Veroval®
SELF-TEST

HARTMANN

Do antibiotics help?

Rapid test for the detection of a bacterial infection during a cold

5 min

Accuracy > 95 %

Medical self-tests for home use

Virus or bacteria – that is the question

Antibiotics are a very effective kind of medicine. But they only have an effect against bacteria – not viruses.
With the „Do antibiotics help" rapid test you now can quickly and safely check if your infection is bacterial, and if the use of antibiotics makes sense. Once you know the result, you can talk to your physician about further steps.

How reliable is the Veroval® test?

The "Do antibiotics help" rapid test was developed for the purpose of making the accuracy and dependability of modern diagnostics also available for private use at home. The test determines the CRP (C-reactive protein concentration in the blood. CRP formation is the immune system's response to the initial bacterial inflammation. **Accuracy, as evidenced in a performance evaluation study, is greater than 95 %.**

CRP test specificity testing with negative (–) and positive (+) control samples spiked with microorganisms

Number of tests	microorganism	CRP negative sample	CRP positive sample
10	Campylobacter fetus	all (–)	all (+)
10	Campylobacter jejuni	all (–)	all (+)
10	E. coli	all (–)	all (+)

Interference study

Number of tests	Clinical sample CRP negative	CRP test results	Number of tests	Clinical sample CRP negative	CRP test results
5	Acetaminophen, 20 mg/dl	all (–)	5	Glucose, 10 mg/ml	all (–)
5	Salicylic acid, 20 mg/dl	all (–)	5	Ketones, 40 mg/dl	all (–)
5	Albumin, 20 mg/ml	all (–)	5	Mestranol, 3 mg/dl	all (–)
5	Ascorbic acid, 20 mg/dl	all (–)	5	Nitrites, 20 mg/dl	all (–)
5	Atropine, 20 mg/dl	all (–)	5	Penicillin, 40,000 U/dl	all (–)
5	Bilirubin, 10 mg/dl	all (–)	5	Prostatic acid phosphatase, 1 mg/ml	all (–)
5	Caffeine, 20 mg/dl	all (–)	5	Sodium Heparin, 3 mg/dl	all (–)
5	Creatinine, 20 mg/dl	all (–)	5	Triglycerides, 500 mg/dl	all (–)
5	Gentisic acid, 20 mg/dl	all (–)	5	Lithium Heparin, 3 mg/dl	all (–)
5	Glucose, 2000 mg/dl	all (–)			

CRP test sensitivity testing with negative (–) and positive (+) control samples, undiluted and diluted

Test Lot	# of replicates	Negative control	Undiluted positive control	1 in 4 diluted positive control	1 in 10 diluted positive control	1 in 20 diluted positive control
A	5	all (–)	all (+)	all (+)	all (+)	all (+)
B	5	all (–)	all (+)	all (+)	all (+)	all (+)
C	5	all (–)	all (+)	all (+)	all (+)	all (+)

Positive test results = visible test and control band on test cassette strip
Negative test results =no visible test band but visible control band on test cassette strip

What should I pay attention to?

Warnings and important notes:

- Store at +4° to +30 °C and prevent from freezing and humidity
- The test must be used before the date of expiry at the latest (stated on the package), if it remains closed in the undamaged foil.
- Do not use the test if the protective foil has been damaged.
- The product does not contain substances harmful to people and the environment.
- After performing the test, dispose the test and its parts as municipal waste.
- The test is intended exclusively for in vitro diagnostics; for external use and self-test only; every test is intended for single use.
- Keep out of the reach of children.
- No adverse effects have been found by using this test.
- The test result is influenced by potential increase of C-reactive protein concentration in blood. We recommend repeating the test after 12 hours.
- Unless the course of the disease improves, or the health condition worsens, immediately seek the medical advice
- This test is not intended for other uses than for the determination of the CRP concentration range in the sample of human blood or serum.
- False negative* results can be caused by technical or procedural factors as well as potential interference with other substances contained in blood.
- Normal physiological CRP concentrations do not completely exclude the presence of a smaller inflammation or chronic disease, in which the immune system's response is minimum (e.g. progressive systemic sclerosis, lupus erythematosus, and ulcerative colitis).
- The CRP production can also be impaired by liver cell impairment or a functional disorder of immune system cells.

Important note:
CRP is a strong indicator of ongoing infection and inflammation. However, final determination of the clinical diagnosis should be performed by a physician. After the use of antibiotics, we recommend repeating the self-test using a new kit to monitor their effect.

* **False negative** = a negative test result is wrongly displayed, even though the result is actually positive.

Materials

- 1 CRP test (IVD Medical Device - 98/79/EC) and 1 pipette in foil bag with desiccant
CE 1023
- 1 container with sample dilution buffer
- 2 automatic lancing devices (1 spare) with sterile lancet for taking the blood sample

Owen Mumford Ltd.
Brook Hill, Woodstock
Oxfordshire, OX20 1TU,
UK

STERILE R CE 0120

- 1 glass capillary tube in protective container
- 1 alcohol swab

PAUL HARTMANN AG
Paul-Hartmann-Straße 12
89522 Heidenheim,
Germany
CE

- 1 plaster

PAUL HARTMANN AG
Paul-Hartmann-Straße 12
89522 Heidenheim,
Germany
CE

- 1 instruction leaflet

Explanation of symbols

Consult instruction leaflet	IVD In vitro diagnostic product (for use outside the body)	Expiry date (see imprint on packaging)
4 °C 30 °C Store in a dry place at +4 °C to +30 °C. Do not freeze	Σ 1 Contents sufficient for 1 test	Dispose of the used package to the relevant waste bin.
Manufacturer	STERILE R Sterilised by irradiation	LOT Batch number (see imprint on packaging)

