

T4 FIA Rapid Test Device (Whole Blood/Serum/Plasma)

FI2-T4-001

A rapid test for detecting Total Thyroxine (T4) in whole blood, serum, or plasma with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000). For professional *in vitro* diagnostic use only.

INTENDED USE

The Biopanda T4 FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Total Thyroxine (T4) in whole blood, serum, or plasma. Measurement of T4 is used as an aid in the assessment of 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.^[2] In humans, the ratio of T4 to T3 released into the blood is approximately 14:1.^[3] 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.

PRINCIPLE

The T4 FIA Rapid Test Device detects T4 based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. T4 in the sample will compete with the T4 antigen coated on the membrane. The less 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 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 T4 in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device to show T4 concentration in 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 T4 FIA Rapid Test 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.
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

- 25 x foil wrapped T4 test Devices
- 25 x Specimen collection tubes with dilution buffer
- 25 x Capillary Droppers
- 25 x Disposable Droppers
- 1 x ID card (T4)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

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.

BLOOD SAMPLE TAKING

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. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be used within 1 day of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
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 and Heparin sodium, can be used as the anticoagulant for collecting the specimen.

SAMPLE DILUTION / SAMPLE STABILITY

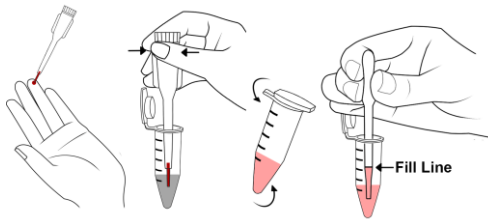
1. Transfer **20 µL of whole blood, serum, or plasma** to the buffer tube with a micro pipette.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately 1 minute.
4. The diluted sample should then be used as soon as possible.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device 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. **Whole Blood/Serum/plasma:** Transfer 20 µl of whole blood, serum, or plasma into the buffer tube, mix the specimen and the buffer well.
4. **Add diluted specimen with a Pipette:** Pipette 75 µl of diluted specimen into the sample well of the test Device. Start the timer at the same time.



- There are two test modes for the Biopanda Fluorescence Immunoassay Device; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Device for details.

“Quick test” mode: Insert the test Device 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 Device 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 T4 is calculated by the Biopanda Fluorescence Immunoassay Device and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device.

The normal reference range is 65-155nmol/L.

QUALITY CONTROL

Each Biopanda T4 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 Biopanda Fluorescence Immunoassay Device 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

- The Biopanda T4 FIA Rapid Test Device is for professional *in vitro* diagnostic use and should only be used for the quantitative detection of T4.
- The Biopanda T4 FIA Rapid Test Device will only indicate the presence of T4 antigen in the specimen and should not be used as the sole criterion for evaluating thyroid function.
- As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- The results of the Biopanda T4 FIA Rapid Tests are based on measuring the levels of T4 in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

Concentrations	Clinical Reference
<65 nmol/L	Deficiency
65-155 nmol/L	Healthy
>155 nmol/L	Excess

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.

PERFORMANCE CHARACTERISTICS

- ACCURACY:** The test deviation is $\leq \pm 15\%$.
- ASSAY RANGE AND DETECTION LIMIT**
Assay Range: 12.87-300 nmol/L
Detection Limit (Analytical sensitivity): 12.87 nmol/L.

PRECISION

INTRA-LOT PRECISION

Within-run precision has been determined by using 10 replicates of 2 specimens of T4 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 concentrations of T4 control. C.V. is $\leq 15\%$.

REFERENCES

- Irizarry L (23 April 2014). "Thyroid Hormone Toxicity". *Medscape*. WedMD LLC. Retrieved 2 May 2014.
- 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

	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 T4 FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.



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