TSH FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

Catalogue Number: FI2-TSH-001

A Fluorescence Immunoassay for the quantitative detection of Thyroid Stimulating Hormone (TSH) 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 TSH FIA Rapid Test is based on fluorescence immunoassay for the quantitative determination of Thyroid Stimulating Hormone (TSH) in whole blood, serum or plasma samples. The measurement of TSH is useful to aid in the screening of adult populations for primary hypothyroidism by medical professionals. It can also be used in screening neonates for hypothyroidism.

BACKGROUND

Thyroid-stimulating hormone (also known as thyrotropin, thyrotropic hormone, TSH, or hTSH for human TSH) is a pituitary hormone that stimulates the thyroid gland to produce thyroxine (T4), and then triiodothyronine (T3) which stimulates the metabolism of almost every tissue in the body. It is a glycoprotein hormone synthesized and secreted by thyrotrope cells in the anterior pituitary gland, which regulates the endocrine function of the thyroid. TSH (with a half-life of about an hour) stimulates the thyroid gland to secrete the hormone thyroxine (T4), which has only a slight effect on metabolism. T4 is converted to triiodothyronine (T3), which is the active hormone that stimulates metabolism. About 80% of this conversion is in the liver and other organs, and 20% in the thyroid itself. Laboratory testing of thyroid stimulating hormone levels in the blood is considered the best initial test for hypothyroidism.

TEST PRINCIPLE

The Biopanda TSH FIA Rapid Test Device detects TSH based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains TSH, it attaches to the TSH antibody which is conjugated with fluorescent microspheres. Then the complex will be captured by the capture antibody coated on the nitrocellulose membrane. The concentration of TSH in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of TSH in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) to show the concentration of TSH in the specimen.

REAGENTS

The test uses TSH detection antibody coated particles and TSH capture 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 tests.
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.
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.
6. 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.
7. Wear protective clothing such as laboratory coats, disposable gloves and safety glasses when specimens are assayed.
8. Do not interchange or mix reagents from different lots.
9. Extremes in humidity and temperature can adversely affect results.
10. Used testing materials should be discarded in accordance with local regulations.
11. The Biopanda TSH FIA Rapid Test should only be used with the Biopanda Fluorescence Immunoassay Analyzer 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 TSH test devices
- 25 x Specimen collection tubes with dilution buffer
- 25 x Capillary droppers
- 25 x Disposable droppers
- 1 x ID card (TSH)
- 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 repeated freeze-thaw cycles.
5. EDTA K2 and Heparin sodium can be used as the anticoagulant for collecting the specimen. A clean tube without coagulants can be used to collect serum specimens.

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. **<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. 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.

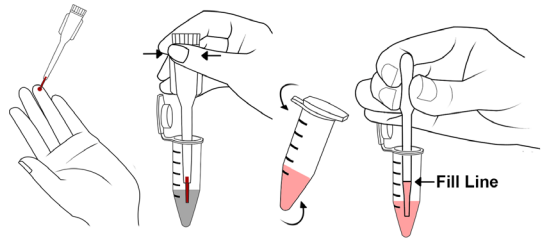

Figure 1

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.

EXPECTED RESULTS

Concentrations	Clinical Reference
0.27–4.2 µIU/mL	Healthy

Each laboratory should determine its own reference range.

QUALITY CONTROL

Each Biopanda TSH FIA Rapid Test 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 "N/A" message on the analyzer. Insufficient sample 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. **Accuracy**
   The test deviation is ≤±15%.
2. **Analytical Sensitivity**
   The test device can detect levels of TSH as low as 0.1 µIU/mL in whole blood, serum or plasma.
3. **Detection range**
   Assay range is 0.1-200 µIU/ml.
4. **Precision**

Intra-lot Precision

Within-run precision has been determined by using 10 replicates of 2 different concentrations of TSH specimens. 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 TSH specimens. C.V. is ≤ 15%.

5. **Method Comparison**
   The assay was compared with a commercially available test with 145 samples. The correlation coefficient(r) is 0.990.

LIMITATIONS OF THE TEST

1. The Biopanda TSH FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of TSH.
2. The test will only indicate the presence of TSH 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. The results are based on measuring the levels of TSH in a specimen. It should not be used as the sole criterion for treatment decisions.

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

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