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IL-6 Fast Test Kit
(Immunofluorescence Assay)

IF1088 for Getein1100
IF5088 for Getein1160
IF3088 for Getein1180
REF IF4088 for Getein1200
IF2088 for Getein1600

User Manual

INTENDED USE

IL-6 Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of interleukin 6 (IL-6) in human serum, plasma, whole blood and peripheral blood samples. IL-6 is an early marker in acute inflammation and this test can be used as an aid in the inflammatory diseases.

SUMMARY

IL-6 is a cytokine that functions in inflammation and maturation of B cells. The protein is primarily produced at sites of acute and chronic inflammation, where it is secreted into the serum and induces a transcriptional inflammatory response. This classical responsiveness to IL-6 is governed by a receptor complex consisting of two membrane-bound subunits, an 80-kDa cognate Alpha-chain (IL-6R Alpha), and a ubiquitously expressed 130-kDa Beta-chain receptor (gp130) which acts as the universal signal transducing element for all IL-6 family cytokines.

Many different cells are capable of IL-6 synthesis including monocytes/macrophages, fibroblasts, endothelial cells, keratinocytes, mast cells, T cells and many tumor cell lines. In vivo and in vitro, IL-6 acts as a differentiation factor for B cells and an activation factor for T cells.

IL-6 is a potent growth factor of different human myelomas and is active in concentrations less than 10 pg/mL. IL-3 and IL-6 show in vitro synergistic effects in the differentiation of hematopoietic progenitor cells. Elevated IL-6 serum or plasma levels may occur in different diseases including sepsis, autoimmune diseases, lymphomas, AIDS, alcoholic liver disease and in patients with infections, or transplant rejection.

PRINCIPLE

The test uses an anti-human IL-6 monoclonal antibody I conjugated with fluorescence latex coated on the junction of nitrocellulose membrane and sample pad,and another anti-human IL-6 monoclonal antibody Ⅱ coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human IL-6 antibody I binds with the IL-6 in sample and forms marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by anti-human IL-6 antibody Ⅱ. The fluorescence intensity of test line increases in proportion to the amount of IL- 6 in sample.

Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of IL-6 in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein IL-6 test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card: 1 piece/box

2. A kit for Getein1160/Getein1180 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein IL-6 test card in a sealed pouch with desiccant
2) Disposable pipet
3) SD card: 1 piece/box
4) User manual: 1 piece/box
5) Whole blood buffer: 1 bottle/box

3. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/box, 2×48 tests/box
Sealed cartridge with 24/48 Getein IL-6 test cards
User manual: 1 piece/box

Materials required for Getein1200/Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box

4. sample diluent composition:
Phosphate buffered saline, protein stabilizer and surfactant.

5. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad (the end of pad is coated with fluorescence latex-labelled anti-human IL-6 monoclonal antibody I), nitrocellulose membrane (test line is coated with another IL-6 monoclonal antibody Ⅱ and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.

For test card of Getein1200/Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma, whole blood and peripheral blood samples***, other bodily fluids may cause incorrect or inaccurate results.
2. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma. Only EDTA can be used as anticoagulant for peripheral blood sample. Samples should be free of hemolysis.
3. The test should be performed within 4 hours after whole bloodcollection.
4. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2~8°C or stored at -20°C for 6 months before testing. Whole blood and peripheral blood samples should not be frozen, and stored at 2~8°C for 3 days.
5. Refrigerated or frozen sample should reach room temperatureand be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples or hemolysis samples.
7. SAMPLE VOLUME ***(for Getein1100): 40 μL.***
(for Getein1160/Getein1180): 100 μL.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform"SD card" calibration when necessary.
4. Enter testing interface of Getein1100.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***40 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port on the test card.
8. ***Reaction time: 15 minutes.*** Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:
9. Confirm SD card lot No. in accordance with test kit lot No..Perform "SD card" calibration when necessary.
10. Enter testing interface of Getein1160/Getein 1180.
11. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
12. Put the test card on a clean table,horizontally placed.
13. Using sample transfer pipette, deliver ***100 μL*** of sample into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 μL sample on the test card).
14. ***Reaction time: 15 minutes.*** Insert the test card into

Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1200/Getein1600:

15.Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.

16.Place the sample diluent at the correct position in Getein1200/Getein1600.

17.Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein1200/Getein1600.

Others:

Measuring range of the IL-6 is 1.5 pg/mL~ 4000.0 pg/mL. Dilute the sample which concentration is higher than the upper limit with negative sample, and the dilution ratio should be less than 5 times.

EXPECTED VALUE

The expected normal value for IL-6 was determined by testing 300 samples from apparently healthy individuals. The reference range of IL-6 is 7.0 pg/mL calculated by using normal distribution method (95% confidence interval).

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	1.5 ~4000.0 pg/mL
Lower Detection Limit	≤ 1.5 pg/mL
Within-run Precision	≤ 10%
Between-run Precision	≤ 15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Triglyceride	Bilirubin
Concentration (Max)	10 g/L	0.2 g/L

REFERENCES

1. Song M, Kellum JA. Interleukin-6. CritCare Med, 2005, 33 (12): 463-465.
2. Joe Verghese, Rose Holtzer, Mooyeon Oh-Park et al. Inflammatory Markers and Gait Speed Decline in Older Adults. Journal of Gerontology: MEDICAL SCIENCES, 2011, 66A (10): 1083-1089.
3. Goran Pesic, Jovana Jeremic, Tamara Nikolic,et al.. Interleukin-6 as possible early marker of stress response after femoral fracture. Molecular and Cellular Biochemistry, 2017, 430 (1-2).
4. Yukio Shimura, Hisashi Kurosawa, Masaru Tsuchiya, et al. Serum interleukin 6 levels are associated with depressive state of the patients with knee osteoarthritis irrespective of disease severity. Clinical Rheumatology, 2017, 36 (12).
5. Sabrina Zidi, Mouna Stayoussef, Bano L, et al. Relation ships between Common and Novel Interleukin-6 Gene Polymorphisms and Risk of Cervical Cancer: a Case-Control Study. Pathology & Oncology Research, 2017, 23 (2).
6. Kh. M. Sallam, N. M. Sidkey, N. N. Abed, et al. Lipopoly-saccharide-stimulated interleukin-6 production for radioimmunoas say. Journal of Radioanalytical and Nuclear Chemistry, 2017, 313 (2).

7.16.Bin Jiang, Shujuan Zhu, Songshu Xiao, et al. MiR-217 Inhibits M2-Like Macrophage Polarization by Suppressing Secretion of Interleukin-6 in Ovarian Cancer. Inflammation, 2019, 42 (5).

8. Cormican Sarah,Griffin Matthew D. The Complex Role of Interleukin 6 in Regulatin T-cell Responses during Acute Glomerulone phritis. Journal of the American Society of Nephrology : JASN, 2019, 30 (8).
9. Simondurairaj C, Krishnakumar R, Sundaram Sandhya, etal.Interleukin-6 Receptor (IL-6R) Expression in Human Gastric Carcinoma and its Clinical Significance. Cancer investigation, 2019, 37 (7).
10. Barney Thaddeus M, Vore Andrew S, Gano Anny, Mondel loJamie E, et al. The influence of central interleukin-6 on behavioral changes associated with acute alcohol intoxication in adult male rats. Alcohol (Fayetteville, N.Y.), 2019, 79.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on IL-6 Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1：2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
Σ	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/ European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing IL-6 Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

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