FT3 FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

Catalogue Number: FI2-FT3-001

A Fluorescence Immunoassay for the quantitative detection of free Triiodothyronine (FT3) in whole blood, serum or plasma using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda FT3 FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of free Triiodothyronine (FT3) in whole blood, serum or plasma. 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. 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.
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.

TEST PRINCIPLE

The Biopanda FT3 FIA Rapid Test Device 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 analyzer 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 safety glasses when specimens are assayed.
7. Do not interchange or mix reagents from different lots.
8. Extremes in humidity and temperatures 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 Device should only be used with the Biopanda Fluorescence Immunoassay Device (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 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 FT3 test devices
- 25 x Buffer tubes
- 25 x Capillary Droppers
- 25 x Disposable Droppers
- 1 x ID card (FT3)
- 1 x Package Insert

EQUIPMENT REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION AND PREPARATION

Venipuncture Specimens

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 3 days; for long term storage, store below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger-prick 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 freeze-thaw cycles.
5. EDTA, K2, heparin sodium, citrate sodium, and potassium oxalate, can be used as the anticoagulant for collecting specimen.

For Finger-pricked Whole Blood Specimens, please refer to the DIRECTIONS FOR USE for further information.

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 information.

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 '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 foil pouch and place it on a clean, level surface. Testing should start immediately after opening the foil pouch.
3. Follow the appropriate steps below for the prepared specimen type:
   a. **<u>For venipuncture whole blood/serum/plasma specimens:</u>**
      i. Pipette **20 µL of whole blood/serum/plasma** into the buffer tube.
      ii. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.
      iii. **Pipette 75 µL of diluted specimen** into the specimen well (S) of the test device.
   b. **<u>For finger-prick whole blood specimens:</u>**
      i. Wash hands with soap and warm water or clean finger with an alcohol pad. Allow to dry.

ii. 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.
iii. Use a sterile lancet (not provided) to puncture the skin and wipe away the first sign of blood.
iv. Gently apply pressure from palm to the pricked finger so a rounded drop of blood forms over the puncture site.
v. Using the capillary dropper provided and ensuring the dropper is level, touch the open end to the rounded drop of blood without squeezing the dropper bulb. The dropper will automatically collect the correct volume of blood (approx. 20 µL), *see Figure 1 below*.
vi. Dispense the whole blood specimen into the buffer tube by squeezing the dropper bulb.
vii. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.
viii. Using a disposable dropper, **draw the diluted specimen to the fill line** marked on the dropper (approx. 75 µL), then add to the specimen well (S) of the test device.

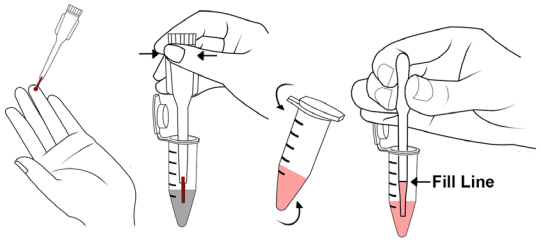

Figure 1

4. Insert the test device into the analyzer test device slot. Then according to user requirements, select either 'Standard test' or 'Quick test' mode.
5. **Test results should be read at 15 minutes** using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

The results are calculated by the Biopanda Fluorescence Immunoassay Device displayed on the analyzer screen. For additional information, please refer to the user 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)

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 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 device. 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 is ≤ ±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 Device 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 should be considered before confirming a diagnosis.
3. For patients receiving high dose biotin (approx. >5 mg/day), samples can be collected 8 hours after the last biotin dose.

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 Device. Please read this manual carefully before operating to ensure proper use.

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