Testosterone FIA Rapid Test Device
(Serum/Plasma)

Catalogue Number: FI2-TST-001

A Fluorescence Immunoassay for the quantitative detection of testosterone in serum or plasma using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

For professional in vitro diagnostic use only.

INTENDED USE

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

BACKGROUND

Testosterone (17ß-hydroxyandrost-4-en-3-one) is an anabolic steroid synthesized primarily by Leydig cells in testes, ovaries, and adrenal glands. 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.

TEST PRINCIPLE

The Biopanda Testosterone FIA Raid Test Device 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.
3. Do not use the test if the foil pouch is damaged.
4. Do not reuse tests.
5. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
6. Do not eat, drink or smoke in the area where the specimens and tests are handled.
7. 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.
8. Wear protective clothing such as laboratory coats, disposable gloves and safety glasses when specimens are assayed.
9. Do not interchange or mix reagents from different lots.
10. Extremes of humidity and temperature can adversely affect results.
11. Used testing materials should be discarded in accordance with local regulations.
12. The Biopanda Testosterone FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device 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. Do not freeze.
2. The test must remain in the sealed pouch until use.
3. 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 CONTENTS

- 25 x Foil wrapped Testosterone test devices
- 25 x Specimen collection tubes with dilution buffer
- 1 x ID card (Testosterone)
- 1 x Package insert

EQUIPMENT REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device

SPECIMEN COLLECTION AND PREPARATION

1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
3. 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.
4. 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.
5. EDTA can be used as the anticoagulant for collecting the specimen.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device User Manual for the complete instructions on operating the device. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: *Standard Test* mode and *Quick Test* mode.

***Standard Test* mode** is a 'set and forget' method where the test will automatically be read after 15 minutes.

***Quick Test* mode** provides an instant result but the user must monitor the 15 minute test time themselves. It is suitable when running multiple tests simultaneously.

Refer to the user manual for further details.

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

1. Turn on the analyzer and insert the ID card into the analyzer 'Code' port and wait for the 'ID card imported successfully' pop-up. Fill in the necessary details in the 'Test Info' section.
2. Remove the test device from the sealed foil pouch and place on a clean, level surface. Start testing immediately after opening the foil pouch.
3. Transfer **75 µl of serum/plasma** into the buffer tube. Shake the tube for approximately 10 seconds to mix the specimen and buffer well. Let the tube sit for 1 minute.
4. Using a pipette, **transfer 75 µl of diluted specimen** into the sample well of the test device.
5. Insert the test device into the analyzer test device slot. According to user requirements, select either 'Standard test' or 'Quick test' mode.
6. **Test results should be interpreted at 15 minutes** by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

The test results are calculated by the Biopanda Fluorescence Immunoassay Device and displayed on the analyzer screen after testing is complete. For additional information, please refer to the user manual.

Linearity range of the test is 1.0 –20 ng/ml.

QUALITY CONTROL

Each Biopanda Testosterone FIA Rapid Test Device 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 Device.

An invalid result from the internal control causes an error message on the 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.

EXPECTED RESULTS

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

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

PERFORMANCE CHARACTERISTICS

1. **Accuracy**
   The product was evaluated with 70 clinical specimens compared with a commercial predicate device, and the correlation coefficient (r) was 0.975.
2. **Analytical sensitivity**
   The Biopanda Testosterone FIA Rapid Test Device can detect levels of testosterone as low as 1.0ng/ml (3.47nmol/l) in serum and plasma.
3. **Linearity range**
   1.0 – 20ng/mL (3.47 – 69.4nmol/l), R ≥ 0.990
4. **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%.
5. **Cross-Reactivity**
   Cross reactivity studies were carried out with the following analytes at the indicated concentrations:

Estradiol	600 ng/ml
Estriol	500 ng/ml
Progesterone	600 ng/ml
Danazol	500 ng/ml
Cortisol	500 ng/ml

   The results showed no cross-reactivity.
6. **Interfering Substances**
   The following substances do not interfere with the test at the indicated concentrations:

Haemoglobin	500 mg/ml
Bilirubin	1 ng/ml

LIMITATIONS OF THE TEST

1. The Biopanda Testosterone FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of testosterone.
2. The test 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.

INDEX OF SYMBOLS

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

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

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Revision date: 03/02/2026