. For further information, refer to the Operation Manual for the Finecare™ FIA System.
2. Finecare™ FIA System will prompt "No Sample or sample volume insufficient!" when insufficient sample volume or liquid is not fully crawled across the test line, then recommends adding sample again.

QUALITY CONTROL

Each Finecare™ Progesterone Rapid Quantitative Test contains an internal control for routine quality control requirements. This internal quality control is performed each time a patient sample is tested, If an invalid result from the internal control occurs, the meter will display an error message, indicating that another test should be conducted.

LIMITATIONS OF PROCEDURE

1. This test is developed for testing human whole blood, serum or plasma specimen.
2. The results of Finecare™ Progesterone Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If test results do not agree with the clinical evaluation, additional tests should be performed accordingly.
3. The false positive results include cross-reactions with some components of blood from individual to antibodies; and non-specific adhesion of some components in human blood that have similar epitopes to capture and detector antibodies. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of progesterone antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The performance of the test is highly sensitive to the storage and handling conditions of kits and sample specimens at optimal conditions.
4. There is the possibility that factors such as technical or procedural errors, as well as additional substances in blood specimens that are not listed in the Cross-Reactivity section, may interfere the test and cause erroneous results.

INTERPRETATION

Reference range of Progesterone in human blood:

Gender	Phase	(ng/mL)
Male	--	0.2-1.5
Female	Follicular Phase	0.2-2.0
	Ovulatory Phase	0.7-3.5
	Luteal Phase	3.0-30.0
	Postmenopausal	0.1-0.9
	7th Week of Pregnancy	24.5±7.6
	9-12th Week of Pregnancy	38.0±13.0

Each Laboratory should establish a reference range that is representative of the population to be evaluated.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study using 232 human serum samples demonstrated good correlation with Roche Elecsys Progesterone II Immunoassay on Cobas e Analyzers (R2>0.95).

Detection Limit

The detection limit of this test device is 1.5ng/mL

Detection Range

The detection range is 1.5~60 ng/mL.

Precision

Intra-Lot Precision: CV≤15%
To study intra-lot precision, 10 replicates of each of three concentrations were tested from a single lot.

Inter-Lot Precision: CV≤15%
To study inter-lot precision, 10 replicates of each of three concentration of control reagent were tested from 3 different lots.

Linearity

The Finecare™ Progesterone Rapid Quantitative Test is linear from 1.5~60 ng/mL. Samples were tested at 5 concentration levels for three times, the correlation coefficient is ≥0.990.

Interference and Cross-Reactivity

The following cross-reactivities at the indicated concentrations were found not detectable in a sample that did not contain the analyte of interest:

Cross Reactivity Materials	Concentration（ng/mL）
Estradiol	800
17β-estradiol	800
Estriol	800
Estrone	800
Hydrocortisone	800
corticosterone	600
Aldosterone	600
Testoterone	1000
Ethinylestradiol	1000
Ethisterone	1000
Norethindrone	1000
Hydroxyprogesterone acetate	1000
Altrenogest	1000
Testoterone Propionate	1000
Danazol	800

The following substances do not interfere with the Progesterone test result under the indicated concentrations:

Interfere Material	Concentration
Hemoglobin	1000 mg/mL
Bilirubin	0.5 ng/mL
Triglyceride	4ng/mL
Rheumatoid factor	2000IU/mL

INDEX OF SYMBOLS

1. Ulrich Westphal, Stephen D. Stroup and Su-Li Cheng. (1977), Progesterone Binding To Serum Proteins. Annals of the New York Academy of Sciences, 286:10-28.
2. Qi Lu, Yuhong Li, Hong Shi, Xiao Lang, Yudong Wang. The value of ratio of hCG, progesterone in local blood of pregnancy location versus venous blood in the diagnosis of ectopic pregnancy. Int J Clin Exp Med, 2015 Jun 15; 8(6): 9477-9483
3. Bernd R. Gardill, Michael R. Vogl, et al. Corticosteroid-Binding Globulin: Structure-Function Implications from Species Differences. PLoS ONE,2012, 7 (12): e52759.
4. D. L. Willcox and N. W. Bruce. Protein binding of progesterone in rat plasma. J.Reprod.Fert,1983, 68: 105-112.
5. ULRICH WESTPHAL AND BILLY D. ASHLEY. Steroid-Protein Interactions . Steroid-Protein Interactions, 1958, 233(1): 57-62.
6. Manik Ganguly, Robert H. Carnighan, Ulrich Westphal. Steroid-Protein Interactions. XIV. Interaction between Human Alpha-Acid Glycoprotein and Progesterone. BIOCHEMISTRY, 1967, 6(9): 2803-2814.

INDEX OF SYMBOLS

IVD *In Vitro* Diagnostic Use	See Instruction for Use	Expiry Date
Tests per Kit	Manufacturing Date	Keep Dry
LOT Batch Number	EC REP Authorized Representative	Keep away from Sunlight
30°C 4°C Store between 4～30℃	Do not reuse	REF Catalog #

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