Insulin FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

Catalogue No.: FI2-INS-001

A Fluorescence Immunoassay for the quantitative detection of Insulin 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 Insulin FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Insulin in whole blood, serum, or plasma. This test can be used as an indicator of insulin sensitivity or resistance.

BACKGROUND

Insulin is a protein hormone secreted by pancreatic β-cells in the pancreas stimulated by endogenous or exogenous substances such as glucose, lactose, ribose, arginine, and glucagon. It was first discovered in 1921 by Canadians F.G. Banting and C.H. Best. Insulin began to be used clinically in 1922. The insulin molecule consists of two polypeptide chains, the α-chain with 21 amino acids and the β-chain with 30 amino acids, and has a relative molecular mass of 5,808. The biosynthesis of this hormone takes place in the β-cells of the pancreatic islets in the form of a single-chain islet of insulinogen, which is immediately cleaved to produce insulinogen. Specific proteases break down insulinogen into insulin and C-peptide, which enters the bloodstream simultaneously. Insulin is the only hormone in the body that lowers blood glucose while promoting glycogen, fat, and protein synthesis. Usually, insulin levels are not used in the diagnosis and treatment of diabetes. However, they are useful in evaluating a patient's fasting hypoglycemia, determining insulin resistance in the general population, assessing beta cell levels, and assessing abnormalities in beta cell secretion. In addition, insulin levels are also used to study the pathology of diabetes.

TEST PRINCIPLE

The Insulin FIA Rapid Test Device is based on fluorescence immunoassay to detect the concentration of Insulin in human whole blood, serum or plasma. The sample moves from sample pad to absorbent pad. If the specimen contains Insulin, it attaches to the fluorescent microspheres-conjugated Insulin antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of Insulin 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 Insulin in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device to show Insulin concentration in specimen.

REAGENTS

The test includes anti-Insulin antibody coated on fluorescent microspheres and anti-Insulin antibody 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.
5. 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.
6. 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. The Biopanda Insulin 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. 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 Insulin test devices
- 25 x Specimen collection tubes with extraction buffer
- 25 x Capillary droppers
- 25 x Disposable droppers
- 1 x ID card (Insulin)
- 1 x Package insert

EQUIPMENT REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION AND PREPARATION

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 repeat freeze-thaw cycles.
5. EDTA and heparin sodium can be used as the anticoagulant for collecting the blood specimen.

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

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 device, 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. **<u>For venipuncture whole blood/serum/plasma specimens:</u>**
      i. Pipette **20 µl of whole blood/serum/plasma** 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 diluted specimen homogenise for approximately 1 minute.
      iv. **Pipette 75 µl of diluted specimen** into the specimen well (S) of the test device.
   b. **<u>For finger-prick whole blood specimens:</u>**
      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 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 device.

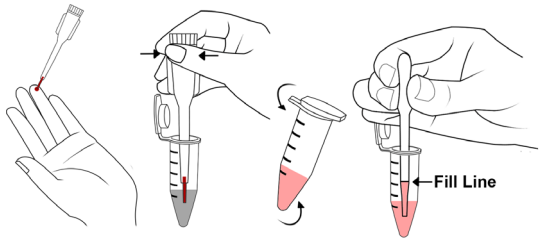

Figure 1

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 1.0-1000 mU/L.

EXPECTED RESULTS

Fasting levels of healthy individuals reference interval: 2.6-24.9 mU/L.

The reference ranges vary between countries due to differences in body size and nutrition. Each laboratory should determine the applicability of the reference range through experiments, and establish its own reference value range if necessary to ensure that it can correctly reflects the situation of a particular population.

QUALITY CONTROL

Each Biopanda Insulin 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.

PERFORMANCE CHARACTERISTICS

1. **Accuracy**
   The test deviation is ≤ ±15%.
2. **Analytical sensitivity**
   The Insulin FIA Rapid Test Device can detect levels of insulin as low as 1.0 mU/L in whole blood, serum or plasma specimens.
3. **Detection range**
   The detection range is 1.0-1000 mU/L.
4. **Precision**

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 different concentrations of insulin specimens. C.V. is ≤ 15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 different concentrations of insulin specimens. C.V. is ≤15%.

5. **Interfering Substances**
   The following substances do not interfere with the test results at the indicated concentrations:
   Ascorbic Acid at 100 mg/L, Haemoglobin at 5 g/L, Triglyceride at 15 g/L, Bilirubin at 1,000 mg/dL.
6. **Method comparison**
   The Biopanda Insulin FIA Rapid Test Device was evaluated with 122 clinical samples against a commercially available CLIA test kit. The correlation coefficient(r) is 0.9852.

LIMITATIONS OF THE TEST

1. The Biopanda Insulin FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of insulin in whole blood, serum, or plasma.
2. The test only indicates the presence of insulin in the specimen and should not be used as the sole indicator of insulin sensitivity or resistance.
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 results are based on measuring the levels of insulin 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 ensure 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 Insulin FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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