



FSH FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

FI2-FSH-001

A rapid test for detecting Follicle Stimulating Hormone (FSH) in whole blood, serum, or plasma with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000). For professional *in vitro* diagnostic use only.

INTENDED USE

The Biopanda FSH FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Follicle-stimulating hormone (FSH) in whole blood, serum, or plasma.

SUMMARY

Menopause is the permanent cessation of menstruation but is usually not scientifically diagnosed until one full year after a woman's menstrual periods have stopped. The period leading up to menopause, and the 12 months following, is known as perimenopause. Many women experience symptoms during this time including hot flashes, irregular menstrual cycles, sleep disorders, vaginal dryness, hair loss, anxiety, mood swings, short-term memory loss, and fatigue. The onset of perimenopause is caused by changes in the levels of hormones in the female body that regulate the menstrual cycle. As the body produces less and less estrogen, it increases its production of FSH, which normally regulates the development of a female's eggs.¹⁻³

Therefore, testing for FSH can help determine whether a woman is in the perimenopause stage. If a woman knows she is perimenopausal, she can take the appropriate steps to keep her body healthy and avoid the health risks associated with menopause, which include osteoporosis, increased blood pressure and cholesterol, and increased risk of heart disease.^{4,5}

The Biopanda FSH FIA Rapid Test Device quantitatively detects the FSH level in Whole Blood, Serum or Plasma specimen. The test utilizes a combination of antibodies including a monoclonal anti-FSH antibody to selectively detect elevated levels of FSH. The minimum detection level is 1 mIU/mL.

PRINCIPLE

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

REAGENTS

The test kit includes anti-FSH antibody coated fluorophores and capture reagents 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. 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.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda FSH FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device 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 COMPONENTS

- 25 x foil wrapped FSH test Devices
- 25 x Specimen collection tubes with dilution buffer
- 1 x ID card (FSH)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION AND PREPARATION

PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30°C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it.

BLOOD SAMPLE TAKING

1. Collect the 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 should be stored at 2-8 °C if the test is to be used within 1 day of collections. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA, K2, Heparin sodium, Citrate sodium, and Oxalate potassium can be used as the anticoagulant for collecting the blood specimen.

SAMPLE DILUTION / SAMPLE STABILITY

1. Transfer **75 µL of whole blood, serum, or plasma** to the buffer tube with a micro pipette.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately 1 minute.
4. The diluted sample can then be used immediately or stored for up to 8 hours on an ice pack if not used immediately. Allow sample to return to room temperature before testing.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device 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.
2. Take out the ID card and insert it into the Analyser port.
3. **Whole blood/Serum/plasma:** Transfer 75 µl of whole blood/ serum/ plasma into the buffer tube, mix the specimen and the buffer well.
4. **Add diluted specimen with a Pipette:** Pipette 75 µl of diluted specimen into the sample well of the test Device. Start the timer at the same time.
5. There are two test modes for the Biopanda Fluorescence Immunoassay Device; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Device for details.

"Quick test" mode: Insert the test Device into the Analyser at 15 minutes after sample application and click "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 sample application, click "New test" at the same time, the Analyser will automatically count down the 15 minutes. After the countdown, the Analyser will give the result at once.

INTERPRETATION OF RESULTS

The result of tests for FSH is calculated by the Biopanda Fluorescence Immunoassay Device and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device.

Linearity range of the Biopanda FSH FIA Rapid Test is 10-80 mIU/mL.
Reference range: 3-25 mIU/mL.

QUALITY CONTROL

Each Biopanda FSH 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 test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Biopanda FSH FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of FSH.
2. The Biopanda FSH FIA Rapid Test Device will only indicate the presence of FSH in the specimen and the test may not be used to determine fertility. It cannot be used to determine the ability to become pregnant. Contraception decisions should not be made based on the results of this test alone.
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. Oral contraceptives and pregnancy may affect the test and produce inaccurate results.
5. The results of the Biopanda FSH FIA Rapid Tests are based on measuring the levels of FSH in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

Gender	Period	Reference Range (mIU/ml)
Male	/	1.5-12.4
Female	Follicular Period	4.5-12.4
	Ovulation	4.9-21.0
	Luteal period	2.0-8.0
	Menopause	20-98.6

Note: The establishment of the reference interval for this test device is only for specimens from local populations. It is recommended that each laboratory establish an actual reference interval based on the population, age, gender, diet, etc. in each region.

PERFORMANCE CHARACTERISTICS

1. **ACCURACY:** The test deviation is $\pm 15\%$.
2. **SENSITIVITY:** The FSH FIA Rapid Test can detect levels of FSH as low as 1 mIU/mL in Whole Blood/Serum/Plasma.
3. **DETECTION RANGE:** 1-100 mIU/mL
4. **LINEARITY RANGE:** 1-100 mIU/mL, $R \geq 0.990$
5. **CROSS-REACTIVITY**

The FSH FIA Rapid Test minimum detection level is 1 mIU/mL. The addition of LH (1,000 mIU/mL), hCG (100 IU/mL), and TSH (1,000 μ IU/mL) to negative (0 mIU/mL FSH) and positive (1 mIU/mL FSH) specimens showed no cross-reactivity.

INTERFERING SUBSTANCES

The following potentially interfering substances were added to FSH negative and positive specimens, respectively.

Acetaminophen: 20 mg/dL Caffeine: 20 mg/dL

Acetylsalicylic Acid: 20 mg/dL Gentisic Acid: 20 mg/dL
 Ascorbic Acid: 20 mg/dL Glucose 2 g/dL
 Acetoacetic Acid: 2 g/dL Hemoglobin: 500 mg/dL
 Bilirubin: 100 mg/dL
 None of the substances at the concentration tested interfered in the assay.

REFERENCES

1. Turkington CA. The Perimenopause Sourcebook. Contemporary Books, New York, NY. 1998.
2. Perry S, O'Hanlan K. Natural Menopause: The Complete Guide. Reading, MA, Addison-Wesley, 1997.
3. Stanford, JL, Weiss NS, et al. Combined Estrogen and Progesterone Hormone Replacement Therapy in Relation to Risk of Breast Cancer, J. Am. Med. Assoc. 1995; 274(2): 137-142.
4. Speroff L, Glass RH, Kase NG, Clinical Gynecologic Endocrinology and Infertility 5th Ed, Williams and Wilkins, Baltimore, MD. 1994; 588.
5. Jacobs DS, Demott DR, Grady HJ, Horvat RT, Huestis DW, Kasten BL, Laboratory Test Handbook 4th Ed, Lippincott Williams and Wilkins, Baltimore, MD. 1996.

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse test
	<i>In vitro</i> diagnostic medical device		Expiration date		Catalogue number
	Storage temperature		Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's FSH FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.



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