

THE SMART WAY TO CHECK YOUR HEALTH

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SI-CRP_IFU_02_8.0 02/2025 **SKU** SI-CRP **REF** SI-CRP

C-REACTIVE PROTEIN

C-Reactive Protein (CRP) is an acute-phase protein that is produced mainly by the liver and increases in concentration as a result of injury, infection and inflammation. Although it is not a specific marker for a particular disorder, CRP is currently used as a generic diagnostic indicator of infection and inflammation and to monitor patients' reactions to treatment and post-operative recovery. CRP levels in the blood are high during bacterial infections and low during viral infections.

For this reason, the dosage of C-reactive protein can be a useful tool to define the origin of an inflammatory state. Monitoring CRP levels over time helps to define the effectiveness of a therapy and evaluate a patient's healing process. CRP levels in the blood reach their peak concentration between 24 and 48 hours after the onset of the first symptoms of infection/inflammation, and then begin to decrease as the infection clears/ inflammation subsides.

The BODY INFLAMMATION SELF-TEST provides a semi-quantitative evaluation of blood CRP levels that helps with therapeutic diagnosis and monitoring.

PRINCIPLE OF THE TEST

The BODY INFLAMMATION SELF-TEST is a rapid immunochromatographic assay for the semi-quantitative detection of the C-Reactive Protein in human blood samples. It uses special gold-conjugated monoclonal antibodies integrated into the reactive strip.

REFERENCES

1. THOMPSON, D.; MILFORD-WARD, A.; WHICHER, J. T. „The value of acute phase protein measurements in clinical practice”. Annals of clinical biochemistry, 1992, 29:2: 123-131.
2. SHAW, A. C. „Serum C-reactive protein and neopterin concentrations in patients with viral or bacterial infection”. Journal of clinical pathology, 1991, 44:7: 596-599
3. C-reactive protein concentrations as a marker of inflammation or infection for interpreting biomarkers of micronutrient status. Vitamin and Mineral Nutrition Information System. Genf: World Health Organization; 2014 (https://www.who.int/nutrition/publications/micronutrients/indicators_c-reactive_protein/en/)
4. <https://www.mayoclinic.org/tests-procedures/c-reactive-protein-test/about/pac-20385228>
5. „Causes and outcomes of markedly elevated C-reactive protein levels” Alexander Landry Peter Docherty, Sylvie Ouellette, Louis Jacques Carlier

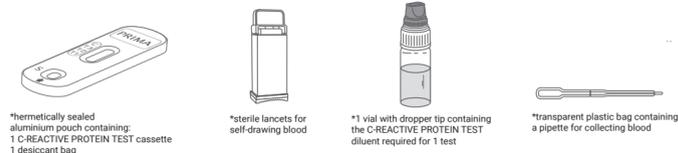


INSTRUCTIONS FOR USE

BODY INFLAMMATION SELF-TEST
Rapid self-test for the semi-quantitative detection of C-Reactive Protein (CRP) in whole blood samples.

CONTENTS OF THE KIT

*The number of the testing devices of the kit may vary. For the exact number of tests contained, please refer to the "content" section on the external box.



*alcohol cleansing gauze
1 instructions for use leaflet

* Material required but not supplied: cotton wool, a device to measure time (i.e. timer, watch).
* Do not open the sealed aluminium bag until just before performing the test. Take care to open it as marked.
* The desiccant packet must not be used. Dispose of it with household waste without opening it.



Medical devices inside the kit:

STERILE R
Lancet
Hualan Tianda Medical Instruments Co., Ltd., No.106 East Songjiang Road Huayin, Economic & Technological Development Zone, 223300 - Huzhou City, Jiangsu - P.R. China

EC REP
Riomexiv Sociedad Limitada
Calle de Alameda 55, 10
Madrid 28039, Spain

Alcohol cleansing gauze

EC REP
Phoenix Innovative Healthcare Manufacturers Pvt. Ltd.
E1, 209, SHI Mahajee Road, Electronic Zone, MIDC,
TTC Industrial Area, Malape, Near Mumbai,
400 710 MH India

