IL-6 FIA Rapid Test Cassette

Catalogue No.: FIA-IL6-001

For use with the Biopanda Fluorescence Immunoassay Analyser.
For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda IL-6 FIA Rapid Test Cassette 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.[1] 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.[2,3]

TEST PRINCIPLE

The Biopanda IL-6 FIA Rapid Test Cassette 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. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of samples by using a new sample collection container for each sample obtained.
4. Do not eat, drink or smoke in the area where the samples and tests are handled. 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.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
6. Do not interchange or mix reagents or ID cards from different lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire test procedure carefully prior to any testing.
10. The Biopanda IL-6 FIA Rapid Test Cassette should only be used with the Biopanda Fluorescence Immunoassay Analyser 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.
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

Materials Provided:

- 10 x foil wrapped cassettes
- 10 x sample collection tubes with buffer solution
- 1 x ID card (IL-6)
- Package Insert

Materials required but not provided:

- Timer
- Pipette
- Sample collection containers
- Biopanda Fluorescence Immunoassay Analyser

SAMPLE COLLECTION AND PREPARATION

- Collect the samples according to standard procedures.
- Do not leave samples at room temperature for prolonged periods. Serum and plasma samples may be stored at 2-8°C for up to 5 days. For long term storage, samples should be kept below -20°C.
  Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be used within 2 days of collection. Do not freeze whole blood samples. Whole blood collected by finger prick should be tested immediately.
- Bring samples to room temperature (15-30°C) prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Avoid repeat freeze thaw cycles. Only use clear, non-haemolysed samples.
- EDTA, sodium citrate, can be used as the anticoagulant tube for collecting blood samples.

Sample dilution / Sample stability

- 75 µl of sample (whole blood, serum or plasma) can be added directly with a micro pipette into the collection tubes with buffer solution.
- Close the lid on the tube and shake vigorously for approximately 10 seconds to mix the sample with dilution buffer.
- Let the diluted sample homogenise for approximately 1 minute.
- The diluted sample can then be used immediately or stored for no more than 8 hours at 2-8°C.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Analyser User Manual for the complete instructions on use of the analyser. The test should be conducted at room temperature.

Allow the test, sample, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. **Choose test mode**: "Standard test" or "Quick test" according to your requirements, and **select sample type**: whole blood or serum/plasma (S/P).
2. Take out the ID card and insert it into the ID Card Slot.
3. Remove the test cassette from the foil pouch and use within an hour of opening. For optimal results, perform test immediately after opening. Place the cassette on a level and clean surface.
4. Pipette **75 µL of sample** into the sample collection tube with buffer. Mix the sample and the buffer well.
   The diluted sample should be used immediately and stored for no more than 8 hours at 2-8°C.
5. Pipette **75 µL of diluted sample** into the sample well of the cassette. Start the timer.
6. Test results should be interpreted at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Analyser.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Analyser: Standard Test mode and Quick Test mode. Please refer to the user manual of for full details.

"Quick test" mode: Insert the test cassette into the analyser 15 minutes after sample application and select "QUICK TEST". Fill in the test information and select "NEW TEST" immediately. The analyser will display the test result after a few seconds.

"Standard test" mode: Insert the test cassette into the analyser immediately after sample application. Select "STANDARD TEST", fill the test information and select "NEW TEST", the analyser will automatically start a 15 minute timer. After the 15 minutes are up, the analyser will display the test result.

INTERPRETATION OF RESULTS

The result of the IL-6 test is automatically calculated by the Biopanda Fluorescence Immunoassay Analyser and displayed on the analyser screen. For additional information, please refer to the user manual.
The assay range of IL-6 is 3.0 – 5000 pg/ml.

QUALITY CONTROL

Each Biopanda IL-6 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 "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.

LIMITATIONS OF THE TEST

1. The Biopanda IL-6 FIA Rapid Test Cassette should be used only with the Biopanda Fluorescence Immunoassay Analyser.
2. The Biopanda IL-6 FIA Rapid Test Cassette 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 result is abnormal, other clinical findings and alternative test methods are recommended to reach proper medical treatments.
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.

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: The establishment of the reference interval for this test cassette is only for samples from a specific local population. It is recommended that each laboratory establish an actual reference interval based on the population, age, gender, diet, etc., in each region.

PERFORMANCE CHARACTERISTICS

Method Comparison

The Biopanda IL-6 FIA Rapid Test Cassette was compared with Siemens Advia Centaur 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

REFERENCES

1. Berti, A., Warner, R., Johnson, K., Cornec, D., Schroeder, D. R., Kabat, B. F., ... & RAVE-ITN Research Group. (2019). The association of serum interleukin-6 levels with clinical outcomes in antineutrophil cytoplasmic antibody-associated vasculitis. Journal of autoimmunity, 105, 102302.
2. Nishimoto, N., & Kishimoto, T. (2006). Interleukin 6: from bench to bedside. *Nature clinical practice Rheumatology*, *2*(11).
3. Nawata, Y., Eugui, E. M., Lee, S. W., & Allison, A. C. (1989). IL-6 is the principal factor produced by synovia of patients with rheumatoid arthritis that induces B-lymphocytes to secrete immunoglobulins. *Annals of the New York Academy of Sciences*, *557*, 23.

SYMBOLS USED

The following symbols are used on the packaging and labelling. They are presented here along with their meaning.

	Manufacturer		Expiration date
	Do not re-use test		*in vitro* diagnostic medical device
	Consult instructions for use		Batch code
	Storage temperature		Contains sufficient for <*n*> tests
	Catalogue number		Do not use if package is damaged

Thank you for purchasing Biopanda's IL-6 FIA Rapid Test Cassette. Please read this manual carefully before operating to ensure proper use.

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