CE

Diagnostic Kit for Interleukin-6

A test for the diagnosis of inflammatory condition and Immune status by measuring IL-6 in whole blood, serum or plasma with the use of Immunofluorescence Analyzer.

English

- For *in-vitro* diagnostic use

PACKING SPECIFICATION
25 Tests/ Kit (07IL5025)

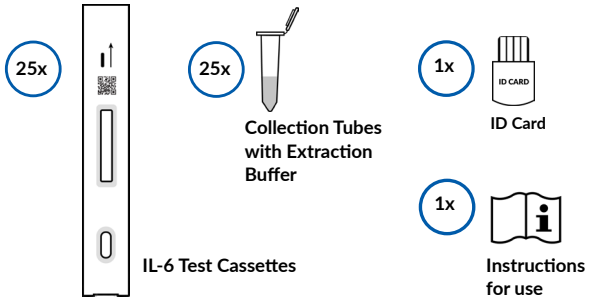
INTENDED USE
The IL-6 Test Cassette (Whole Blood/Serum/Plasma) is based on Fluorescence Immunoassay for the quantitative determination of Interleukin-6 (IL-6) in serum, plasma or whole blood. It is mainly used to monitor the immune status and inflammation of the body Response etc. The test is intended for healthcare professionals use.

SUMMARY
Interleukin-6 (IL-6) is a pleiotropic cytokine with a wide range of biological roles in inflammation, immunomodulatory, hematopoietic and tumor.[1] IL-6 is involved in the occurrence and development of many diseases. Its blood level is closely related to inflammation, viral infection, and autoimmune diseases. It changes earlier than CRP and PCT. Studies have shown that IL-6 increases rapidly after bacterial infection, PCT increases after 2h, and CRP increases rapidly after 6h. Its mechanism is: when the body infected or tissue damage and other white blood cells are activated macrophages, produce interleukin 6 (IL-6), IL-6 induced liver cells after the creation of c-reactive protein (CRP) and calcitonin original (PCT) and inducing mature B cells to produce antibodies, therefore directly related to degree of inflammatory bowel disease and infection.[2,3]

PRINCIPLE
The IL-6 Test Cassette is detects interleukin 6 (IL-6) based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains IL-6, it attaches to the fluorescent microspheres-conjugated anti-IL-6 antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of IL-6 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 IL-6 in the sample can be calculated by Analyzer to show IL-6 concentration in specimen.

REAGENTS
The test include anti-IL-6 antibody coated fluorophore and anti-IL-6 antibody coated on the membrane.

MATERIALS PROVIDED



MATERIALS REQUIRED BUT NOT PROVIDED
- Immunofluorescence Analyzer MPQuanti® (07IMA001)
- Pipette
- Specimen Collection Containers
- Centrifuge (for serum/plasma specimen only)
- Timer

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. 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 eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature 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 IL-6 Test Cassette should only be used with the Analyzer by approved medical professionals.

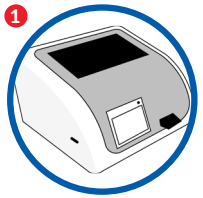
STORAGE AND STABILITY
1. The test should be stored at 4 - 30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the test from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SAMPLE COLLECTION AND PREPARATION

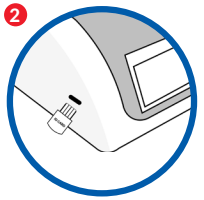
Preperation
1. Collect the specimens according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and Plasma specimens may be stored at 2 - 8 °C for up to 5 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2 - 8 °C if the test is to be used within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
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. Only clear, non-hemolyzed specimens can be used.
4. EDTA, Sodium citrate, can be used as the anticoagulant tube for collecting the blood specimen.

Sample Dilution / Sample Stability
1. The specimen (75 µL of serum/plasma/whole blood) can be added directly with the micro pipette into the buffer.
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 homegenize for approximately 1 minute.
4. The diluted sample can then be used immediately or stored for up to 8 hours.

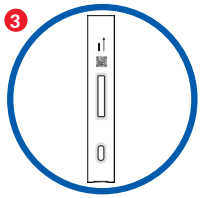
TEST PROCEDURE
Refer to Immunofluorescence Analyzer User Manual for the complete instructions for use of the Test. The test should be in room temperature.
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



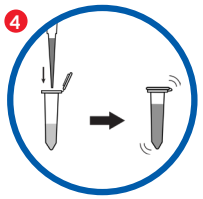
Turn on the Analyzer power.



