

FT4 FIA Rapid Test Device (Whole Blood/Serum/Plasma)

Catalogue Number: FI2-FT4-001

*A Fluorescence Immunoassay for the quantitative detection of Free Thyroxine (FT4) 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 FT4 FIA Rapid Test Device is intended for *in vitro* quantitative determination of free Thyroxine (FT4) in human whole blood, serum, or plasma. The measurement of FT4 is used as an aid to assess thyroid function.

BACKGROUND

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. In humans, the ratio of T4 to T3 released into the blood is approximately 14:1. 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.

TEST PRINCIPLE

The Biopanda FT4 FIA Rapid Test Device 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 Device 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.
3. Do not use the test if the foil pouch is damaged.
4. Do not reuse tests.
5. 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).
6. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
7. Do not eat, drink or smoke in the area where the specimens and tests are handled.
8. 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.

9. Wear protective clothing such as laboratory coats, disposable gloves and safety glasses when specimens are assayed.
10. Do not interchange or mix reagents from different lots.
11. Extremes in humidity and temperatures can adversely affect results.
12. Used testing materials should be discarded in accordance with local regulations.
13. The Biopanda FT4 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 FT4 test devices
- 25 x Specimen collection tubes with dilution buffer
- 25 x Capillary droppers
- 25 x Disposable droppers
- 1 x ID card (FT4)
- 1 x Package insert

EQUIPMENT REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION AND PREPARATION

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 repeat freeze-thaw cycles.
5. EDTA, K2, Citrate Sodium, and Potassium Oxalate can be used as the anticoagulant for collecting the 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 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. **For venipuncture whole blood/serum/plasma specimens:**
 - 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. **For finger-prick whole blood specimens:**
 - 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.

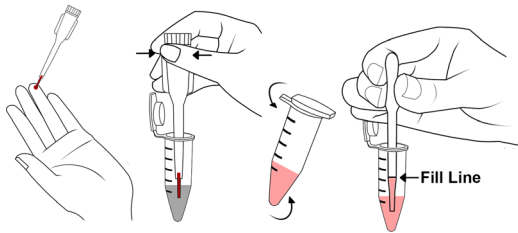


Figure 1

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 and displayed on the analyzer screen. For additional information, please refer to the user manual.

Test range is 1-100 pmol/L (0.08-7.75ng/dL).

The normal reference range is 9-19.05 pmol/L (0.7-1.48ng/dL).

EXPECTED RESULTS

| Concentrations | Clinical Reference |
|---------------------------------|--------------------|
| <9 pmol/L (0.7 ng/dL) | Hypothyroidism |
| 9-19.05 pmol/L (0.7-1.48 ng/dL) | Healthy |
| >19.05 pmol/L (1.48 ng/dL) | Hyperthyroidism |

Note: 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 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

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. (0.08-7.75ng/dL)

4. Precision

Intra-lot precision

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

LIMITATIONS OF THE TEST

1. The Biopanda FT4 FIA Rapid Test Device should be used only with the Biopanda Fluorescence Immunoassay Device.
2. The test is for professional *in vitro* diagnostic use and should only be used for the quantitative detection of FT4 in whole blood, serum or plasma.
3. 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 antigens with time and temperature.
4. 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.
5. The 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. Abnormal results (high or low) should be confirmed with other clinical findings from alternative methods.
6. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

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 FT4 FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.



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