

BEFORE PERFORMING THE TEST, READ THE INSTRUCTIONS CAREFULLY

CRP TEST

The disposable home test for determining the concentration of C-reactive protein (CRP) in the blood.
Medical device for self-testing.

INTRODUCTION

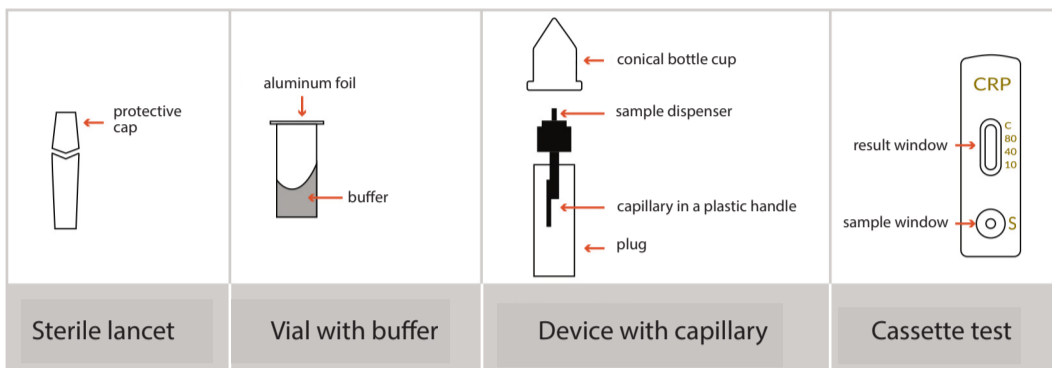
CRP, also known as C-reactive protein, belongs to the so-called acute-phase proteins. Its concentration increases with developing infections and various inflammations of the body.

CRP test enables the detection of C-reactive protein in four ranges: below 10 mg/L, 10-40 mg/L, 40-80 mg/L and equal to or higher than 80 mg/L. Usually, the test result above 10 mg/L CRP indicates a developing infection or inflammation of the body. The determination of CRP levels can be used in particular to differentiate bacterial from viral infections. The test is performed with blood from the finger. The test result is read by interpreting the colored lines after 5 minutes.

PACKAGE CONTENTS

The package contains the equipment necessary to perform one test:

- » 1 sealed foil pouch containing: 1 cassette test and 1 desiccant
- » 1 device with capillary for blood sampling from a finger
- » 1 plastic vial with buffer
- » 1 disposable sterile lancing device
- » 1 package insert

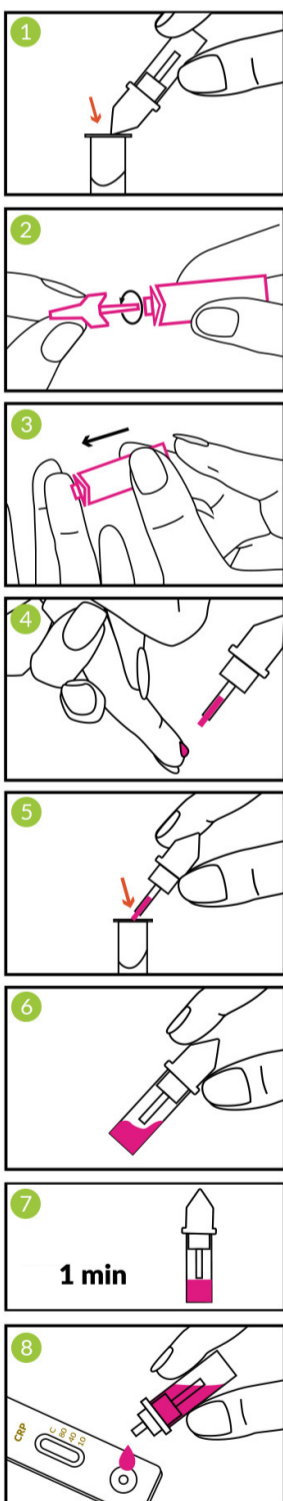


The cassette test should be removed from the foil packaging immediately before the test is performed. The desiccant contained in the package should be disposed of with the household waste. Before performing the test, prepare a fingertip disinfectant (e.g. a cotton swab soaked in 70% alcohol), timer, which will be needed to measure the time.

