Finecare™ Testosterone Rapid Quantitative Test

Catalog No. W248-C4P1-E

INTENDED USE

The Finecare™ Testosterone Rapid Quantitative Test is a fluorescence immunoassay used along with Finecare™ FIA Meters (Model No.: FS-112, FS-113, FS-114 and FS-205) for quantitative measurement of Testosterone in human whole blood, serum or plasma. The test is to be used as an aid in the diagnosis of diseases related to abnormal testosterone levels.

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

SUMMARY

Testosterone is a C-19 steroid secreted from the testis and the adrenal cortex in men and from the adrenal cortex and the ovary in women. Testosterone is also produced by peripheral tissues from androstenedione.

The majority of circulating testosterone is bound to sex hormone binding globulin (66%) and with lower affinity to albumin (33%). The remaining 1% to 2% of testosterone is in a free, unbound state ("free testosterone"). The combination of free testosterone and albumin-bound testosterone is also referred to as the "bioavailable" forms of testosterone.

PRINCIPLE

The Finecare™ Testosterone Rapid Quantitative Test is a fluorescence immunoassay using a competitive method for quantitative analysis of Testosterone in human whole blood, serum or plasma. When the sample is added into the sample well of the test cassette, the fluorescence-labeled anti-Testosterone monoclonal antibodies on the sample pad bind to testosterone in blood specimen and form immune complexes. As the fluorescence-labeled anti-Testosterone monoclonal antibodies not bound to Testosterone migrate on the nitrocellulose membrane by chromatography, it can be captured by Testosterone-BSA conjugated antigens that have been immobilized on test line. Thus, the more testosterone is in blood, the less unbound fluorescence-labeled anti-Testosterone monoclonal antibodies are accumulated on test line. Signal intensity of fluorescence inversely reflects the amount of testosterone and Finecare™ FIA Meters show Testosterone concentrations in blood specimen. The default results unit of Finecare™ Testosterone Rapid Quantitative Test is displayed as XXX ng/mL from Finecare™ FIA Meters. The working range and the detection limit of the test system are 0.2~15 ng/mL and 0.2 ng/mL, respectively.

PRECAUTIONS

1. This kit is for *in vitro* diagnostic use only. Do not swallow.
2. The desiccant is for storage purposes only, not for using in the test procedures.
3. Do not mix components from different kit lots. Please make sure that test cassette, buffer and ID Chip are from the same lot before use.
4. Do not use test kit beyond the expiration date.
5. Protective measure should be taken when sample collection, handling, storage and mixing.
6. The Finecare™ Testosterone Rapid Quantitative Test is only operational in the Finecare™ FIA Meters (Model No.: FS-112, FS-113, FS-114 and FS-205). And 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.
7. The test cassette should remain in its original sealed pouch until ready to use. Do not use the test cassette if the pouch is punctured or not well sealed. Discard after single use.
8. The pipette tip and detector buffer tubes should be used for one specimen only. Discard after single use.
9. Disappearance of the blue line on the right of the result window of the test indicates the test cassette has been used.
10. The test cassette and Meter should be used away from vibration and magnetic field. During normal usage, the Test Device may introduce slight vibration, which should be regarded as normal.
11. Do not pull out the ID Chip when test is in procedure.
12. Bring the test kit to room temperature before open. Test should be performed in the required environment.
13. Do not insert the test in the meter when the cassette cover is bedewed with blood or other fluid. Or else, the meter may be damaged.
14. Do not use whole blood specimen when hemolysis or blood clot appears.
15. Do not smoke, eat, or drink in areas in which specimens or kits are handled.
16. Blood specimens, used test cassettes, pipette tips and detector buffer tubes are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
17. The Finecare™ Testosterone Quantitative Rapid Test should not be interpreted by the physician along with clinical findings and other laboratory test results.
18. The test will be applied on a routine basis and not in emergency situations.
19. According to the requirement of test procedure, the sample mixture of blood specimens and detection buffer cannot be diluted.
20. If you have questions or suggestions during the use of this reagent, please contact the manufacturer.

MATERIAL

Material Provided

1. 25 individual sealed pouches, each containing:
   - test device
   - desiccant pouch
2. One Test Device ID Chip
3. Leaflet with instructions for use
4. 25 Pipette Tips
5. 25 tubes of detector buffer

Reactive ingredients of main components

One test strip includes: nitrocellulose membrane coated the Testosterone-BSA conjugated antigen and chicken IgY antibody, sample pad containing fluorescence-labeled anti-Testosterone monoclonal antibody and fluorescence-labeled goat anti-chicken IgY antibody.

Material Required But Not Provided

1. Testosterone control material
2. Finecare™ FIA Meters (choose one of below):
   Finecare™ FIA Meter (Model No.: FS-112)
   Finecare™ FIA Meter Plus (Model No.: FS-113)
   Finecare™ FIA Meter II Plus SE (Model No.: FS-114)
   Finecare™ FIA Meter III Plus (Model No.: FS-205)
3. Transfer Pipette set
4. Specimen Collection Containers
5. Centrifuge (for serum/plasma specimen only)
6. Timer

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

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

For Whole Blood:

1. Following standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (EDTA is recommended).
2. It is recommended that whole blood specimen is tested at the time of specimen collection. Do not leave the specimens at room temperature for prolonged periods.
3. If the whole blood specimens are not tested within 4 hours, they could be stored at 2ºC ~8ºC for up to 2 days prior to testing.

