IL-6 FIA Rapid Test Device
(Whole Blood/Serum/Plasma)

Catalogue Number: FI2-IL6-001

For the quantitative detection of interleukin-6 (IL-6) in 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 IL-6 FIA Rapid Test Device is a fluorescence immunoassay for the quantitative determination of interleukin-6 (IL-6) in human whole blood, serum, or plasma. It is mainly used to monitor the immune status and inflammatory response of the body.

BACKGROUND
Interleukin-6 (IL-6) is a pleiotropic cytokine with a wide range of biological roles in inflammation, immune response, haematopoiesis and carcinogensis. IL-6 is involved in the occurrence and development of many diseases; IL-6 in blood levels are closely related to inflammation, viral infection, and autoimmune diseases. Studies have shown that IL-6 increases rapidly after bacterial infection, PCT increases after 2 hours, and CRP increases rapidly after 6 hours. Responding to infection or tissue damage, macrophages and other white blood cells secrete IL-6. This then stimulates the production of C-reactive protein (CRP) and procalcitonin (PCT) in the liver, and also induces the growth of B cells and antibody production. Therefore, the elevation of these biomarkers is directly related to the degree of inflammation and infection.

TEST PRINCIPLE
The Biopanda IL-6 FIA Rapid Test Device detects interleukin-6 in a fluorescence immunoassay. The sample moves through the strip from the sample pad to absorbent pad. If the sample contains IL-6, it binds to the fluorescent microsphere-conjugated anti-IL-6 antibodies. Any complexes will be captured by the capture antibodies coated on the nitrocellulose membrane (test line). The concentration of interleukin-6 in the sample correlates linearly with the fluorescence signal intensity captured on the T line. By comparing the intensity of the fluorescence signal to a standard curve, the concentration of IL-6 in the sample can be calculated and displayed by the analyser.

REAGENTS
The test contains anti-IL-6 detection antibody coated fluorophores and anti-IL-6 capture 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.
3. Do not use the test if the foil pouch is damaged.
4. Do not reuse tests.
5. Avoid cross-contamination of samples by using a new sample collection container for each sample obtained.
6. Do not eat, drink or smoke in the area where the samples and tests are handled.
7. Handle all samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of samples.
8. Wear protective clothing such as laboratory coats, disposable gloves and safety glasses when samples are assayed.
9. Do not interchange or mix reagents or ID cards from different lots.
10. Extremes in humidity and temperature can adversely affect results.
11. Used testing materials should be discarded in accordance with local regulations.
12. The Biopanda IL-6 FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) by 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 IL-6 rapid test devices
- 25 x Sample collection tubes with buffer solution
- 25 x Capillary Droppers
- 25 x Disposable Droppers
- 1 x ID card (IL-6)
- 1 x Package insert

EQUIPMENT REQUIRED BUT NOT PROVIDED
- Timer
- Pipette
- Sample collection containers
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SAMPLE COLLECTION AND PREPARATION
- Collect the specimen according to standard procedures.
- Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
- 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.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freeze-thaw cycles.
- EDTA and sodium citrate can be used as the anticoagulant for collecting blood samples.

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 information.

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 '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 foil pouch and place it on a clean, level surface. Testing should start immediately after opening the foil pouch.
3. Follow the appropriate steps below for the prepared specimen type:
   a. **<u>For venipuncture whole blood/serum/plasma specimens:</u>**
      i. Pipette **75 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. **Pipette 75 µL of diluted specimen** into the specimen well (S) of the test cassette.
   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 rounded drop of blood without squeezing the dropper bulb. The dropper will automatically collect the correct volume of blood (approx. 75 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.

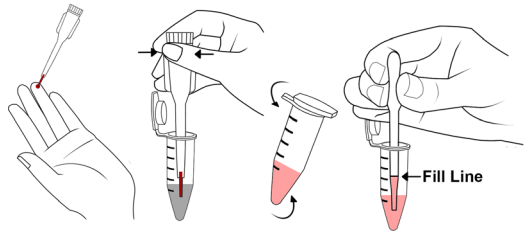

Figure 1

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

The assay range is 3.0–5000 pg/ml.

EXPECTED RESULTS

Concentrations	Clinical Reference
< 10.0 pg/ml	Normal
10 – 150 pg/ml	The possibility of viral infection is relatively high
150 – 250 pg/ml	Possible acute bacterial infection. Check whether IL-6 concentration has decreased after 24 hours.
> 250 pg/ml	High risk of sepsis

Note: It is recommended that each laboratory establish an actual reference interval based on the population, age, gender, diet, etc., in each region.

QUALITY CONTROL

Each IL-6 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 "N/A" message on the analyser. Insufficient sample 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

Method Comparison

A comparison study was conducted with the Biopanda IL-6 FIA Rapid Test Device and a commercially available Interleukin-6 test with 80 samples. The overall correlation coefficient (r) is 0.996.

Accuracy

The test deviation is ≤±15%.

Assay Range and Detection Limit

- Assay range: 3–5000 pg/ml
- Minimum detection limit (Analytical Sensitivity): 3 pg/ml

Linearity Range

3–5000 pg/ml, R ≥ 0.990

Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 3 samples containing 10 pg/ml, 100 pg/ml, and 1000 pg/ml of Interleukin-6. C.V. is ≤ 15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 3 samples containing 10 pg/ml, 100 pg/ml, and 1000 pg/ml of Interleukin-6. C.V. is ≤15%.

Interfering Substances

The following substances do not interfere with the test results at the indicated concentrations:

Substance	Concentration
Bilirubin	20 mg/mL
CRP	100 mg/mL
Haemoglobin	1 g/dL
PCT	50 ng/mL
SAA	300 mg/mL

LIMITATIONS OF THE TEST

1. The Biopanda IL-6 FIA Rapid Test Device should be used only with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
2. The test is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of interleukin-6. This test should not be used as the sole criteria for clinical result. If the test result is abnormal, other clinical findings and alternative test methods should be considered before making a diagnosis.
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. High concentrations of IL-6 may produce a dose hook effect, resulting in incorrect interpretation of IL-6 levels. A dose hook effect has not been observed with this test at up to 10 ng/ml of IL-6.
5. The test assay range of this test kit is 3.0–5000 pg/ml. When the concentration of the sample exceeds the upper limit of the test, the high-concentration sample should be diluted with calf serum or negative samples, and the maximum dilution factor should not exceed 4 times.

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 IL-6 FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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