C-peptide FIA Rapid Test Device

(Whole Blood/Serum/Plasma/Urine)

Catalogue No.: FI2-CPEP-001

A Fluorescence Immunoassay for the quantitative detection of C-peptide in human 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 C-peptide FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of C-peptide in whole blood, serum, plasma, or urine as an aid in the diagnosis of diabetes.

BACKGROUND

C-peptide is a single-chain polyPeptide consisting of 31 amino acids, with a molecular weight of 3021 Da. C-peptide is generated by the cleavage of proinsulin and plays an important role in the formation of the disulfide bonds of the insulin and the structure of the insulin dimer (A chain and B chain).
C-Peptide, insulin and blood glucose tests are used in combination to assist in the differential diagnosis of hypoglycaemia. The level of C-peptide can more accurately reflect insulin secretion through quantitative detection. Therefore, C-peptide can assist in assessing the insulin secretory level of patients with early type 1 diabetes, and can also be used to distinguish latent autoimmune diabetes in adults and type 2 diabetes. C-peptide can be used for efficacy evaluation and monitoring of the pancreas, pancreatic resection, and C-peptide levels in both blood and urine can be used to evaluate pancreas function. The possible factors for increased C-peptide levels are hyperinsulinemia due to increased small cell activity, renal dysfunction, and obesity.

TEST PRINCIPLE

The C-peptide FIA Rapid Test Device is a quantitative membrane-based fluorescence immunoassay for the detection of C-peptide in human whole blood, serum, plasma or urine specimens. During testing, the sample moves through the strip from sample pad to absorbent pad. C-peptide in the sample will combine with the C-peptide antigen coated on the membrane. The fluorescent microspheres coupled to the C-peptide antibody showed a positive correlation with the C-peptide concentration in the specimen, which can be captured by the C-peptide antigen coated on the membrane (Test line). According to the fluorescence intensity of the test and the standard curve, the concentration of C-peptide in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device to show C-peptide antigen concentration in specimen.

REAGENTS

The test contains C-peptide coated with cellulose nitrate membrane and C-peptide antibody which conjugated with fluorescence particles.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package.
3. Do not use the test if the foil pouch is damaged.
4. Do not reuse tests.
5. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
6. 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 safety glasses when specimens are assayed.
7. Do not interchange or mix reagents from different lots.
8. Extreme humidity and temperatures can adversely affect results.
9. Used testing materials should be discarded in accordance with local regulations.
10. Read the entire procedure carefully prior to any testing.
11. The Biopanda C-peptide 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. 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 C-peptide test devices
- 25 x Specimen collection tubes with extraction buffer
- 25 x Capillary droppers
- 25 x Disposable droppers
- 1 x ID card (C-peptide)
- 1 x Package insert

EQUIPMENT REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION AND PREPARATION

Venipuncture Specimens

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 freezing and thawing of specimens.
5. EDTA and Heparin Sodium can be used as the anticoagulant for collecting the blood specimen.
6. To ensure the accuracy of the C-peptide test, whole blood, serum, or plasma specimens should be collected under fasting conditions.

***For Finger-pricked Whole Blood Specimens, please refer to the DIRECTIONS FOR USE for further information*.**

Urine Specimens

1. A urine specimen must be collected in a clean and dry container. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.
2. Do not leave specimens at room temperature for prolonged periods; urine specimens may be stored at 15-25°C for up to 4 hours, or 2-8°C for up to 24 hours. For long term storage, specimens should be kept below -20°C, which is valid for 30 days.

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 details.

Allow the test cassette, specimen, and buffer tube to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyzer and insert the ID card into the analyzer '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 sealed foil pouch and place on a clean,

level surface.

3. Follow the appropriate steps below for the prepared specimen type:
   a. **For venipuncture whole blood/serum/plasma/urine specimens:**
      i. Pipette **20 µL of whole blood/serum/plasma or 5 µl of urine** 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. Let the mixture homogenise for about 1 minute. Diluted specimens should be used as soon as possible.
      iv. **Pipette 75 µL of diluted specimen** into the specimen well (S) of the test cassette.
   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 cassette.

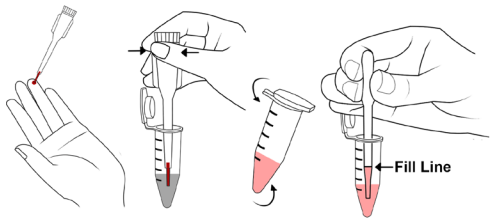

Figure 1

4. Insert the test device into the analyzer test device slot. 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 test results are calculated by the Biopanda Fluorescence Immunoassay Device and displayed on the analyzer screen after testing is complete. For additional information, please refer to the user manual.

Linearity range of the test is 0.04-160 ng/mL.

QUALITY CONTROL

Each Biopanda C-peptide 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. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Device. 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

Concentrations	Clinical Reference
0.8-4.2 ng/mL (Whole blood/Serum/Plasma); 36.4-81.36 µg/24h (Urine)	Not indicative of Diabetes
>4.2 ng/mL (whole blood/Serum/Plasma); >81.36 µg/24h (Urine)	Indicative of Diabetes

PERFORMANCE CHARACTERISTICS

1. **Accuracy**
   The test deviation is ≤±15%.
2. **Sensitivity**
   The C-peptide FIA Rapid Test Device can detect levels of C-peptide as low as 0.04 ng/mL in whole blood/serum/plasma, or 0.16 ng/mL in urine.
3. **Detection range**
   Whole Blood/Serum/Plasma: 0.04-40.0 ng/mL
   Urine: 0.16-160.0 ng/mL
4. **Linearity range**
   Whole Blood/Serum/Plasma: 0.04-40.0 ng/mL, R≥0.990
   Urine: 0.16-160.0 ng/mL, R≥0.990
5. **Precision**
   Intra-lot precision
   Within-run precision has been determined by using 10 replicates of 2 different concentrations of C-peptide specimens. C.V. is ≤ 15%.
   Inter-lot precision
   Between-run precision has been determined by using 10 replicates of 2 different concentrations of C-peptide specimens. C.V. is ≤15%.
6. **Cross-reactivity**
   Cross-reactivity studies were carried out with following analytes:
   HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-*H.pylori*, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no cross-reactivity.
7. **Interfering Substances**
   The following potentially interfering substances were added to 2 specimens containing 0.5 ng/mL and 5 ng/mL of C-peptide.
   Acetaminophen: 20 mg/dL, Caffeine: 20 mg/dL, Acetylsalicylic Acid: 20 mg/dL Gentisic Acid: 20 mg/dL, Ascorbic Acid: 20 mg/dL, Albumin: 10,500 mg/dL, Creatin: 200 mg/dL, Hemoglobin: 1,000 mg/dL, Bilirubin: 1,000 mg/dL, Oxalic Acid: 600 mg/dL, Cholesterol: 800 mg/dL, Triglycerides: 1,600 mg/dL.
   None of the substances at the concentration tested interfered in the assay.
8. **Method comparison**
   The product was evaluated with 107 clinical samples compared with commercial CLIA test kit. The correlation coefficient(r) is 0.9782.

LIMITATIONS OF THE TEST

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

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

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