

β-hCG FIA Rapid Test

(Serum/Plasma)

FIA-BHCG-001

A rapid test for detecting β-human chorionic gonadotropin (β-hCG) in serum or plasma with the use of the Biopanda Fluorescence Immunoassay Analyser.
For professional *in vitro* diagnostic use only.

INTENDED USE

The Biopanda β-hCG FIA Rapid Test is based on Fluorescence Immunoassay for the quantitative determination of β-human chorionic gonadotropin (β-hCG) in serum or plasma.

SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both serum or plasma as early as 7 to 10 days after conception.^{1,2,3,4} It is heterodimeric, with an α (alpha) subunit identical to that of luteinizing hormone (LH), follicle-stimulating hormone (FSH), thyroid-stimulating hormone (TSH), and β (beta) subunit that is unique to hCG. This procedure is employed to ensure that tests do not make false positives by confusing hCG with LH and FSH. (The latter two are always present at varying levels in the body, whereas the presence of hCG almost always indicates pregnancy.)

Human chorionic gonadotropin (hCG) is a hormone produced by the placenta after implantation.^{5,6} The presence of hCG is detected in some pregnancy tests (HCG pregnancy strip tests). Some cancerous tumours produce this hormone; therefore, elevated levels measured when the patient is not pregnant may lead to a cancer diagnosis and, if high enough, paraneoplastic syndromes, however, it is not known whether this production is a contributing cause, or an effect of carcinogenesis. The pituitary analog of hCG, known as luteinizing hormone (LH), is produced in the pituitary gland of males and females of all ages.^{5,7} This tests employ a monoclonal antibody, which is specific to the β-subunit of hCG (β-hCG).

The Biopanda β-hCG FIA Rapid Test quantitatively detects the β-hCG level in serum or plasma specimens. The test utilizes a combination of antibodies including a monoclonal anti-β-hCG antibody to selectively detect elevated levels of β-hCG. The minimum detection level is 5mIU/mL.

PRINCIPLE

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

REAGENTS

The test kit includes anti-β-hCG 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 β-hCG FIA Rapid Test should only be used with the Biopanda Fluorescence Immunoassay Analyser 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

- 10 x foil wrapped β-hCG test cassettes
- 10 x Specimen collection tubes with dilution buffer
- 1 x ID card (β-hCG)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Analyser

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.
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 **15 µL of 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 Analyser 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. **Serum/plasma:** Transfer 15 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 cassette. Start the timer at the same time.
5. There are two test modes for the Biopanda Fluorescence Immunoassay

Analysers; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser for details.

“Quick test” mode: Insert the test cassette 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 cassette 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 β -hCG is calculated by the Biopanda Fluorescence Immunoassay Analyser and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser.

Linearity range of the Biopanda β -hCG FIA Rapid Test is 5-10,000 mIU/ml.

QUALITY CONTROL

Each Biopanda β -hCG FIA Rapid Test Cassette 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 Analyser. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Analyser 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

- The Biopanda β -hCG FIA Rapid Test is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of β -hCG. The test works only when the test procedures are precisely followed.
- High concentrations of β -hCG may produce a dose hook effect, resulting in incorrect interpretation of β -hCG levels. High dose hook effect has not been observed with this test up to 10,000 mIU/mL of β -hCG.
- A number of conditions other than pregnancy, including testicular tumours, prostate cancer, breast cancer, and lung cancer, cause elevated levels of β -hCG.⁸ Therefore, the presence of β -hCG in sample should not be used to diagnose pregnancy unless these conditions have been ruled out.
- The results of β -hCG Tests are based on measuring the levels of β -hCG 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

Concentrations	Clinical Reference
>25 mIU/ml	The result is positive and patient is pregnant
<25 mIU/ml	The result is negative and the patient is not pregnant or it is too early to detect pregnancy.

PERFORMANCE CHARACTERISTICS

- ACCURACY:** The test deviation is $\leq \pm 15\%$.
- SENSITIVITY:** The Biopanda β -hCG FIA Rapid Test can detect levels of β -hCG as low as 5 mIU/mL in serum or plasma.
- DETECTION RANGE:** 5-10,000 mIU/mL.
- LINEARITY RANGE:** 5-10,000 mIU/mL, $R \geq 0.990$
- CROSS-REACTIVITY**
The Biopanda β -hCG FIA Rapid Test Cassette minimum detection level is 5mIU/mL. The addition of LH (300mIU/ml), FSH (1,000mIU/ml), and TSH (1,000 μ IU/ml) to negative (0 mIU/mL HCG) and positive (25 mIU/mL HCG) 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:20mg/dL
Atropine:20 g/dL
Bilirubin:2mg/dL

Glucose 2 g/dL
Hemoglobin:500 mg/dL

None of the substances at the concentration tested interfered in the assay

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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 β -hCG FIA Rapid Test. Please read this manual carefully before operating to ensure proper use.



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