β-hCG FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

FI2-BHCG-001

A rapid test for detecting β-human chorionic gonadotropin (β-hCG) 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 β-hCG FIA Rapid Test Device is based on fluorescence immunoassay for the quantitative determination of β-human chorionic gonadotropin (β-hCG) in whole blood, serum, or plasma samples.
The minimum detection level is 5mIU/mL.

BACKGROUND

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after implantation. It is a heterodimer composed of an α (alpha) subunit, which is shared with luteinizing hormone (LH), follicle-stimulating hormone (FSH), and thyroid-stimulating hormone (TSH), and a β (beta) subunit, which is unique to hCG. The β-subunit provides analytical specificity, allowing immunoassays to distinguish hCG from structurally related hormones such as LH and FSH, which are normally present in varying concentrations in the body.
In a normal pregnancy, hCG can be detected in serum or plasma as early as 7 to 10 days after conception, and its levels rise rapidly during early gestation. Detection of hCG is widely used to confirm pregnancy.
In addition to pregnancy, elevated hCG levels may be observed in certain pathological conditions, including trophoblastic diseases and some non-trophoblastic tumors. For this reason, hCG testing can occasionally aid in clinical evaluation beyond pregnancy detection.

TEST PRINCIPLE

The β-hCG FIA Rapid Test Device 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 linearily 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 Device 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. 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 safety glasses when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Extremes in humidity and temperatures 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 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.
2. The test must remain in the sealed foil 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 CONTENTS

- 25 x Foil wrapped β-hCG Rapid Test Device
- 25 x Specimen collection tubes with dilution buffer
- 25 x Capillary Droppers
- 25 x Disposable Droppers
- 1 x ID card (β-hCG)
- Package Insert

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 patient's name or ID on it.

Blood sample collection

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

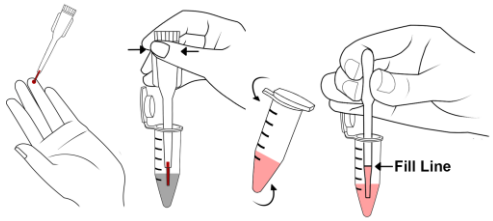
1. Transfer **15 µL of whole blood, serum, or plasma** to the buffer tube with a micro pipette.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenise for approximately 1 minute.
4. The diluted sample can then be used immediately or stored for up to 8 hours on an ice pack if not used immediately. Allow sample to reach room temperature before testing.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device User 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 select the test mode and/or sample type according to testing needs.
2. Insert the ID card provided with the kit into the analyser port.
3. Remove the test cassette from the sealed foil pouch and start testing as soon as possible.
4. Take the tube of diluted specimen, and **pipette 75 µl of diluted specimen** into the sample well (S) of the test. Start the timer.



5. Test results should be read at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: *Standard Test mode and Quick Test mode*. Refer to the User Manual for further information.

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 concurrently.

INTERPRETATION OF RESULTS

Test results are calculated by the Biopanda Fluorescence Immunoassay Device and displays the result on the screen. For additional information, please refer to the analyser user manual.

Linearity range of the Biopanda β-hCG FIA Rapid Test Device is 2-200,000 mIU/ml.

QUALITY CONTROL

Each Biopanda β-hCG 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.

EXPECTED RESULTS

Gestational weeks	Serum/plasma β-hCG reference values mIU/ml
0.2-1	5-50
1-2	50-500
2-3	100-5000
3-4	500-10,000
4-5	1,000-50,000
5-6	10,000-100,000
6-8	15,000-200,000
8-12	10,000-100,000

Note: Whether there is a high or low level of the hormone is not the key indicator of a healthy pregnancy. This is because many factors can influence hCG levels, including maternal smoking, body mass index (BMI), ethnicity, parity (the number of times a woman has given birth), and hyperemesis gravidarum (severe morning sickness) and so on.

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **SENSITIVITY**: The Biopanda β-hCG FIA Rapid Test Device can detect levels of β-hCG as low as 2 mIU/mL in whole blood, serum, or plasma.
3. **DETECTION RANGE**: 2-200,000 mIU/mL.
4. **LINEARITY RANGE**: 2-200,000 mIU/mL, R≥0.990
5. **CROSS-REACTIVITY**

   The Biopanda β-hCG FIA Rapid Test Device reference range level is 5mIU/mL. The addition of LH (300mIU/ml), FSH (1,000mIU/ml), and TSH (1,000µIU/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 β-hCG 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	Glucose:	2 g/dL
Atropine:	20 g/dL	Haemoglobin:	500 mg/dL
Bilirubin:	2mg/dL		

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

LIMITATIONS OF THE TEST

1. The Biopanda β-hCG FIA Rapid Test Device 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.
2. 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.
3. 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.
4. 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.

REFERENCES

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2. Nwabuobi, C., Arlier, S., Schatz, F., Guzeloglu-Kayisli, Ö., Lockwood, C. J., & Kayisli, U. A. (2017). hCG: Biological functions and clinical applications. International Journal of Molecular Sciences, 18(10), 2037. https://doi.org/10.3390/ijms18102037
3. Iles, R. K., Javid, M. K., Gunn, L. K., & Chard, T. (1999). Cross-reaction with luteinizing hormone β-core is responsible for the age-dependent increase of immunoreactive β-core fragment of human chorionic gonadotropin in women with nonmalignant conditions. Clinical Chemistry, 45(4), 532-538. https://doi.org/10.1093/clinchem/45.4.532

INDEX OF SYMBOLS

	Manufacturer		Tests per kit		Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
	Storage temperature	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

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

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