



IL-6 Fast Test Kit (Immunofluorescence Assay)

IF1088 for Getein 1100
IF5088 for Getein 1160
IF3088 for Getein 1180
IF4088 for Getein 1200
REF IF2088 for Getein 1600



Instructions for Use

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 fingertip blood samples. IL-6 is an early marker in acute inflammation and this test can be used as an aid in the inflammatory diseases. For professional and laboratory use.

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.

IL-6 is an important marker for the early screening of acute infections. In inflammatory responses, the rise in IL-6 levels precedes other cytokines, as well as CRP and PCT, and it lasts longer, therefore it can be used to assist in the early screening of acute infections. After bacterial infection, IL-6 levels rise rapidly, peaking within 2 hours. The increase in IL-6 is positively correlated with the severity of the disease, and the magnitude of the increase reflects the severity of the condition. In critically ill patients, it can be expressed at high levels for an extended period and can serve as a sensitive indicator for assessing the severity and prognosis of patients with sepsis and multiple organ dysfunction syndrome (MODS).

PRINCIPLE

IL-6 Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been

applied to the test strip, the fluorescence latex-labelled IL-6 monoclonal antibody binds with the IL-6 in sample and forms a 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 another IL-6 monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of IL-6 in sample. Fluorescent signals intensity can be analyzed by applicable device thus the IL-6 in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
IL-6 test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10 tube	25 tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

* IL-6 test card

A test card main consists of: Fluorescence latex-labelled IL-6 monoclonal antibody, IL-6 monoclonal antibody and polyclonal IgG antibody.

** Sample diluent

(1) Sample diluent for Getein 1100/ Getein 1160/ Getein 1180 in each tube main consists of: phosphate buffer (20 mmol/L), NaN3 (<0.1%).

(2) Sample diluent for Getein 1200/ Getein 1600 is an independent packing box main consists of:

- Phosphate buffer (20 mmol/L), NaN3 (<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),

- Box with pipette tips (96 tips/box),

- Mixing plate (1 piece/box).

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".

2. Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer

Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months. Use the test card for Getein 1100/Getein 1160/Getein 1180 within 1 hour once the foil pouch is opened. For test card of Getein 1200/Getein 1600: 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 instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum, plasma, whole blood and fingertip 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 and whole blood. Only EDTA can be used as anticoagulant for fingertip blood sample. Samples should be free of hemolysis.
3. It is recommended to test the sample within 4 hours after collection. Stable in serum and plasma for 5 days when stored at 2~8°C and 6 months when stored at -20°C. Stable in whole blood and fingertip blood for 3 days when stored at 2~8°C.
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. **SAMPLE VOLUME (for Getein1100/Getein1160/Getein1180): 20 μ L.**

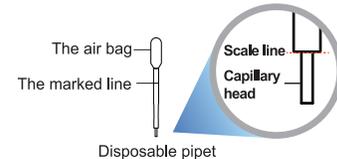
TEST PROCEDURE

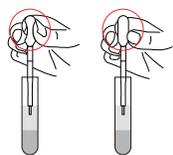
1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
 2. Test kit and sample should be brought to room temperature before testing.
- For Getein 1100:**
- 1) Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
 - 2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
 - 3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
 - 4) Using disposable pipet or pipette, deliver **20 μ L** of sample into one tube of sample diluent, mix thoroughly. Then drop **100 μ L** of sample mixture into the sample well on the test card.
 - 5) Reaction time: **15 minutes**. After reaction time is elapsed, insert the test card into Getein1100 and press "ENT" button (click on "Start" icon for Android Getein1100). The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

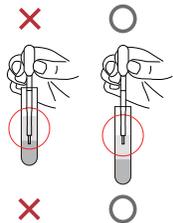
- 1) Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- 2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- 3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- 4) Using disposable pipet or pipette, deliver **20 μ L** of sample into one tube of sample diluent, mix thoroughly. Then drop **100 μ L** of sample mixture into the sample well on the test card.
- 5) Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (**15 minutes**) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For using the disposable pipet:

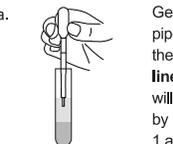




Note1: Do not depress the air bag of the disposable pipet with your finger during sampling.



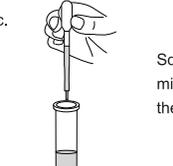
Note 2: The capillary head of the disposable pipette touches the sample level gently and draws the sample automatically.



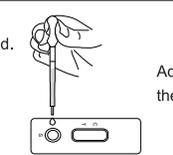
a. Gently hold the air bag of the disposable pipet and insert the disposable pipette into the sample collection tube until the **scale line** reaches the liquid level. The sample will be sucked into the disposable pipette by capillary action. (Please refer to note 1 and note 2 for more details.)



b. Insert the disposable pipette into the sample diluent. Squeeze the air bag 8 to 10 times to ensure the sample is fully mixed with the sample diluent.



c. Squeeze the air bag, suck the sample mixed solution to the **marked line** on the disposable pipette.



d. Add all the sucked sample vertically to the sampling area of test card.

For Getein 1200/Getein 1600:

1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.
2. Place the sample diluent at the correct position in Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 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 for Getein1100/ Getein1160/Getein1180.
2. It is suggested to calibrate once for one batch of kits for Getein 1100/Getein 1160/Getein 1180.
3. Make sure the test card and the sample insertion are correct and complete.

TEST RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

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 sample diluent, and the dilution ratio should be less than 3 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
Limit of Detection	≤ 1.5 pg/mL
Within-run Precision	≤ 10%
Between-lot 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. Interferents in samples 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

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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.
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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 details 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		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Caution

Thank you for using IL-6 Fast Test Kit (Immunofluorescence Assay). Please read this Instructions for use carefully before operating to ensure proper use.

Version: WIF73-S-10



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