FT3 FIA Rapid Test

(Whole Blood/Serum/Plasma)

Catalogue Number: FIA-FT3-001

A rapid test for detecting free Triiodothyronine (FT3) 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 FT3 FIA Rapid Test is based on Fluorescence Immunoassay for the quantitative determination of free Triiodothyronine (fT3) in whole blood, serum or plasma. 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. Hypothalamic-pituitary-thyroid axis can control the synthesis, release and function of thyroid hormone. It is secreted from the hypothalamus Thyrotropin releasing hormone (TRH) stimulates the synthesis and release of thyrotropin or TSH. In turn, TSH Stimulate the synthesis, storage, secretion and metabolism of thyroxine (T4) and triiodothyronine (T3). In the blood, there is Free and combined forms of T4 and T3. In blood circulation, more than 99% of T4 and T3 bind to carrier proteins. The remaining Less than 1% of T4 and T3 are free. Such unbound or free hormone levels are associated with thyroid function in most humans. It depends on the energy state.[1-2]
Free T3 and free T4 regulate normal growth and development by maintaining body temperature and stimulating heat generation. In addition, free T4 with free T3 also affects all aspects of carbohydrate metabolism and some aspects of fat and vitamin metabolism. Foetal and Thyroid hormones are also needed for newborn development.[1-2]

TEST PRINCIPLE

The Biopanda FT3 FIA Rapid Test Cassette detects FT3 based on Fluorescence Immunoassay technology. The specimen moves along the strip from the sample pad to the absorbent pad. If FT3 is present in the specimen, it will compete with the T3 antigen coated on the strip. The less FT3 in the specimen, the more fluorescent microspheres conjugate with anti-T3 antibodies and will be captured by the T3 antigen coated on the strip. The concentration of FT3 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 the standard curve, the concentration of FT3 in the sample can be calculated using the analyser to show FT3 concentration in the specimen.

REAGENTS

The test contains FT3 antibody coated fluorescent microspheres and FT3 antibody 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.
5. 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.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Do not interchange or mix reagents from different lots.
8. Extremes in humidity and temperature can adversely affect results.
9. Used testing materials should be discarded in accordance with local regulations.
10. Read the entire procedure carefully prior to any testing.
11. The Biopanda FT3 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 CONTENTS

- 10 x foil wrapped FT3 test cassettes
- 10 x Buffer tubes
- 1 x ID card (FT3)
- 1 x Package Insert

REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Analyser

SPECIMEN COLLECTION AND PREPARATION

1. Collect specimen according to standard procedures.
2. To collect finger-prick whole blood specimens:
   - Wash hands with soap and warm water or clean finger with an alcohol pad. Allow to dry.
   - Massage the hand without touching the puncture site by applying pressure down the hand towards the finger to be pricked. The middle or ring finger is recommended.
   - Use a sterile lancet to puncture the skin. Wipe away the first sign of blood.
   - Gently apply pressure from palm to the pricked finger so a rounded drop of blood forms over the puncture site.
   - Use a pipette to collect **20 µl of blood**, taking care to avoid air bubbles. Finger-pricked whole blood specimens should be tested immediately. **See 'DIRECTIONS FOR USE' for further instructions.**
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.
   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.
4. 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.
5. 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 tubes, 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 and choose the appropriate specimen type.
2. Take out the ID card and insert it into the Analyser port.
3. Remove the test cassette 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. Mix the specimen and buffer by shaking the tube well.
5. Pipette **75 µl of the diluted specimen** into the specimen well (S) of the test cassette. Start the timer at the same time.
6. **Results should be interpreted at 15 minutes** using the Biopanda Fluorescence Immunoassay Analyser.

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 cassette 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 cassette 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 FT3 FIA Rapid Test is: 1.5-46 pmol/L (0.97-29.8 pg/mL)
Normal Reference range (adult): 3.1-6.8 pmol/L (2.0-4.4 pg/mL)
Conversion factor as unit of pmol/L (SI unit) = 1.54 x pg/mL

EXPECTED RESULTS

Concentrations	Clinical Reference
<3.1 pmol/L (2.0 pg/mL)	Hypothyroidism
3.1-6.8 pmol/L (2.0-4.4 pg/mL)	Healthy
>6.8 pmol/L (4.4 pg/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 FT3 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.

PERFORMANCE CHARACTERISTICS

1. **METHOD COMPARISON**:
   The assay was compared with a commercially available CLIA test kit with 140 samples. The correlation coefficient (R) is 0.996.
2. **ACCURACY:**
   The Test deviation ≤ ±15%
3. **LINEARITY RANGE:**
   1.5-46 pmol/L (0.97-29.8 pg/mL), R≥0.990
4. **PRECISION**:
   Intra-lot precision
   Within-run precision has been determined by using 10 replicates of 2 different concentrations of FT3 C.V. is ≤ 15%.
   Inter-lot precision
   Between-run precision has been determined by using 10 replicates for each of three lots using 2 different concentrations of FT3 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.

LIMITATIONS OF THE TEST

1. The Biopanda FT3 FIA Rapid Test Cassette is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of Free T3 in whole blood, serum or plasma specimens only.
2. The results of the Biopanda FT3 FIA Rapid Test will only indicate the presence of FT3 in a specimen. It should not be used as the sole diagnostic tool for hyperthyroidism or hypothyroidism. If the result is below or above normal, other clinical findings and alternative test methods are recommended to reach proper medical treatments.
3. For patients receiving high dose biotin (approx. >5 mg/day), samples can be collected 8 hours after the last biotin dose.

REFERENCES

1. Gornall, AG, Luxton, AW, Bhavnani, BR. Endocrine Disorders. In Applied biochemistry of clinical disorders. 1986; 305-318. Philadelphia, PA: J. B. Lippincott Co.
2. White, GH. Recent advances in routine thyroid function testing. CRC - Critical Reviews in Clinical Laboratory Sciences. 1987; 24: 315-362.

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 FT3 FIA Rapid Test. Please read this manual carefully before operating to ensure proper use.

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