IMPORTANT NOTES BEFORE PERFORMING THE TEST

- » If the test has been stored at 2-8°C, remove it from the refrigerator half an hour before testing to allow it to reach the room temperature.
- » Before the test, wash your hands with soap and warm water (to increase the blood supply to the finger that will be punctured) and dry them thoroughly.
- » It is not required to be fasting before the test is performed.
- » The test must be performed strictly in accordance with the instructions below.

Remove the cassette test from the foil pouch and place it on a level, clean surface. Also, take the sterile lancing device from the packaging, with which you will prick the fingertip and the device with the capillary, which will be needed to collect blood from the finger. The test should be performed within 1 hour after opening the foil pouch.



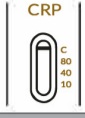
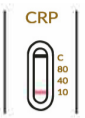
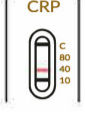
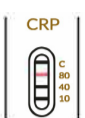
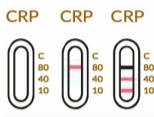
TEST PROCEDURE

- » Pierce the aluminum foil backing on the buffer vial with the conical bottle cap on the device with capillary for blood sampling. ❶
- » Gently massage the finger to be pricked for a minimum of 30 seconds (usually the middle or ring finger is pricked).
- » Disinfect the tip of the middle or ring finger. After disinfecting, wait 30-60 seconds until the skin is completely dry.
- » Remove the protective cap from the sterile lancet by turning it 90°. ❷
The sterile lancet is now ready for use.
- » Place the sterile lancet with the open part against the side of the disinfected fingertip so that it adheres closely to it and press it until you hear a characteristic "click". ❸
The finger has been punctured.
- » Lower the hand with the pricked finger down so that a large and full drop of blood is formed. To make it easier, you can additionally press the pricked finger several times on both sides as shown in figure. ❹
- » Collect blood from this drop using a capillary device. To do this, remove the transparent bottle cap from the device and touch the capillary to the drop of blood. Blood will start flowing into the capillary due to capillary forces. Touch the capillary to the drop until it is completely filled with blood. It is important that the capillary is completely filled with blood. ❺
- » Immediately after blood collection, without removing the capillary from the holder, insert the part of the device with the capillary filled with blood into the buffer vial in which the aluminum protective foil was previously pierced and press firmly until you feel resistance. ❻
- » Shake the buffer vial vigorously for about 10 seconds until the blood is released from the capillary and the sample and buffer are well mixed. ❼
- » Leave the diluted sample in the vial for 1 minute. ❼
- » Unscrew the conical bottle cap from the device containing the diluted sample. Tilt the vial and, while pressing against the sides of the buffer and sample vial, insert 3 full drops of the solution into the round sample window on the test plate. ❽ Start the timer. Read the test result 5 minutes after adding the solution. Results read after more than 7 minutes should be ignored.
- » Pour the remaining solution into the toilet and rinse with water. After reading the result, throw the test, lancing device, device with capillary and empty vial into your household waste.

PRECAUTIONS

- » The test is for external use only.
- » The package with the test should be stored at 2-30°C. Do not freeze.
- » Do not use the test after the expiry date stated on the package.
- » Do not use the test if the foil pouch is damaged, as moisture in the air may have damaged the test.
- » Do not use the lancet if it is incomplete or damaged.
- » The test, lancet and capillary device are for single use only.
- » The used test, lancet and device with capillary should be disposed of like any other household waste.
- » Keep the test out of the reach of children.
- » Do not make any medical decisions without first consulting your doctor.