For Serum and Plasma:

1. Following standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA is recommended).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
3. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
4. If the Serum or Plasma specimens are not tested within 8 hours, they could be stored at 2ºC ~ 8ºC for up to 7 days prior to testing. For long-term storage, specimens should be kept below -20ºC.

Note:

1) Other anticoagulants have not been validated and may give incorrect result.

2) 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. Severe hemolytic or heat-inactivated specimens are not recommended

TEST PROCEDURE

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

Step1: Preparation

Allow the test cassette, detection buffer and specimen to equilibrate to room temperature prior to testing. Take out the ID chip, and make sure that the test cassette lot number matches with ID Chip lot number. Insert ID Chip into the chip port of Meters. Be aware not to touch the insertion tip of the ID chip.

Step2: Sampling

Pipette 75 µL of whole blood or serum or plasma and add into the detection buffer tube.

Step3: Mixing

Close the lid of detection buffer tube and mix the sample mixture thoroughly by shaking it well.

Step4: Loading

Pipette 75 µL of sample mixture into the sample well of the test cassette.

Step5: Testing

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

a) For Standard Test mode: Insert the test cassette into the test cassette holder of the Meter right after adding the sample to the sample well, and click "Test". The meter will start to countdown and read the test result automatically in 15 minutes.

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 cassette onto the test cassette holder of Meter. Press "Test" to start testing. Meter will

start scanning the sample-loaded test cassette immediately.

Step6: Reading results

Results are displayed on the main screen of Meter and can be printed out by clicking “Print”.

Step7: Withdraw

Discard the used test cassette according to local regulations and procedures after released from the instrument.

Traceability: Values of this product are traced to the Certificate reference material NMIJ CRM-6002 Testosterone assigned by ID-GC/MS based on the respective instrument calibration traceability.

INTERPRETATION OF RESULTS

The Finecare™ FIA Meters calculates Testosterone test results automatically and displays the concentration of Testosterone on the screen as form of XXX ng/mL. For further information, refer to the Operation Manual for the FinecareTM FIA Meters.

Finecare™ FIA Meters will prompt “No Sample or sample volume insufficient!” when insufficient sample volume or liquid is not fully flowed across the test line. Then, it is recommended to conduct another test.

The test result will be shown as ＜0.2 ng/mL if the Testosterone concentration is below 0.2 ng/mL and the test result will be shown as＞15 ng/mL if the Testosterone concentration is more than 15 ng/mL.

Normal Reference Interval:

Gender	Age (years old)	Reference interval (ng/mL)
Male	20~49	1.91 – 8.41
	≥50	1.61 – 8.01
Female	20~49	≤0.80
	≥50	≤0.71

Conversion formula : ng/mL x 3.47 = nmol/L

Note: Recommend that each laboratory formulates its own reference range to actual situation.

QUALITY CONTROL

Each Finecare™ Testosterone Rapid Quantitative Test device contains internal control for routing quality control requirements. This internal control is performed each time when a patient sample is tested. This control indicates that the test cassette was inserted and read properly by Finecare™ FIA Meters. An invalid result from the internal control leads to display an error message on the Finecare™ FIA Meters, indicating that another test should be conducted.

Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum, plasma specimen only.
2. The results of the test should be evaluated with all clinical and laboratory data available. If Testosterone test results do not agree with the clinical evaluation, additional tests should be performed.
3. Tests may yield false positive results due to the direct binding of non-specific components such as heterophilic antibodies and antigen structural analogs in blood specimens and fluorescence-labeled detector antibodies.
4. Tests may yield false negative results due to (i) non-responsiveness of antigen to the antibodies by some certain unknown components are masking its epitope, such that antigen cannot be detected or captured by the antibodies; (ii) Testosterone antigen decomposed, such that they become no longer recognizable by antibodies.
5. Other factors may interfere with the test and may cause erroneous results. These include technical or operational errors, as well as additional substances that are not listed in the Cross-Reactivity section.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study using 106 human blood samples, demonstrated good correlation with a commercially available CE-marked kit.

Comparison between the Finecare™ Testosterone Rapid Quantitative Test and the Roche Testosterone Reagent Kit for 106 clinical samples, the coefficient of correlation (R) is 0.986.

Assay Range and Detection Limit

- **Assay Range:** 0.2~15 ng/mL
- **Detection Limit (Analytical Sensitivity):** 0.2 ng/mL

Cross-Reactivity

The following substances do not interfere with the Testosterone test results at the indicated concentrations:

Interferents	Acceptable Range
Dihydrotestosterone	≤100 ng/mL
Aldosterone	≤8000ng/mL
Bilirubin	≤25mg/dL
Triglyceride	≤3000mg/dL
Cholesterol	≤1000mg/dL
Rheumatoid Factor (RF)	≤1000IU/mL
Hemoglobin	≤1.0g/dL
Total protein	≤120g/L
Human anti Mouse antibody (HAMA)	≤1000ng/mL

Linearity

Five concentrations of Testosterone controls from 0.2~15 ng/mL were each tested for three times with one batch of tests, the coefficient of correlation (R) is ≥ 0.9900.

Precision

Intra-Lot Precision

Within-run precision has been determined by using two concentrations of of Testosterone precision controls with one batch of tests. C.V. is ≤ 15%.

Inter-Lot Precision

Between-run precision has been determined by using two concentrations of Testosterone precision controls with three batches of tests. C.V. is ≤ 15%.

BIBLIOGRAPHY OF SUGGESTED READING

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INDEX OF SYMBOLS

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

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