

Testosterone FIA Rapid Test

(Serum/Plasma)

FIA-TST-001

*A rapid test for detecting Testosterone in serum or plasma with the use of the Biopanda Fluorescence Immunoassay Analyser.
For professional in vitro diagnostic use only.*

INTENDED USE

The Biopanda Testosterone FIA Rapid Test is based on Fluorescence Immunoassay for the quantitative determination of Testosterone in serum or plasma.

SUMMARY

Testosterone (17 β -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 levels 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 is in its unbound or biologically active form. The remaining testosterone is bound to serum proteins.

PRINCIPLE

The Biopanda Testosterone FIA Rapid Test detects testosterone based on Fluorescence Immunoassay. The specimen moves through the strip from sample pad to absorbent pad. Testosterone in the specimen will compete with the Testosterone antigen coated on the membrane. The less Testosterone in the specimen, the more chance that fluorescent microspheres-conjugated anti-Testosterone antibodies can be captured by the Testosterone antigen coated on the membrane (Test line). The concentration of Testosterone in the specimen is inversely related to the intensity of the fluorescent signal captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of Testosterone in the sample can be calculated by the Biopanda Fluorescence Immunoassay Analyser to show Testosterone concentration in specimen.

REAGENTS

The test kit includes anti-Testosterone antibody coated fluorophores and Testosterone antigen coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda Testosterone FIA Rapid Test should only be used with the Biopanda Fluorescence Immunoassay Analyser by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.

3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS

- 10 x foil wrapped Testosterone test cassettes
- 10 x Specimen collection tubes with dilution buffer
- 1 x ID card (Testosterone)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Analyser

SPECIMEN COLLECTION AND PREPARATION

PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30°C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it.

SPECIMEN COLLECTION AND PREPARATION

1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 1 day, for long term storage, specimens should be kept below -20 °C.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA can be used as the anticoagulant for collecting the specimen.

SAMPLE DILUTION / SAMPLE STABILITY

1. Transfer **75 μ L of serum or plasma** to the buffer tube with a micro pipette.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately 1 minute.
4. The diluted sample can then be used immediately or stored for up to 4 hours at 2-8°C.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Analyser Operation Manual for the complete instructions on use of the Test. The test should be conducted at room temperature.

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. **Serum/plasma:** Transfer 75 μ l of serum/plasma into the buffer tube, mix the specimen and the buffer well.
4. **Add diluted specimen with a Pipette:** Pipette 75 μ l of diluted specimen into the sample well of the test cassette. Start the timer at the same time.
5. There are two test modes for the Biopanda Fluorescence Immunoassay Analyser; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser for details.

"Quick test" mode: Insert the test cassette into the Analyser at 15 minutes after sample application and click "New Test", the Analyser will automatically give the test result after a few seconds.

"Standard test" mode: Insert the test cassette into the Analyser immediately after sample application, click "New Test" at the same time, the Analyser will automatically count down the 15 minutes. After the countdown, the Analyser will give the result at once.

INTERPRETATION OF RESULTS

The result of tests for Testosterone is calculated by the Biopanda Fluorescence Immunoassay Analyser and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser.

Linearity range of the Biopanda Testosterone FIA Rapid Test is 1.0-20 ng/ml.

QUALITY CONTROL

Each Biopanda Testosterone FIA Rapid Test Cassette contains an 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 device was inserted and read properly by the Biopanda Fluorescence Immunoassay Analyser. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Analyser indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Biopanda Testosterone FIA Rapid Test Cassette is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of Testosterone.
2. The Biopanda Testosterone FIA Rapid Test Cassette will only indicate the presence of Testosterone in the specimen and should not be used as the sole criterion for clinical decisions.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED RESULTS

Normal Reference Range	Gender
0~2ng/ml (0~6.9nmol/l)	Adult Female
2.6~12ng/ml (9~41.6nmol/l)	Adult Male

Note: Due to differences in geography, race, environment, gender, etc., each laboratory should establish its own reference intervals.

PERFORMANCE CHARACTERISTICS

ACCURACY: The product was evaluated with 70 clinical specimens compared with a produce of the same methodology on the market, and the correlation coefficient (*r*) was 0.975.

ANALYTICAL SENSITIVITY

The Biopanda Testosterone FIA Rapid Test can detect levels of Testosterone as low as 1.0 ng/ml (3.47nmol/l) in serum and plasma.

LINEARITY RANGE: 1.0-20 ng/mL (3.47~69.4nmol/l), R₂0.990

PRECISION

INTRA-LOT PRECISION

Within-run precision has been determined by using 10 replicates of 2 specimens containing 1.0 mg/L, 10.0 mg/L of Testosterone. C.V. is ≤ 15%.

INTER-LOT PRECISION

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 1.0 mg/L, 10.0 mg/L of Testosterone. C.V. is ≤ 15%.

INTERFERING SUBSTANCES

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

Cross Reactivity Materials	Concentration (ng/ml)
Estradiol	600
Estriol	500
Progesterone	600
Danazol	500
Cortisol	500

CROSS-REACTIVITY

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

Cross Reactivity Materials	Concentration
Haemoglobin	500mg/ml
Bilirubin	1ng/ml

REFERENCES

1. Wilson, J.D., George, F.W., and Griffin, J.E. The hormonal control of sexual development. Science, 1981, 211: 1278 – 1284.

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse test
	<i>In vitro</i> diagnostic medical device		Expiration date		Catalogue number
	Store between 4-30°C		Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's Testosterone FIA Rapid Test. Please read this manual carefully before operating to ensure proper use.



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