

IL-6

Interleukin 6 Test Kit
(Fluorescence Immunoassay Method)

Instructions for Use

Version:A/2

REF HP-Palm-IL-6-25

Manufacturer

Shijiazhuang Hipro Biotechnology Co.,Ltd.
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Product Name

General Name: Interleukin 6 Test Kit
(Fluorescence Immunoassay Method)

Package Specification

25 Tests/Kit

Note: other specifications are available, 10Tests/Kit, 50 Tests/Kit, 100 Tests/Kit

Intended Use

The Hipro Interleukin-6(IL-6) test kit is an vitro diagnostic test for the quantitative measurement of Interleukin-6 in human serum, plasma or whole blood.

IL-6 is an important factor to the acute inflammatory response. IL-6 production induces the production of C-reactive protein (CRP) and calcitoninogen (PCT), which are directly related to the inflammatory disease and degree of infection. IL-6 provides a faster diagnosis of early inflammation and early warning of sepsis. In addition, IL-6 has a shorter half-life than CRP and PCT that allowing a faster response to antibiotic therapy.

Test Principle

The IL-6 test kit is a rapid quantitative assay based on the principle of double antibodies sandwich fluorescence immunoassay.

Interleukin 6 in the sample reacts with mouse anti-human

IL-6 antibody in the pad, to form antigen-antibody complexes. The complexes migrate upward, firstly captured by mouse monoclonal anti-IL-6 antibody on the T line and then by polyclonal goat anti-mouse IgG on the C line coated in the membrane. After the reaction, the fluorescence immunoassay analyzers will calculate the total IL-6 concentration by detecting the fluorescence intensity of T and C line.

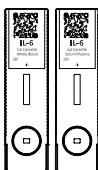
Material Provided

Component	25Kits
Sample Diluent	25
Calibration Cassette	2
Test Cassette	25
Instructions for Use	1
Disposable tube with 100μL	50

Sample Diluent

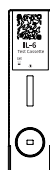


Calibration Cassette



QR code is with built-in parameter for each assay.

Test Cassette



Disposable tube with 100μL



Volume
100μL

IFU



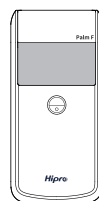
Material Needed but Not Provided

Timing device

Storage&Validity

- 1.Store test kit at: 2°C-30°C. Avoid exposure to direct sunlight. The test kit is stable for 18months when unopened.
- 2.Perform the test within 1 hour when opened.
- 3.Product lot number, production and expiration date are shown on the label.

Applicable Instrument



**Palm F Fluorescence
Immunoassay Analyzer**

Specimen type

The specimen type of Hipro IL-6 test kit is human serum, plasma or whole blood.

1. Take blood samples in observance of the standard precautions for the withdrawal of biological fluids.
2. Do not use samples that have remained at room temperature for more than 8 hours.
3. Due to possible evaporation effects, samples on the analyzer should be measured within 2 hours.

Storage

Fresh collected specimens are stable if stored at 2°C-8°C for up to 24 hours. For longer storage, aliquot, cap tightly, and freeze at -20°C for up to 3months.

Avoid repeated freezing and thawing.

Avoid hemolysate.

Required volume

100μL is required for serum or plasma,used for direction reaction.

100μL is required for whole blood, used for dilution.

100μL is required of diluted sample for each determination. This volume does not include the dead volume(unusable volume in the sample container) or the additional volume required to make replicate test or other tests to be performed on the same sample.

IL-6 Test Kit Instructions Guide

Before You Begin

- 1a** Please read the IL-6 IFU and applicable instrument User Manual carefully before operation. Please follow the instructions strictly.

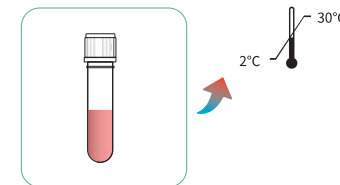


- 1b** A timing device (phone, clock or timer) is required but not provided.



Before You Begin

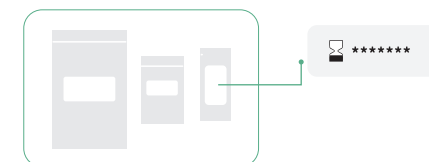
- 1c** Allow the sample back to room temperature.



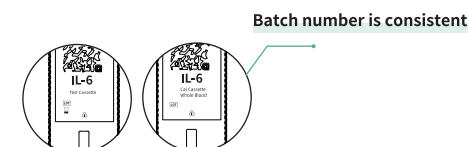
- 1d** Ensure the test kit is at room temperature for at least 30 minutes prior to use.



- 1e** Check on the expiration date on labels of different component.

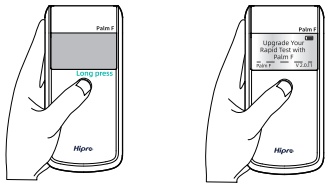


- 1f** Make sure the lot number on calibration cassette and test cassette are same.
Do not misuse the cassettes with different lot.



Test Procedures

- 2a Turn on the applicable instrument according to the User Manual.

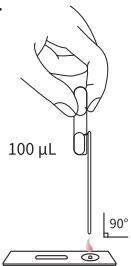


- 2b Insert the calibration cassette into the analyzer as the direction shows, to let the built-in parameter be read.



3a Specimen serum/plasma:

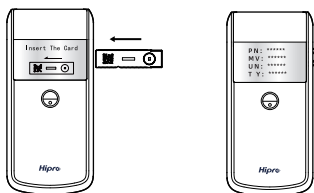
Use the disposable tube to collect and add 100μL specimen(serum/plasma) onto the sample well of test cassette.



