LH FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

FI2-LH-001

A rapid test for detecting Leuteinising hormone (LH) 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 LH FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Leuteinising hormone (LH) in whole blood, serum or plasma.

SUMMARY

Ovulation is the release of an egg from the ovary. The egg then passes into the fallopian tube where it is ready to be fertilized. In order for pregnancy to occur, the egg must be fertilized by sperm within 24 hours after its release. Immediately prior to ovulation, the body produces a large amount of luteinising hormone (LH) which triggers the release of a ripened egg from the ovary. This "LH surge" usually takes place in the middle of the menstrual cycle.[1]

The LH FIA Rapid Test is a complete system to help predict the time of ovulation, and peak fertility. It is during this fertile time that pregnancy is most likely to occur.

The LH FIA Rapid Test detects the LH surge in whole blood, serum, or plasma, signalling that ovulation is likely to occur in the next 24-36 hours. The test utilizes a combination of antibodies including a monoclonal LH antibody to selectively detect elevated levels of LH.

Important: The LH surge and ovulation may not occur in all menstrual cycles. The test utilizes a combination of antibodies including a monoclonal anti-LH antibody to selectively detect elevated levels of LH. The minimum detection level is 1 mIU/mL.

PRINCIPLE

The LH FIA Rapid Test Device detects LH based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains LH, it attaches to the fluorescent microspheres-conjugated anti-LH antibodies. Then the complex will be captured by the capture antibody coated on the nitrocellulose membrane. The concentration of LH 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 LH in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device to show LH concentration in specimens.

REAGENTS

The test kit includes anti-LH 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 LH FIA Rapid Test 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 LH test Devices
- 25 x Specimen collection tubes with dilution buffer
- 1 x ID card (LH)
- 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^{o}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 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 LH 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 LH FIA Rapid Test is 1-300 mIU/ml.

QUALITY CONTROL

Each Biopanda LH 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 LH FIA Rapid Test Device is for professional *in vitro* diagnostic use and should only be used for the quantitative detection of LH. The test works only when the test procedures are precisely followed.
2. The Biopanda LH FIA Rapid Test Device will only indicate the presence of LH in the specimen and the test may not be used as a form of birth control.
3. Like 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 test results should not be affected by pain relievers, antibiotics and other common drugs. Medication containing hCG or LH may affect the test and should not be taken while using the LH FIA Rapid Test. In addition, the test will not work properly for subjects who are pregnant, in menopause, or taking birth control pills.
5. The results of LH Tests are based on measuring the levels of LH 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	/	1.7-8.6
Female	Follicular Period	2.4-12.6
	Ovulation	14.0-95.6
	Luteal period	1.0-11.4
	Menopause	7.7-58.5

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 ≤±15%.
2. **SENSITIVITY**: The Biopanda LH FIA Rapid Test can detect levels of LH as low as 1 mIU/mL in whole blood, serum or plasma.
3. **DETECTION RANGE**: 1-300 mIU/mL.
4. **LINEARITY RANGE**: 1-300 mIU/mL, R≥0.990
5. **CROSS-REACTIVITY**

The Biopanda LH FIA Rapid Test Device has been tested with commonly known drugs and hormones including FSH (1,000 mIU/ml), TSH (1,000 µIU/ml), and hCG (100 mIU/ml). At the levels tested, none of these substances interfered with the expected test results.

REFERENCES

1. Elkind-Hirsch, K; Goldzieher, JW; Gibbons, WE and Besch, PK. Obstetrics and Gynecology, 67(3): 450-453, 1986.

Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalogue #
	Store between 4-30°C	LOT	Lot Number		Consult instructions
	Do not use if package is damaged		Manufacturer		

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

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