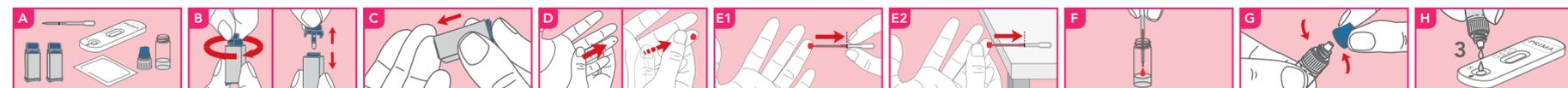
EC REP
Adventia Ltd., Tower Business Centre,
2nd Fl. Tower Street, Swatara,
BKR 4013, Malta

Symbols:

- IVD** In vitro diagnostic device
- STERILE R** Sterilised using irradiation
- EC REP** Authorised Representative in the European Community
- Do not reuse**
- Sufficient for N tests**
- Expiry date (last day of the month)**
- REF** List number
- LOT** Lot number
- CE** CE marking
- Legal manufacturer**

PRECAUTIONS

1. In vitro diagnostic device for individual use.
2. Read these instructions for use carefully before performing the test. The Test is reliable only if all the instructions are followed correctly.
3. Keep the Test out of the reach of children.
4. Do not use the Test after the expiry date, if the package is damaged or if the aluminium pouch is not sealed and intact.
5. Follow the procedure exactly, using only the specified quantities of blood and diluent.
6. Use the BODY INFLAMMATION SELF-TEST cassette immediately after removal from the aluminium pouch.
7. To maintain the proper test functionality, store the components at temperatures between +4°C and +30°C. Do not freeze.
8. Use the Test and lancing device once only.
9. The test is for external use only, DO NOT SWALLOW.
10. Not recommended for people who take anti-coagulant medications (blood thinners) or people suffering from haemophilia.
11. After using, please dispose of all components according to your local waste disposal laws. Ask your pharmacist for advice.
12. If you test another person, handle the blood samples as if containing a blood-borne infectious agent. Wear disposable gloves during use.



TEST PROCEDURE

- 1) Wash hands with soap and warm water, rinse with clean water and allow to dry. Note: The use of warm water facilitates capillary blood collection as it induces vasodilation.
- 2) Lay out the material needed as follows: open the aluminium bag, take out only the test cassette and dispose of the desiccant packet. Open the plastic packet containing the pipette. Open the vial by unscrewing the white cap, making sure it does not fall to the ground. -fig. A
- 3) Carefully rotate the protective cap of the sterile lancet 360° without pulling it, then extract and discard the cap. -fig. B
- 4) Carefully massage the finger chosen for the puncture (the side of the ring finger is recommended). It is important that the massage is done from the palm of the hand to the fingertip, to improve blood flow. Press the open end of the lancet (the side the cap has been extracted from), against the fingertip -fig. C. The tip of the lancet automatically retracts after use. If the lancet does not work properly, discard it and use the second one supplied. If the second one is not required, it can be disposed of without special precautions.
- 5) Holding the hand downwards, massage the finger until a large drop of blood forms. It is important to massage from the palm of the hand to the fingertip to improve blood flow. -fig. D
- 6) Take the pipette without pressing the bulb. Two sampling methods are suggested: -fig. E1: hold the pipette horizontally without pressing the bulb place it in contact with the drop of blood, it will enter the pipette by capillarity. Move the pipette away when the black line is reached. If there is not enough blood, continue to massage the finger until the black line is reached. -fig. E2: place the pipette on a clean, flat surface with the tip protruding from the surface, then place the drop of blood in contact with the pipette, it will enter by capillarity. If blood is not sufficient, continue massaging the finger until the blood has reached the black line. Avoid, as far as possible, to continuously move the tip of the pipette away from the finger in order to prevent the formation of air bubbles.
- 7) Deposit the blood collected with the pipette into the previously opened vial. Press the pipette bulb 2 or 3 times to ensure that all the blood has moved into the diluent solution. Replace the screw cap onto the vial and mix well for at least 10 seconds. -fig.F
- 8) Unscrew the blue cap from the dropper vial (leave the white cap tightly screwed on). -fig.G. Deposit 3 drops into the well shown on the cassette. -fig. H
- 9) Wait 5 minutes and then read the results as indicated.

