Hipro Hipro Biotechnology Co.,Ltd

EN
ENGLISH

CRP

C-reactive Protein Test Kit
(Fluorescence Immunoassay Method)
Instructions for Use

Version:A/0

Manufacturer

Shijiazhuang Hipro Biotechnology Co.,ltd.
No. 3 Building, Block C, Fangyi Science Park, No. 313 Zhujiang-dadao Road, Hi-tech Zone, Shijiazhuang, 050000, Hebei, China.
After sale service: 400-0191-606
www.hipro.us

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Tel: +31644168999

Product Name

General Name: C-reactive Protein (CRP) 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 C-reactive Protein (CRP) test kit is an in vitro diagnostic test for the quantitative measurement of C-reactive protein in human serum. plasma or whole blood. It is intended for aid use in evaluation of conditions thought to be associated with inflammation. It is used in conjunctions with other laboratory and clinical findings.

For in vitro diagnostic use only .

For prescription use only.

Test Principle

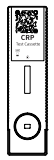
The C-reactive Protein (CRP) test kit is a rapid quantitative assay based on the principle of double antibodies sandwich fluorescence immunoassay method.

C-reactive protein antigen in the sample reacts with mouse anti-human CRP antibody, to form antigen-antibody complexes. The complexes migrate upward, firstly captured by mouse monoclonal anti-CRP antibody on the T line and then by polyclonal goat anti-mouse IgG antibody on the C line coated in the membrane. After the reaction, the fluorescence immunoassay analyzer calculates the CRP concentration according to the fluorescence intensity of T and C line.

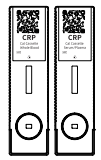
Material Provided

Component	25Kits
Test Cassette	25
Calibration Cassette	2
Sample Diluent	25
Capillary device with dropper	25
Instructions for Use	1

Test Cassette



Calibration Cassette

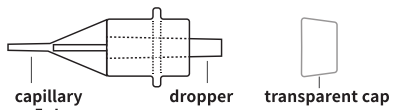


QR code is with built-in parameter for each assay.

Sample Diluent

Instructions for Use

Capillary device with dropper



Material Needed but Not Provided

Timing device

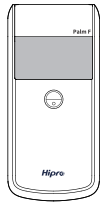
Storage&Validity

Store test kit at: 2°C-30°C until the expiration date indicated on the label.

Avoid exposure to direct sunlight. The test kit is stable for 18months when unopened.

Perform the test within 1 hour when opened.

Applicable Instrument



Palm F Fluorescence Immunoassay Analyzer

Specimen type

The specimen type of Hipro CRP 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

5μL is required for serum, plasma or whole blood used for direct reaction.

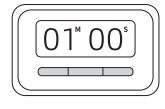
5μL is required of diluted sample for each determination. This volume does not include the dead volume(unusable volume in the sample container) or the additional volume required to make replicate test or other tests to be performed on the same sample.

CRP Test Kit Instructions Guide

Before You Begin

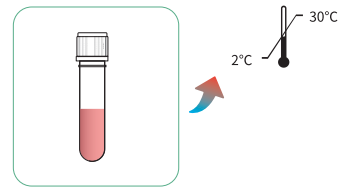
1a Please read the CRP IFU and applicable instrument User Manual carefully before operation. Please follow the instructions strictly.

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



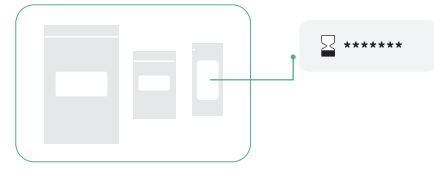
Before You Begin

1c Allow the sample back to room temperature.



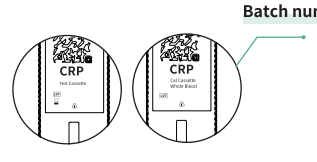
1d Ensure the test kit is at room temperature for at least 30 minutes prior to use.

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



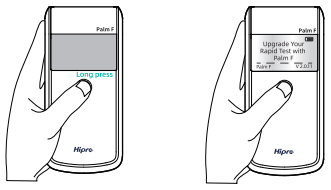
1f Make sure the lot number on calibration cassette and test cassette are same.

Do not misuse the cassettes with different lot.

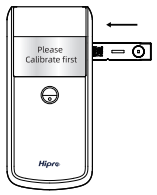


Test Procedures

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

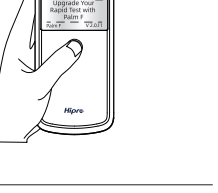


2b Insert the calibration cassette into the analyzer as the direction shows, to let the built-in parameter be read.

