T3 FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

Catalogue Number: FI2-T3-001

A rapid test for detecting Triiodothyronine (T3) in whole blood, serum, or plasma with the use of the Biopanda Fluorescence Immunoassay Analyser. For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda T3 FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Triiodothyronine (T3) in human whole blood, serum, or plasma specimens. The measurement of T3 is used as an aid in the assessment of thyroid function.

BACKGROUND

The physiological actions of thyroid hormones can be categorised as growth and development and control of metabolic processes in the body. Thyroid hormones play a major role in the growth and development of the brain and central nervous system in humans from the 15th week of gestation to 3 years of age.[1] The other physiological role of thyroid hormones is to control several metabolic processes in the body. These include carbohydrate, fat, protein, vitamin, and mineral metabolism.[2]

Triiodothyronine (T3) is the biologically active thyroid hormone. In normal subjects, approximately 20% of T3 is secreted from the thyroid gland, and approximately 80% of T3 derives from the conversion of thyroxine (T4) to T3 in extrathyroidal peripheral tissues.[3] It has the biological activity of promoting the metabolism of substance and energy, and promoting the growth and development of the body. It is an important diagnostic index of thyroid diseases, and also has auxiliary diagnostic value for some non-thyroid diseases.

TEST PRINCIPLE

The Biopanda T3 FIA Rapid Test Device detects T3 based on Fluorescence Immunoassay. The blood specimen moves through the strip from the specimen pad to absorbent pad. T3 in the specimen will compete with the T3 antigen coated on the membrane. The less T3 in the specimen, the more fluorescent microspheres conjugated with anti-T3 antibodies can be captured by the T3 antigen coated on the nitrocellulose membrane. The concentration of T3 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 product standard curve, the concentration of T3 in the specimen can be calculated by the Biopanda Fluorescence Immunoassay Analyser to show T3 concentration in specimen.

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. Extremes of 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 T3 FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Analyser (BR-FIA-2000) by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the foil pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the kit contents 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 T3 FIA Rapid Test Device
- 25 x Buffer tubes
- 25 x Capillary Droppers
- 25 x Disposable Droppers
- 1 x ID card (T3)
- 1 x Package Insert

REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION AND PREPARATION

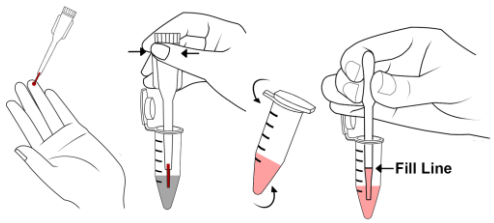
1. Collect specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 1 day, for long term storage, specimens should be kept below -20°C.
   Whole blood collected by venipuncture can be stored at 2-8°C for up to 2 days if immediate testing is not possible. **Do not freeze whole blood specimens.** Finger-pricked whole blood specimens should be tested with immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeat freeze-thaw cycles.
4. EDTA, K2, heparin sodium, citrate sodium, and potassium oxalate, can be used as the anticoagulant for collecting specimen.

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. Choose the appropriate specimen type.
2. Take out the ID card and insert it into the Analyser port.
3. Remove the test device from the foil pouch and place on a clean, level surface. For optimal test performance, run test immediately after opening the pouch.
4. Using a pipette, add **20 µl of specimen** into a buffer tube and mix the specimen by shaking the tube well.
5. Pipette **75 µl of the diluted specimen** into the specimen well (S) of the test device. Start the timer at the same time.



6. **Results should be interpreted at 15 minutes** using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Analyser: Standard Test mode and Quick Test mode. Please refer to the manual for more information.

Quick test mode: Insert the test device into the analyser 15 minutes after specimen application and select "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 specimen application and select "New test". The analyser will automatically set a timer for 15 minutes. After 15 minutes, the analyser will display the result.

INTERPRETATION OF RESULTS

The result is calculated by the Biopanda Fluorescence Immunoassay Analyser and displays the result on the analyser screen. For additional information, please refer to the manual.

Linearity range of the Biopanda T3 FIA Rapid Test is 0.4-6.0 ng/mL (0.62-9.24 nmol/L).
Normal Reference range (Adult): 0.8-2.0 ng/mL (1.23-3.08 nmol/L)
Conversion factor as unit of nmol/L (SI unit) = 1.54 x ng/mL

EXPECTED RESULTS

Concentrations	Clinical Reference
<1.23 nmol/L (0.8 ng/mL)	Hypothyroidism or Low T3 Syndrome
1.23-3.08 nmol/L (0.8-2.0 ng/mL)	Normal
>3.08 nmol/L (>2.0 ng/mL)	Hyperthyroidism

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 T3 FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient specimen 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 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 and contact your local distributor.

PERFORMANCE CHARACTERISTICS

1. **METHOD COMPARISON**
   The assay was compared with a commercially available CLIA test kit with 100 specimens. The correlation coefficient (R) is 0.996.
2. **ACCURACY**
   The test deviation is ≤ ± 15%
3. **LINEARITY RANGE**
   0.4-6.0 ng/mL (0.62-9.24 nmol/L), R ≥ 0.990
4. **PRECISION**
   Intra-lot Precision
   Within-run precision has been determined by using 10 replicates of 2 specimen concentrations of T3. C.V. is ≤ 15%.
   Inter-lot Precision
   Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimen concentrations of T3. C.V. is ≤15%.
5. **INTERFERING SUBSTANCES**
   The following substances do not interfere with the test results at the indicated concentrations: Ascorbic Acid at 200 mg/L, Haemoglobin at 10 g/L, Triglyceride at 30 g/L, Bilirubin at 1,000 mg/dL, Uric Acid at 200 mg/L.
6. **CROSS-REACTIVITY**
   The test result is no higher than 3.1 nmol/L (2ng/mL) when tested against T4>500 ng/mL, and TSH>20 mU/L.

LIMITATIONS OF THE TEST

1. The Biopanda T3 FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of T3 in whole blood, serum. or plasma specimens only.
2. The test will only indicate the presence of T3 in the specimen and should not be used as the sole criterion for evaluating thyroid function.
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.
4. Test results can be affected by iodine-rich foods, drugs containing iodine, and thyroid-affecting drugs. Medication containing iodine and certain Chinese herbal medicines may affect test performance, and therefore should not be taken while taking blood samples for testing.
5. For patients receiving high-dose biotin (i.e. >5 mg/day), specimens can be collected at least 8 hours after the last biotin dose.

REFERENCES

1. Fisher, D. A., & Delange, F. M. (1998). *Thyroid hormone and iodine requirements in man during brain development. In: Iodine in Pregnancy.* Stanbury J.B., Delange F., Dunn J.T and Pandav C.S., Oxford University Press Publication, pp. 1-33.
2. Delange, F. M., Bourdoux, P., Chanoine, J. P., & Ermans, A. M. (1986). *Physiopathology of iodine nutrition during pregnancy, lactation and early postnatal life.* In International Symposium on Vitamins and minerals in pregnancy and lactation (pp. 205-214).
3. Pilo, A., Iervasi, G., Vitek, F., Ferdeghini, M., Cazzuola, F., & Bianchi, R. (1990). *Thyroidal and peripheral production of 3, 5, 3'-triiodothyronine in humans by multicompartmental analysis.* American Journal of Physiology-Endocrinology and Metabolism, 258(4), E715-E726. https://doi.org/10.1152/ajpendo.1990.258.4.E715

INDEX OF SYMBOLS

	Manufacturer	Σ	Tests per kit	2	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 T3 FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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