- 3b Wait for 15 minutes.



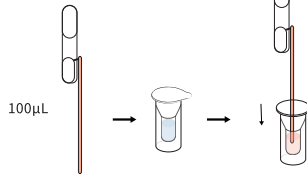
- 3c Insert the test cassette into the analyzer and the analyzer will display the results automatically.



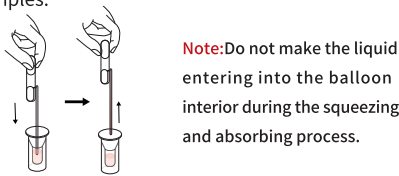
Test Procedures

4a Specimen whole blood

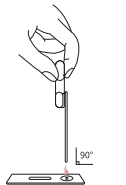
Use the disposable tube to collect and add 100 μL specimen (whole blood) into the sample diluent.



- 4b Repeated squeezing and absorbing to mix the samples.



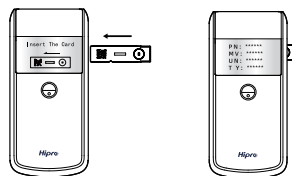
- 4c Use a 100μL disposable tube to collect and add the mixed liquid onto the sample well of test cassette.



- 4d Wait for 15 minutes.



- 4e Insert the test cassette into the analyzer and the analyzer will display the results automatically.



Avoid bubbles when collecting samples.

Reference Value

The normal reference range is <7pg/mL.

153 healthy patients were measured and the results (95%) meet the linearity range <7pg/mL.

Recommended that each laboratory establish its own reference range.

Performance Characteristics

1. Appearance

The inside package should be sealed tightly and no air leakage; the information on label is complete and clear. The surface of the test cassette should be smooth.

2. Strip width

The width of strip should be ≥ 2.5 mm.

3. Liquid flow speed

The speed should be ≥ 10 mm/min.

4. Linearity

Within range 3-1500pg/mL, the correlation coefficient (r) should be ≥ 0.990 .

5. Within-lot precision

The coefficient of variation (CV) should be $\leq 15\%$.

6. Between-lot precision

The coefficient of variation (CV) should be $\leq 20\%$.

7. Accuracy

The relative deviation should be $\leq 15\%$.

8. Limit of blank(LoB)

The LoB should be ≤ 2.5 pg/mL.

Precautions and limitations

1.The Hipro Interleukin-6(IL-6) test kit is an vitro diagnostic test for the quantitative measurement of Interleukin-6 in human serum, plasma or whole blood.

2.For diagnostic purposes, the results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings.

3.As with all immunoassays, testing the same sample with different reagents from different manufacturers may cause different results; therefore, the results can not be compared to avoid incorrect medical interpretations.

4.The results of this test can be influenced by factors present in some patients' specimens. The factors include hemoglobin>4mg/mL, bilirubin>0.2mg/mL triglyceride>10mg/mL.

5.When the sample contains of antibiotics the test results will not be influenced. The factors include Roxithromycin>80pg/mL, Aspirin>10.0μg/mL, Ibuprofen ≤ 30 μg/mL, Fenbid ≤ 8.0 μg/mL.

6.When the IL-6 concentration ≤ 4500 pg/mL, there will not be Hook effect.

Precautions

1.For in vitro diagnostic us, do not reuse, do not use expired product.

2. All samples should be considered potentially infectious and suitable protective measures should be taken. Laboratory gloves should be worn while handling patient' sample, disposal of waste, storage, mixing and testing. Disposal of all wast material should be in accordance with local guidelines.

Do not use damaged test kits, or expired test cassette.

3.Make sure the lot number on ID card and test cassette are same.Do not misuse the reagents with different lot.

4.The desiccant inside the package not to be used for other purposes.°

5.The test cassette and the components are only match with the suitable fluorescence immunoassay analyzer.

6.Avoid electromagnetic or vibration environment for analyzer.; The vibration of the instrument is normal when it working.

7.Do not insert the polluted cassette into analyzer. Please dispose the used test cassette properly.

8.Any questions or suggestions about the test kits, please contact the manufacturer.

Symbols used on labels

Symbol	Usage
	Use-By date
	Batch code
	Manufacturer
	Keep Away from Sunlight
	Temperature Limit
	In Vitro Diagnostic Medical device
	Authorized Representative in the European Community
	CE Mark
	Consult Instructions for use
	Do not freeze
	Contains sufficient for <n> tests
	Biological risks
	Do not use if package is damaged
	Date of manufacture
	Do Not Reuse

Reference

1.Zhang PL,Levy AM,Ben-Simchon L,et al. Induction of neuronal and myelin-related gene expression by IL-6-receptor/IL-6:a study on embryonic dorsal root ganglia cells and isolated Schwann cells[J].Exp Neurol,2007,208(2):285-296.

2.Soygur H,Palaoglu O,Akarsu ES,et al.Interleukin-6 levels and HPA axis activation in breast cancer patients with major depressive disorder[J].Prog Neuropsychopharmacol Biol Psychiatry,2007,31(6):1242--1247.

3.Naya M,Tsukamoto T,Morita K,et al.Plasma interleukin-6 and tumor necrosis factor-alpha can predict coronary endothelial dysfunction inhypertensive patients[J].Hypertens Res,2007,30(6):541-548.

Approval Date &Revision Date

Approval Date: Apr 24, 2023

Revision Date: Dec 22, 2023

Revision Date: Aug 1, 2024

工艺： 70g双胶纸， 双面印刷， 横向4折页， 竖向对折 展开尺寸： 32*25cm