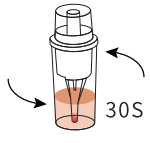


3a Use the quantitative capillary to collect blood. Make sure the transparent cap is screwed tightly onto the dropper part.

3b Insert the capillary(with collected blood) into the tube.

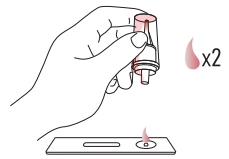


3c Make sure the tube and the capillary device are tightly screwed and shake from left to right for 30seconds; During shake, make sure the transparent cap tightly covers the dropper and screws with the device and make sure the capillary is down toward.



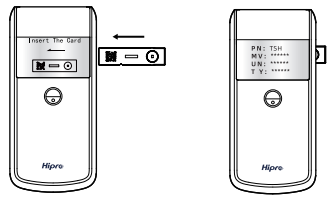
Test Procedures

3d Add 2 drops of mixed liquid from the sample diluent tube onto the sample well of test cassette.



4a Wait for 5 minutes before reading results.

4b 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 <10 mg/L.

200 healthy patients were measured and the results (95%) meet the linearity range 10mg/L.

The value is indicative only and may differ from other published values as a result of differences in methods and in the population being studied. It is recommended that each laboratory establish its own reference range.

Performance Characteristics

1. **Strip width**

   The width of strip should be ⩾2.5mm.

2. **Liquid flow speed**

   The speed should be ⩾10mm/min.

Performance Characteristics

3. **Linearity**

   Within range 0.5~200 mg/L, the correlation coefficient (r) should be ⩾0.990.

4. **Within-lot precision**

   The coefficient of variation (CV) should be ⩽15%.

5. **Between-lot precision**

   The coefficient of variation (CV) should be ⩽20%

6. **Accuracy**

   The relative deviation should be ⩽15%.

7. **Limit of blank(LoB)**

   The LoB should be ⩽0.5mg/L.

Precautions and limitations

For in vitro diagnostic use

Only experienced laboratory personnel should use this test and handling all laboratory reagents should be based on normal precautions required.

Safety precautions

1. Do not smoke, eat or apply cosmetics in areas in which patients' samples or kit reagents are handled.
2. Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
3. Disposal of all waste material should be in accordance with local guidelines.
4. Avoid electromagnetic or vibration environment for analyzer.
5. Do not insert the polluted cassette into analyzer.

Potential biohazard warning

Some reagents of Hipro test kits contain material of animal origin, even if they are certified as deriving from healthy animals, it is recommended to handle them with the same precaution used for potentially infectious samples.

Limitations-interference

As with all immunoassays, the results of this test can be influenced by factors present in some patients' specimens. The factors include hemoglobin>5g/L, triglyceride>15mg/mL, bilirubin>0.2mg/mL.

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.

When the CRP concentration ⩽600mg/L, there will not be Hook effect.

Safety Phases

S 37 Wear suitable gloves

S 60 This material and /or its container must be disposed of as hazardous waste.

Symbols used on labels

Symbol	Usage
	Use-By date
LOT	Batch code
	Manufacturer
	Keep Away from Sunlight
2℃ 30℃	Temperature Limit
IVD	In Vitro Diagnostic Medical device
EC REP	Authorized Representative in the European Community
CE	CE Mark
	Consult Instructions for use
	Do not freeze
Σ	Contains sufficient for <n> tests
	Biological risks
	Do not use if package is damaged
	Date of manufacture
	Do Not Reuse

Reference

1. Yang Huijian, Lian, Tian Xiangting, et al. Study on the correlation between plasma malondialdehyde and high sensitivity C-reactive protein and acute myocardial infarction [J]. Modern Hospital, 2011,1 (7) : 35-37.

2. Powell L J.C-reactive protein a review[J].Am J Med Technol,1979,45(2):138-142.

3, Wu Xueyi, Xu Shujing, Shi Lixin. The relationship between ankle-brachial index and C-reactive protein, white blood cell count in type 2 diabetes patients [J]. Journal of Use Medicine, 2011,27 (5) : 819-820.

Approval Date &Revision Date

Approval Date: Aug. 9,2022

CE IVD

工艺：70g双胶纸，双面印刷，横向4折，竖向对折　展开尺寸：32*25cm