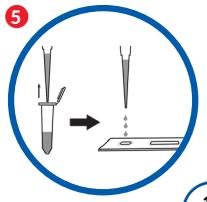
Take out the ID card and insert it into the Analyzer ID Card Slot. Choose test mode and/or sample type according to needs.



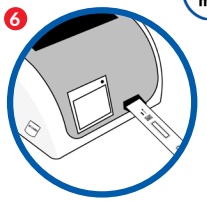
Remove the test cassette from the sealed foil pouch and use it within 1 hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.



Place the test on a flat and clean surface.
Pipette **75 µL of serum/plasma/whole blood** into the buffer tube, mix the specimen and the buffer well.



Pipette **75 µL of diluted specimen** into the sample well of the cassette. Start the timer at the same time.



Test results should be interpreted at **15 minutes** with the use of Immunofluorescence Analyzer.

Caution: There are different test modes of the Immunofluorescence Analyzer. The difference between them is incubation of the test cassette is outside or inside the analyzer. Choose test mode accordingly and confirm sample type. Consult the user manual of the analyzer for detailed operation information.
Operator must consult the Immunofluorescence Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

INTERPRETATION OF TEST RESULTS

Results read by Immunofluorescence Analyzer.

The result of tests for IL-6 is calculated by Immunofluorescence Analyzer and display the result on the screen. For additional information, please refer to the user manual of Immunofluorescence Analyzer.

Assay range of IL-6 is 3.0 - 5,000 pg/mL.

QUALITY CONTROL

Each IL-6 Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was tested and read properly by Immunofluorescence Analyzer. An invalid result from the internal control causes message on Immunofluorescence Analyzer and indicates 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.

LIMITATIONS

1. The IL-6 Test Cassette (Whole Blood/Serum/Plasma) is for professional *in-vitro* diagnostic use, and should only be used for the quantitative detection of IL-6.
2. The IL-6 Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of IL-6 antigen in the specimen and should not be used as the sole criterion for evaluating inflammatory conditions.
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. High dose hook effect has not been observed with this test up to 10 ng/mL of IL-6.
5. The test assay range of this test kit is 3.0 - 5,000 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.
6. The results of IL-6 Tests are based on measuring the levels of IL-6 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.

EXPECTED VALUES

Concentrations	Clinical Reference
<10.0 pg/mL	Normal
10 ~ 150 pg/mL	The possibility of virus infection is relatively high
150 ~ 250 pg/mL	It may be an acute bacterial infection, antibacterial treatment, Check whether the IL-6 concentration has decreased after 24 hours
>250 pg/mL	Generally sepsis

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

PERFORMANCE CHARACTERISTICS

1. Accuracy

The test deviation ≤±15%

2. Assay Range and Detection Limit

- Assay Range: 3 – 5,000 pg/mL
- Minimum Detection Limit (Analytical Sensitivity): 3 pg/mL

3. Linearity Range

3 – 5,000 pg/mL, R≥0.990

4. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 3 specimens containing 10 pg/mL, 100 pg/mL and 1,000 pg/mL of IL-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 specimens containing 10 pg/mL, 100 pg/mL 1,000 pg/mL of IL-6. C.V. is ≤15%.

5. interfering substances

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

50 ng/mL PCT,
100 mg/L CRP,
20 mg/dL bilirubin,
300 mg/L SAA,
1 g/dL hemoglobin

6. Method Comparison

The assay was compared with IL-6 test of Siemens Advia Centaur with 80 samples. The correlation coefficient(r) is 0.996.

BIBLIOGRAPHY

1. Berti A, Warner R, Johnson K, et al. The association of serum interleukin-6 levels with clinical outcomes in antineutrophil cytoplasmic antibody-associated vasculitis[J]. Journal of Autoimmunity, 2019,105:102302.
2. Nishimoto N, Kishimoto T. Erratum: Interleukin 6: from bench to bedside[J]. Nature Clinical Practice Rheumatology, 2006,2(12).
3. Y N, M E E, W L S, et al. IL-6 is the principal factor produced by synovia of patients with rheumatoid arthritis that induces B-lymphocytes to secrete immunoglobulins.[J]. Annals of the New York Academy of Sciences, 1989,557.

SYMBOLS

MP Biomedicals Germany GmbH
Thueringer Str. 15
37269 Eschwege
Germany

Customer Service:
+49 (0) 5651 – 921-186
+49 (0) 5651 – 921-181
diagnostics@mpbio.com

Rev: 07IL5025-014-03-42-EN
Effective date: 20.03 2024