Finecare™

FSH Rapid Quantitative Test

Catalog No. W245

INTENDED USE

The Finecare™ FSH Rapid Quantitative Test is a fluorescence immunoassay used along with Finecare™ FIA System (Model No.: FS-112 / FS-113 / FS-205) for quantitative measurement of follicle-stimulating hormone (FSH) in human whole blood, serum or plasma.
This test used as an aid to evaluate the ovarian functions in clinical.

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

SUMMARY

Follicle-stimulating hormone (FSH) is the core hormone in the reproductive process of mammal. Follicle-stimulating hormone (FSH) and luteinizing hormone (LH) cooperatively regulate the physiological process such as development and reproduction. Basal FSH reflects the secretory function of ovary and is an important index to evaluate the ovarian function clinically.

PRINCIPLE

The Finecare™ FSH Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ FSH Rapid Quantitative Test uses a sandwich immunodetection method. When sample is added into the sample well of the Test Cartridge, the fluorescence-labeled detector anti-FSH antibodies on the sample pad bind to FSH antigens in blood specimen and they form immune complexes. As the complexes migrate on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibodies and FSH are captured to anti-FSH antibodies that have been immobilized on test strip. Thus the more FSH antigens in blood specimen, the more complexes accumulated on test strip. Signal intensity of fluorescence of detector antibodies reflects the amount of captured FSH.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Carefully follow the instructions and procedures described in this insert.
3. Lot number of all the test components (Test Cartridge, ID Chip and Detection Buffer) must match with each other.
4. Do not interchange the test components from different lots or use the test components beyond the expiration date printed on package.
5. The Finecare™ FSH Rapid Quantitative Test kit is only operated in Finecare™ FIA System. Tests should be applied by professionally trained staff working in certified laboratories and clinics at which the sample(s) is taken by qualified medical personnel.
6. The Test Cartridge should remain in its original sealed pouch until use. Do not use the Test Cartridge if the pouch is damaged or already opened.
7. A Detection Buffer vial and Pipette Tip should be used for processing one sample only. Similarly a Test Cartridge should be used for testing one processed sample only. Both the Detection Buffer vial as well as the test cartridge should be discarded after single use.
8. The Test Cartridge and Finecare™ FIA System should be used away from vibration and/or magnetic field. During normal usage, the Test Cartridge may produce minor vibrations which should be regarded as normal.
9. Do not smoke, eat, or drink in the areas where specimens or test reagents are being handled.
10. Blood specimens, used Test Cartridges, Pipette Tips and Detection Buffer vials are potentially infectious. They should be handled carefully and disposed of by an appropriate method in accordance with relevant local regulations.
11. The Finecare™ FSH Rapid Quantitative Test should be interpreted by the physician along with clinical findings and other laboratory test results.
12. The test should be applied on a routine basis but not in emergency situations.

MATERIAL

Material Provided

Components of Finecare™ FSH Rapid Quantitative Test:

■Test Cartridge	25
■ ID Chip	1
■ Detection Buffer	25
■ Pipette Tip	25
■ Leaflet with Instructions for Use	1

Material Required But Not Provided

■Finecare™ FIA System
■Transfer Pipette Set (100 µL size)
■Specimen Collection Containers
■Centrifuge (for serum/plasma specimen only)
■Timer

STORAGE AND STABILITY

1. Store the test kit at 4℃~30℃ up to the expiration date printed on package.
2. If removed from refrigerator, allow the test kit for 30 minutes to return to room temperature before testing.
3. Do not remove the Test Cartridge from the pouch until use. The Test Cartridge should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

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

For Whole Blood Collected by Venipuncture

1. According to standard phlebotomy procedure, collect a venipuncture whole blood specimen with a blood collection tube which contains suitable anticoagulant (EDTA).
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged period. If the specimens are not tested immediately, they should be kept at 2℃~8℃.
3. It is not suitable to test the whole blood specimen which have been kept at 2℃~8℃ for more than 2 days.

For Serum and Plasma:

1. According to standard phlebotomy procedure, collect a venipuncture whole blood specimen. If you need to collect plasma, please use a blood collection tube which contains suitable anticoagulant (EDTA).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.

Test should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged period. Specimens should be kept at 2℃~8℃ for up to 7 days. For long time storage, specimens should be kept below -20℃.

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

TEST PROCEDURE

For complete information and operating procedures, please refer to Finecare™ FIA System Operation Manual. Test should be performed at room temperature.

Step 1: Preparation

Before testing, activate “use” in setting then save it.
Ensure that the lot number of the Test Cartridge matches ID Chip as well as the Detection Buffer. Insert ID Chip into Finecare™ FIA System.

Step 2: Sampling

Draw 75 µL of whole blood or serum or plasma with a transfer pipette and add into the Detection Buffer tube.