5 min Reaction time in the test cassette	Rapid test for self-testing	2 Do not re-use	21 PAP Label of the material used for package

IVT IMUNO, s.r.o.
Pavlovická 59
CZ-772 00 Olomouc

Distributed by:
GB – PAUL HARTMANN Ltd.
Heywood OL10 2TT

Instructions for use: English
Date of issue November 2015
Last revision: April 2016

Veroval®
SELF-TEST

HARTMANN

This is how it's done:

1

- Lay out the test components on the table in front of you.

(1) Container with sample dilution buffer
(2) Alcohol swab
(3) Automatic lancing device
(4) Glass capillary tube in protective container
(5) + (6) Test cassette with pipette in foil bag
(7) Plaster

2 **Preparation**

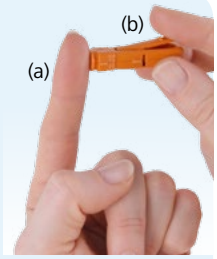
- Open the protective container (4) and carefully remove the glass capillary tube.

Take the container (4) and add 10 drops of dilution (1) by pressing the bottle.
Close the container tightly with the lid.

3

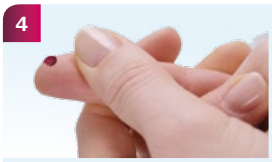
- Twist the grey cap of an automatic lancing device (3) until it detaches. Then twist fully another 2 times.

- Massage the tip of your index finger and clean with the alcohol swab (2). Allow your finger to dry.

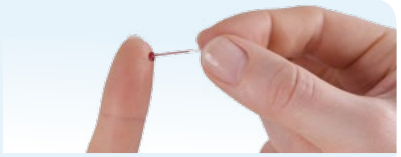


- Press the lancing device with the round opening against the side of the clean fingertip (a) and activate the release mechanism (b).

4



- Take the glass capillary tube and gently press a drop of blood from the fingertip.



- Hold the glass capillary tube horizontally into the drop of blood until it has filled completely.
- Use the enclosed plaster (7) if required.

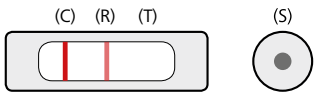
5

- Place the filled glass capillary tube into the container with the sample dilution buffer (4).
- Close the container tightly with the lid. Now shake the container a few times until the blood from the glass capillary tube has mixed completely with the solution and the liquid has collected again at the bottom of the container. Now open the container lid.

6

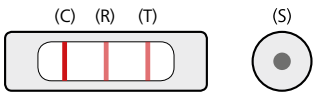
- Open the foil packaging shortly before use and lay the test cassette on a flat surface.
- Using the pipette (6), remove a few drops of the diluted sample.
- With the filled pipette (6), drop 4 drops from above into the round application field (S) of the test cassette (5). **Please ensure that no liquid is applied to the result window (T), (R) or (C).** After applying the drops, do not touch or move the test cassette.
- **After adding the 4 drops, read off the result after exactly 5 minutes.**
- After 7 minutes the results can not be considered conclusive.

Normal CRP level:
less than 10 mg/l



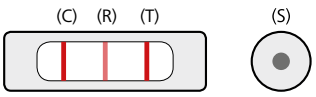
There is a stripe in the control line (C) and another in the reference line (R). There is no stripe in the test line (T). This result means that the sample contains a normal CRP level. A bacterial infection has not been proven, and the use of antibiotics will probably not improve your health condition. If the infection does not improve, you had better consult your physician.

Elevated CRP level:
10–30 mg/l



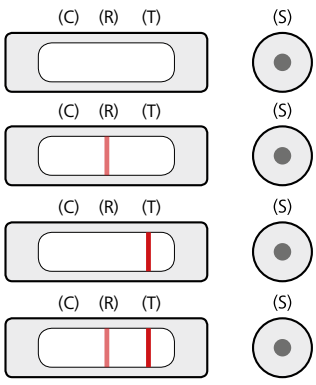
There is a stripe in the control line (C) and another in the reference line (R). There is a stripe of lower intensity in the test line (T). The elevated CRP level usually corresponds to a mild bacterial infection, although there might be other causes as well. We recommend confirming the result after 12 hour by repeating the test, and then consulting your physician.

Significantly elevated CRP level:
more than 30 mg/l



There are three stripes and the stripe in the test line (T) has a higher colour intensity than the stripe in the reference line (R). The stronger and more intense the test line (T) is, the higher the CRP concentration detected. A significantly elevated CRP level confirms a bacterial infection, and the use of antibiotics is probably reasonable. We recommend repeating the test after 12 hours and then consulting your physician.

Invalid



The test is invalid when there is no stripe, only a stripe in the reference line (R) or test line (T) or if there are stripes in reference line and test line. Repeat the test again.

Please note:

- In case of unclear test results other suitable clinical examinations must be performed.
- With regard to the different permeability of C-reactive protein to capillary blood (unlike the venous blood), the test can show slightly different results from laboratory determinations from venous blood.