TES Rapid Quantitative Test

Catalog No.BT2211

INTENDED USE

The Biotime TES Rapid Quantitative Test is intended to quantify the concentration of testosterone in human serum on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of androgen level.
-Fluorescence immunoassay
-Androgen level test
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

Testosterone(17β-hydroxyandrost-4-en-3-one) is an anabolic steroid synthesized primarily by Leydig cells in the testes of male, the ovary of female, and adrenal glands of both sexes[1]. It is synthesized from cholesterol, androstenediol, Dehydroepiandrosterone(DHEA), progesterone, and pregnenolone acting as some of the intermediate substrates. Testosterone level in male increase 10 to 20-fold during puberty, driving the physiological changes associated with male puberty. It also exerts a powerful, wide-ranging influence over emotional well-being, sexual function, muscle mass and strength, energy, cardiovascular health, bone integrity, and cognitive ability throughout a man's entire life. In the blood only 1% to 15% of testosterone molecules are free form or biologically active form. The remaining testosterone molecules are bound to serum proteins.

PRINCIPLE

This reagent is based on fluorescent lateral flow immunoassay competition method.
While the sample and the buffer are mixed, testosterone in specimen is dissociated and forms a reaction complex with mouse anti-testosterone monoclonal antibody labeled with fluorescent microsphere (contain Europium). While moving to T line, coated with testosterone antigen, free labled antibodies are captured and gives fluorescent signal upon stimulation. Thus the fluorescent signals are negatively correlated with the concentrations of testosterone.
The fluorescent signal will be quantified and calculated according to the calibration curve (provided with the reagents) to represent the concentration of testosterone in specimen.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only, please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for one-time use. Once the pouch is opened, it should be used within 30 minutes to avoid failure caused by the moisture absorption.
4. While using the test cartridge and instruments, vibration and electromagnetic environment should be avoided.
5. Lot number of buffers and test cartridges must be matched.
6. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. It may cause damages to the instrument.

MATERIAL

Material Provided
1. Test cartridge 25 tests/kit
2. Detection buffer 25 tubes/kit
3. SD card 1 piece/kit
4. Instructions for use 1 copy/kit

Material Required But Not Provided
1. Biotime FIA Analyzer
2. Transfer Pipette Set (5~50μL and 10~100μL size)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-8℃, the shelf life is 24 months.
2. Store TES Rapid Quantitative Test Cartridge at 2-30℃, the shelf life is 24 months.
3. Test Cartridge should be used within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with serum specimen.
2. The specimen collection container should be pro-coagulant tube for serum.
3. The collection of the sample: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures. The serum can be stored in refrigerator at 2-8℃ upto 7days，or at -20℃ upto 6months if test cannot be performed immediately. Samples should be recovered to the room temperature before test.
4. Separate the serum from blood as soon as possible to avoid hemolysis.

TEST PROCEDURES

Please refer to the operation manual of Biotime FIA Analyzers for details.
The test should be operated at room temperature（~25℃）.
Step 1: Preparation
Check/insert SD card into the equipment.
Take out one tube of buffer from refrigerator and balance it to room temperature.
Step 2: Sampling
Take 20μL of serum with a transfer pipette to the buffer tube.
Step 3: Mixing
Mix well the specimen with buffer by tapping or inverting the tube.
Step 4: Loading
Take 80μL mixture from buffer tube and load it into the well of the test cartridge.
Note: Step 2 to step 4 should be completed within 1 minute to ensure the accuracy of the test results.
Step 5: Testing
Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 10 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal Reference Value: Male(2.6-10.45ng/mL), Female(0.27-0.95ng/mL)
Note: Individual reference range is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. The test sample shall be serum.
2. Human anti-mouse antibody (HAMA) may be presented in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies.
3. Other factors also can induce the false result, including technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy
Test cartridges from same batch were tested with testosterone control of three different levels of concentration, mean and Bias% were calculated, Bias% was within ±15%.
Assay Range and Detection Limit
Assay Range: 0.2-20ng/mL
The Lowest Detection Limit: 0.2ng/mL
Linearity
A serial concentration of testosterone controls at 0.2-20ng/mL were tested, the Correlation Coefficient (R) is≥0.99.
Precision
Intra-lot Precision
Intra-lot precision was determined by testing of testosterone reference materials using 10 test cartridges from the same lot. The C.V. is ≤ 15%.
Inter-lot Precision
Inter-lot precision was determined by testing of testosterone reference materials using 30 test cartridges from 3 consecutive batches randomly (10 test cartridges from each lot). The C.V. is ≤ 20%.
Specificity

Crossed factors	Concentration	Test Result
Progesterone	500ng/mL	＜0.2 ng/mL
Estradiol	100ng/mL	＜0.2 ng/mL
Cortisol	500ng/mL	＜0.2 ng/mL
Aldosterone	500ng/mL	＜0.2 ng/mL
Estriol	100ng/mL	＜0.2 ng/mL
17α-Estradiol	500ng/mL	＜0.2 ng/mL
Oestrone	50ng/mL	＜0.2 ng/mL

SYMBOLS

Symbol	Description	Symbol	Description
REF	Catalogue number	IVD	In vitro diagnostic medical device
LOT	Batch code		Consult instructions for use

	Date of manufacture		Keep dry
	Use-by date		Keep away from sunlight
	Manufacturer		Store at 2-8℃
	Do not re-use		Store at 2-30℃
	Authorized representative in the European		CE mark

BIBLIOGRAPHY OF SUGGESTED READING

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EC REP

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