FRENOVO

Testosterone Rapid Test Kit

Instructions For Use

PRODUCT NAME

Testosterone Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

FRENOVO Testosterone Rapid Test Kit is a lateral flow, qualitative immunoassay. It is intended for qualitative detection of testosterone, with a minimum detection concentration of 10 ng/mL 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.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Testosterone is very important and powerful steroid hormone in both men and women. In males, testosterone is secreted primarily by the Leydig cells of the testes. In females 50% of circulating testosterone is derived from peripheral conversion of androstenedione, 25% from the ovary and 25% from the adrenal glands. Circulating testosterone is 98% protein-bound in males, with slightly less being bound in females. The proteins responsible for biding testosterone are serum albumin and Sex Hormone Binding Globulin (SHBG), also referred to as Testosterone Binding Globulin (TeBG).

Testosterone is responsible for the development of secondary male sex characteristics and its measurements are helpful in evaluating the hypogonadal states. In men, high levels of testosterone are associated to the hypothalamic pituitary unit diseases, testicular tumors, congenital adrenal hyperplasia and prostate cancer. Low levels of testosterone can be found in patients with the following diseases:Hypopituitarism, Klinefelter' s syndrome,Testicular feminization, Orchidectomy and Cryptorchidism, enzymatic defects and some autoimmune diseases. Low testosterone levels can cause changes in sexual function, including:lowlibido, impotence, erectile dysfunction(ED), infertility.Other signs of low testosterone levels include: changes in sleep patterns, difficulty concentrating, lack of motivation, reduced muscle bulk and strength decreased bone density, large breasts in men, depression, and fatigue.

In women, high levels of testosterone are generally found in hirsutism and virilization, polycystic ovaries, ovarian tumors, adrenal tumors and adrenal hyperplasia. Excess testosterone in a woman' s bloodstream can cause: loss of scalp hair, acne, irregular or absent menses, growth of facial hair, infertility. Low testosterone in women can also cause fertility problems, in addition to weak bones and loss of libido.

The test utilizes a combination of antibodies including mouse anti-Testosterone Monoclonal Antibodies to selectively detect elevated levels of testosterone; one conjugated with colloidal gold and another one immobilized on the solid phase.The assay is conducted by adding specimen to the specimen well of the test cassette and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

MATERIALS PROVIDED

Each kit contains:

1. Test Devices: 25 pieces test devices individually pouched.
2. Droppers: 25 pieces droppers of 25 ul.
3. Wash Buffer Solution: 2.5 ml in dropper bottle.
4. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Micropipette
- Centrifuge(for plasma only)
- Lancets(for fingertip whole blood only)

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. FRENOVO Testosterone Rapid Test Kit is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO Testosterone Rapid Test Kit is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The used test device should be discarded according to local regulations.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of wash buffer, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not use the kit past the expiration date (this date is printed on the kit box).
5. Adequate lighting is required to read the test results.
6. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. FRENOVO Testosterone Rapid Test kit should be stored between 2-30°C and the shelf life is 24 months.
2. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
3. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

1. Applicable samples： Whole Blood/Serum/Plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear nonhemolysis specimens.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2~8 ℃ for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20 ℃.Whole blood collected by venipuncture should be stored at 2~8 ℃ if the test is to be run within 2 days of collection.
5. Do not freeze whole blood specimens.
6. Whole blood collected by finger stick should be tested immediately.
7. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
8. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
9. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

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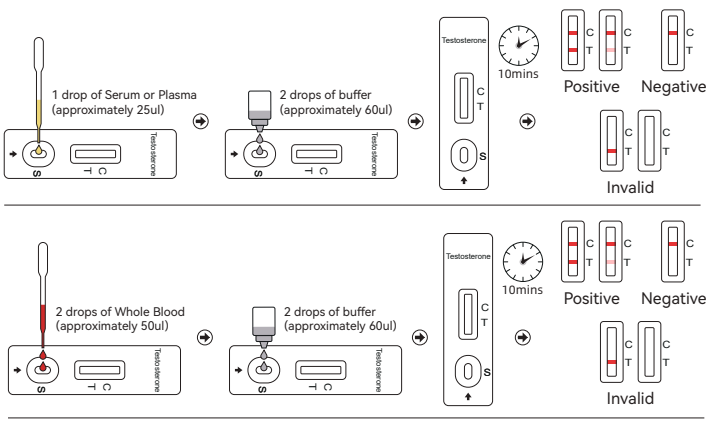
QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST PROCEDURE

Allow the test device, specimen, wash buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.
2. **For Serum or Plasma Specimens**
   Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (one drop /approximately 25ul), then add two drops of buffer(approximately 60ul) to the sample well and start the timer.Avoid trapping air bubbles in the sample well.
   For Whole Blood Specimens
   Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 50ul), then add two drops of buffer(approximately 60ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
3. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

Please refer to the illustration above

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that testosterone has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line T appear, testosterone has been detected and the result is positive.

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line, and the test shall be conducted again.

LIMITATIONS

1. This test has been developed for testing human whole blood, serum, plasma specimen only.
2. The test results of this kit are only for clinical reference and cannot be used as the basis for confirming or excluding cases alone.In order to achieve the purpose of diagnosis,this test result should be used in combination with clinical examination,medical history and other examination results.
3. Patient samples may contain heterophilic antibodies(e.g.human anti-mouse antibodies (HAMA) and rheumatoid factors) that could react in immunoassays to give a falsely elevated or depressed result.This assay has been designed to minimize interference from heterophilic antibodies.Nevertheless,complete elimination of this interference fromall patient specimens cannot be quaranteed.

PERFORMANCE CHARACTERISTICS

Accuracy

A clinical evaluation was conducted comparing the results obtained using the FRENOVO Testosterone Rapid Test and a commercially available CE-marked kit. The study included 136 human blood samples, and both assays identified 74 negative and 62 positive results. The results demonstrated good correlation with the commercially available CE-marked kit.

Analytical sensitivity

The minimum detection limit for FRENOVO Testosterone Rapid Test Kit is 10ng/ml.

Cross-Reactivity

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

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

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2℃ 30℃	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks		

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INSTRUCTION APPROVAL AND REVISION DATE

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