INTERPRETATION OF RESULTS

NEGATIVE RESULT		
	1 red control line (C). There are no test lines (T)	The CRP level in the test sample is below 10 mg/L. This result indicates that the test did not detect any inflammation or infection.
POSITIVE RESULT		
	1 red control line (C) and 1 red test line (T10)	The control line (C) and the test line (T10) appear, but the test line may be faint. The CRP level in the test sample is between 10 mg/L and 40 mg/L. This result indicates the possibility of developing a viral infection. Consult a doctor.
	1 red control line (C) and 2 red test lines (T10 and T40)	The control line (C), one test line (T10), and the second test line (T40) appear, but the second test line may be faint – CRP concentration is above 40 mg/L and below 80 mg/L. This result indicates the possibility of developing a viral or bacterial infection. Consult a doctor.
	1 red control line (C) and 3 red test lines (T10, T40 and T80)	The control line (C), two test lines (T10 and T40), and the third test line (T80) appear, but the third test line may be faint – CRP concentration in the test sample is equal to or higher than 80 mg/L. This result indicates the possibility of developing a bacterial infection. Consult a doctor immediately.
INVALID RESULT		
	No control line (C) The red test lines (T10, T40, T80) may or may not appear	The most common cause of no visible control line is insufficient sample volume or errors made during the test. In this case, it is not possible to interpret the test result. Repeat the test with a new blood sample and a new test.

ATTENTION!

Each test line, even slightly colored, should be included in the interpretation of the test results.

IMPORTANT!

The test indicates the level of CRP at the time of testing. It should be remembered that its level can increase quite quickly. The test result should always be interpreted in conjunction with the clinical symptoms. The decision to use antibiotics or any other form of treatment is always made by the doctor - the test is only a diagnostic aid for the patient before visiting the doctor.

ANSWERS TO THE MOST FREQUENT QUESTIONS

How does the CRP Test work?

The CRP Test is a test for the semi-quantitative determination of the concentration of C-reactive protein in a blood sample. If there is a C-reactive protein in the test blood sample, it will react with anti-CRP antibodies present as distinct lines on the cassette test. Appropriate test lines will appear depending on the level of CRP concentration.

When should the test be performed?

The CRP Test should be performed in the event of clinical symptoms suggesting an infection, such as: low-grade fever, headache, fever, or general weakness. Before going to the doctor, it is worth checking whether the infection is bacterial - requiring an antibiotic, or viral - requiring symptomatic treatment with over-the-counter medications. The CRP Test can be performed at any time of the day.

What does the line that appears next to the letter C on the cassette test mean?

It is the control line. The appearance of a colored line next to the letter C proves that the test is working properly and that the test has been performed correctly.

Should the faintly colored test line be included in the interpretation of the test result?

The intensity of the lines on the CRP Test is irrelevant for the interpretation of the test result. Interpretations are made in accordance with the guidelines contained in this package insert in the section "INTERPRETATION OF RESULTS". Even faintly colored test lines indicate a positive test result.

Will the test result be reliable after more than 7 minutes?

No. The test result should be read 5 minutes after adding the solution, and the reliable result is maintained up to 7 minutes.

What should I do if I get a positive test result?

A positive test result means that there is a concentration of C-reactive protein in the tested blood higher than 10 mg/L. It is recommended to consult a doctor, which will enable further diagnosis, effective treatment and prevent the development of infection.

Attention! A result indicating a bacterial infection should be consulted urgently with a doctor, especially in the case of children, as ignoring a bacterial infection can lead to serious complications and even sepsis.

What should I do if I get a negative test result?

A negative test result means that no C-reactive protein was detected in the tested blood or its concentration is less than 10 mg/L. This does not indicate the development of a bacterial or viral infection, however, if you notice any disturbing symptoms, it is recommended to consult a doctor.

Could the test result be incorrect?

If the user has followed all the instructions in this package insert, the test result will be correct. The abnormal result may be due to the test being used after the expiration date or the test having become wet, or the wrong sample volume may have been used. The device with a capillary included in the package allows for precise collection of the blood volume required for the test.

What is the accuracy of the test?

The conducted clinical trials indicate that the results obtained with the CRP Test are over 95% consistent with the results obtained with the laboratory methods.



Date of the last revision of the package insert: 20/06/2022

Version 3AT/EN

SYMBOLS

For the sterile lancet:

CE 0197

	For single use		Radiation sterilized
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



Manufacturer:

NSP TECH PTE LTD
10 Admiralty Street
Northlink Building #02-06
Singapore 757695

CE 1434

For the test:

	Read the instructions carefully before performing the test		For in vitro diagnostic use only
	For single use		Store at 2-30°C
	Lot number		Expiry date



Manufacturer:

Hydrex Diagnostics Sp. z o.o.
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04-028 Warsaw, Poland
www.hydrex.pl
www.controly.eu

controly
medical devices