

# FT4 FIA Rapid Test

## (Serum/Plasma)

### FIA-FT4-001

A rapid test for detecting Free Thyroxine (FT4) in serum or plasma with the use of the Biopanda Fluorescence Immunoassay Analyser.  
For professional *in vitro* diagnostic use only.

#### INTENDED USE

The Biopanda FT4 FIA Rapid Test is intended for *in vitro* quantitative determination of free Thyroxine (fT4) in human serum or plasma. Measurement of free T4 is used as an aid to assess thyroid function.

#### SUMMARY

Thyroid hormones are two hormones produced and released by the thyroid gland, namely triiodothyronine (T3) and thyroxine (T4). They are tyrosine-based hormones that are primarily responsible for regulation of metabolism. The major form of thyroid hormone in the blood is thyroxine (T4), which has a longer half-life than T3.<sup>[1]</sup> In humans, the ratio of T4 to T3 released into the blood is approximately 14:1.<sup>[2]</sup> So the thyroxine(T4) is a primary diagnostic marker for thyroid function.

The thyroid hormones act on nearly every cell in the body. They act to increase the basal metabolic rate, affect protein synthesis, help regulate long bone growth (synergy with growth hormone) and neural maturation, and increase the body's sensitivity to catecholamines (such as adrenaline) by permissiveness. The thyroid hormones are essential to proper development and differentiation of all cells of the human body. These hormones also regulate protein, fat, and carbohydrate metabolism, affecting how human cells use energetic compounds. They also stimulate vitamin metabolism. Numerous physiological and pathological stimuli influence thyroid hormone synthesis.

Most of the thyroid hormone circulating in the blood is bound to transport proteins, and only a very small fraction is unbound and biologically active. Therefore, triiodothyronine (T3) and thyroxine (T4) measured as free T3 and free T4 can more accurately reflect the functional status of the thyroid.

#### PRINCIPLE

The Biopanda FT4 FIA Rapid Test detects free T4 based on Fluorescence Immunoassay technology. The sample moves along the strip from the sample pad to absorbent pad. Free T4 in the sample will compete with the T4 antigen coated on the membrane. The less free T4 in the sample, the more fluorescent microspheres conjugated with anti-T4 antibodies can be captured by the T4 antigen coated on the nitrocellulose membrane. The concentration of free T4 in the sample is inversely related to the intensity of the fluorescent signal captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of free T4 in the sample can be calculated by the Biopanda Fluorescence Immunoassay Analyser to show free T4 concentration in the specimen.

#### REAGENTS

The test kit includes T4 antibody coated particles and T4-BSA 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. This test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. 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.
6. Do not interchange or mix reagents from different lots.

7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire procedure carefully prior to any testing.
10. The Biopanda FT4 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 FT4 test cassettes
- 10 x Specimen collection tubes with dilution buffer
- 1 x ID card (FT4)
- 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 STORAGE

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 7 days, 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, K2, Citrate Sodium, and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.
5. A clean tube without anticoagulants can be used to collect serum specimens.

#### 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. Remove the test cassette from the sealed foil pouch and use it within 1 hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
4. Place the test on a flat and clean surface.
5. **Serum/plasma:** Transfer 75 µl of serum/plasma into the buffer tube, mix the specimen and the buffer well.
6. **Add diluted specimen with a Pipette:** Pipette 75 µl of diluted specimen into the sample well of the test cassette. Start the timer at the same time.
7. 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 free T4 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.

Working range of the Biopanda free T4 FIA Rapid Test is 1~100 pmol/L. The normal reference range 6.7~16.4 pmol/L.

Each laboratory should determine the applicability of the reference range through experiments, and establish its own reference value range if necessary to ensure that it can correctly reflect the situation of a particular population.

### QUALITY CONTROL

Each Biopanda FT4 FIA Rapid Test 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 free T4 FIA Rapid Test should be used only with the FIA Analyzer.
2. The test should preferably be performed on freshly collected samples. For stored specimens, please refer to specimen storage.
3. The Biopanda FT4 FIA Rapid Test is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of free T4.
4. The test may yield low results due to T4 epitopes being covered by some unknown components. Low results may also be obtained due to instability or degradation of free T4 antigen with time and temperature.
5. Other factors interfering with the test and causing erroneous results include technical/procedural errors, degradation of the test components as well as presence of interfering substances in the test samples.
6. The Biopanda free T4 FIA Rapid Test will only indicate the presence of free T4 in the specimen and should not be used as the sole criteria for evaluating thyroid disease.
7. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
8. The results found on the Biopanda Fluorescence Immonassay Analyzer are only for the concentration of free T4. It should not be used as the only criterion for treatment decisions. If the result is abnormal (low or high), other clinical findings and alternative test methods are recommended to reach proper medical treatments.

### EXPECTED RESULTS

Concentrations	Clinical Reference
<6.7 pmol/L	Hypothyroidism
6.7-16.4 pmol/L	Healthy
>16.4 pmol/L	Hyperthyroidism

### PERFORMANCE CHARACTERISTICS

#### 1. Method comparison

For 105 specimens, the test results of the Biopanda FT4 FIA rapid test were consistent with a commercially available FT4 test and the correlation coefficient (R2) is 0.9877.

#### 2. Accuracy

The test deviation  $\leq \pm 15\%$ .

### 3. Assay Range

Assay Range is 1~100 pmol/L.

### 4. Precision

#### Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 different concentration FT4 control. C.V. is  $\leq 15\%$ .

#### Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 different concentration FT4 controls. C.V. is  $\leq 15\%$ .

### REFERENCES

1. Irizarry L (23 April 2014). "Thyroid Hormone Toxicity". *Medscape*. WedMD LLC. Retrieved 2 May 2014.
2. Pilo A, Iervasi G, Vitek F, Ferdeghini M, Cazzuola F, Bianchi R (April 1990). "Thyroidal and peripheral production of 3,5,3'-triiodothyronine in humans by multicompartmental analysis". *The American Journal of Physiology*. **258** (4 Pt 1):E715–26. doi:10.1152 /ajpendo. 1990.258.4. E715. PMID 2333963.

### Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
	For in vitro diagnostic use only		Use by		Catalogue #
	Store between 4-30°C		Lot Number		Consult instructions
	Do not use if package is damaged		Manufacturer		

Thank you for purchasing Biopanda's FT4 FIA Rapid Test. Please read this manual carefully before operating to ensure proper use.



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