Step 3: Mixing

Close the lid of Detection Buffer tube and mix the sample mixture thoroughly by shaking it about 10 times.

Step 4: Loading

Pipette 75 µL of sample mixture and load it into the sample well of the Test Cartridge.

Step 5: Testing

There are two test modes for Finecare™ FIA System, Standard Test mode and Quick Test mode. Please refer to the Operation Manual of Finecare™ FIA System for details.

a) **For Standard Test mode:** Insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA System right after adding sample mixture to the

sample well. Press “Test” to start testing. (Apply to FS-112, FS-113 and FS-205).

b) **For Quick Test mode:** Set the timer and count down right after adding sample mixture into the sample well and leave it at room temperature for 15 minutes. Then insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA System. Press “Test” to start testing. Finecare™ FIA System will start scanning the sample-loaded Test Cartridge immediately. (Apply to FS-112 and FS-113).

Results are displayed on main screen or be printed by press “**Print**” .

Discard the used Test Cartridge according to local regulations and procedures after released from Finecare™ FIA System.

INTERPRETATION OF RESULTS

The Finecare™ FIA System calculates FSH test results automatically and displays the exact concentrations of FSH on the screen as form of XXX mIU/mL. For further information, please refer to the Operation Manual for the Finecare™ FIA System.

The reference interval of FSH is as following:

Gender	Period	Normal concentration(mIU/mL)
Male	/	1.50~12.40
Female	Follicular period	4.46~12.43
	Ovulation period	4.88~20.96
	Luteal phase	1.96~7.70
	Menopause phase	22.70~130.00

Note: This reagent reference interval is established only for clinical trial samples, due to geographical, ethnic, gender and age differences, it is recommended that the laboratory to establish their own reference interval.

QUALITY CONTROL

Each Finecare™ FSH Rapid Quantitative Test Cartridge contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the Test Cartridge was inserted and read properly by Finecare™ FIA System. An invalid result from the internal control causes an error message on Finecare™ FIA System indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum, plasma specimen only.
2. The test procedure, precautions and interpretations of results for this test must be followed when testing.
3. The results of Finecare™ FSH Rapid Quantitative Test should be evaluated with all available clinical and laboratory data.
4. The false positive results include cross-reactions with some components of serum 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 FSH antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.
5. Other factors may interfere with Finecare™ FSH Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparative study is tested for 225 clinical samples in using Finecare™ FSH Rapid Quantitative Test and Roche Elecsys® FSH test. The Correlation Coefficient (R) is 0.9929.

Specificity

When the concentration of LH does not less than 200 IU/L, the testing result of reagents ≤1 mIU/mL.

When the concentration of TSH does not less than 200 mIU/L, the testing result of reagents ≤1 mIU/mL.

When the concentration of HCG does not less than 1000 IU/L, the testing result of reagents ≤1 mIU/mL.

Assay Range and Detection Limit

- Assay Range: 1 mIU/mL~100 mIU/mL
- Detection Limit: 1 mIU/mL

Linearity

A serial concentration of cortisol controls from 1 mIU/mL~100 mIU/mL were tested for three times each with the same batch Test Cartridges, the Correlation Coefficient (R) is ≥0.9900.

Precision

Intra-Lot Precision:

Determined by using 10 Test Cartridges in the same batch to test with FSH control. C.V. is ≤15%.

Inter-Lot Precision:

Determined by using 3 Test Cartridges in 3 random and continuous batches to test with FSH control. C.V. is ≤15%.

BIBLIOGRAPHY OF SUGGESTED READING

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2. Wilkinson JM, Grand RJA. Comparison of Amino Acid Sequence of Troponin I from Different Striated Muscles. Nature 1978; 271:31-35.
3. Wade R, Eddy R, Shows TB, Kedes L. cDNA Sequences, Tissue-Specific Expression and Chromosomal Mapping of the Human Slow-Twitch Muscle Isoform of Troponin I. Genomics 1990; 7:346-357.
4. Cummins B, Auckland ML, Cummins P. Cardiac-specific troponin-I radioimmunoassay in the diagnosis of acute myocardial infarction. Am Heart J 1987; 113:1333-1344.
5. Fred S. Apple, Cardiac Troponin I. Cardiac Markers Humana Press Inc., Totowa, NJ 1998, pg. 229-243.
6. Bodor GS, Porter S, Landt Y, Landenson JH. Development of Monoclonal Antibodies for an Assay of Cardiac Troponin-I and Preliminary Results in Suspected Cases of Myocardial Infarction. Clin Chem 1992; 38(11): 2203-2214.

INDEX OF SYMBOLS

See Instruction for Use	Tests per Kit	Manufacturing Date
In Vitro Diagnostic Use	Expiry Date	Do not reuse
Store between 4～30℃	Batch Number	Catalog #
Keep away from Sunlight	Keep Dry	Authorized Representative
Manufacturer		