RESULTS INTERPRETATION

READ THE RESULT AT EXACTLY 5 MINUTES. DO NOT READ THE RESULT AFTER 6 MINUTES
The result must be interpreted independently of the colour intensity of the bands that may appear in the reading window.

NEGATIVE, C-REACTIVE PROTEIN BELOW 10 MG/L

A coloured band appears only under the C (Control) sign, as shown in the figure on the right. This result indicates that the concentration of CRP is below 10 mg/L and suggests the absence of infection and inflammation.



POSITIVE, C-REACTIVE PROTEIN BETWEEN 10 AND 40 MG/L

Two coloured bands appear in the reading window, one by the C (Control) sign, the other by the T1 sign, as shown in the figure on the right. It is recommended to consult a physician, as CRP values between 10 and 40 mg/L may be associated with a viral infection or the onset of a bacterial infection. An inflammation caused (for example) by physical trauma can also lead to this kind of result.



POSITIVE, C-REACTIVE PROTEIN BETWEEN 40 AND 80 MG/L

In the reading window, three coloured bands appear, one by the C (Control) sign and two others by the T1 and T2 signs, as shown in the figure on the right. Consult a physician, as this result may be associated with a viral or bacterial infection or physical trauma.



POSITIVE, C-REACTIVE PROTEIN OVER 80 MG/L

our coloured bands appear in the reading window, one by the C (Control) sign and three others by the T1, T2 and T3 signs, as shown in the figure on the right. Consult a doctor, as this result may be associated with a bacterial infection or severe inflammation.



NOTE: The colour intensity in the control and test line regions may vary (as represented in the images). The intensity of the bands is not relevant; only their presence must be considered.

NON VALID RESULT

The control band does not appear (no lines appear or one or more T bands appear without the C band). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for the absence of the control line. Review the procedure and repeat the test with a new device and a new blood sample.



F.A.Q. – QUESTIONS AND ANSWERS

HOW DOES THE BODY INFLAMMATION SELF-TEST WORK?

The test detects the presence of CRP in human whole blood samples using specific antibodies and colloidal gold particles embedded in the test strip.

WHEN CAN THE TEST BE USED?

The BODY INFLAMMATION SELF-TEST may be used in the case of infection or inflammation symptoms such as fever, headache or weakness, or to monitor the healing process following surgery and minor injuries. The test can also be used to monitor the effectiveness of a therapeutic treatment and can be performed at any time of the day.

CAN THE RESULT BE INCORRECT?

The result is correct as long as the instructions are carefully followed and the test is stored under the conditions listed in the „Precautions” section. However, the result may not be correct if: the device comes into contact with other liquids before being used, if the amount of blood and/or diluent is not enough, if the number of drops dispensed in the well is incorrect or if the reading times are not strictly followed. The supplied plastic pipette allows users to be sure they have collected the right amount of blood.

HOW DO I INTERPRET THE TEST IF THE COLOUR AND INTENSITY OF THE TEST AND CONTROL BANDS ARE DIFFERENT?

The colour and the intensity of the lines are not important for the interpretation of the result. Refer to the „Interpretation of results” section and images to correctly evaluate the result.

IS THE RESULT RELIABLE IF READ AFTER 6 MINUTES?

No. The test must be read 5 minutes after the procedure is completed and no later than 6 minutes from this time. Results read after 6 minutes may not be correct.

WHAT SHOULD I DO IF THE RESULT IS POSITIVE?

If the result is positive and the CRP is higher than 10 mg/L, refer to the “Result interpretation” section and contact your doctor as soon as possible, because antibiotic treatment may be required.

WHAT SHOULD I DO IF THE RESULT IS NEGATIVE?

A negative result means that the concentration of CRP is below 10 mg/L, which means that there is neither viral nor bacterial infection in progress. If symptoms persist, seek medical advice.

HOW ACCURATE IS THE BODY INFLAMMATION SELF-TEST?

The BODY INFLAMMATION SELF-TEST showed high concordance with analytical reference methods, with 97% accuracy in distinguishing between normal (< 10 mg/L) and abnormal values.

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NERO		

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