

Chlamydia

Rapid test to detect a chlamydia infection

15 min



Accuracy
> 97%



Infected or not infected?

Chlamydia trachomatis is a sexually transmitted bacteria that causes an infection in the urogenital tract. Chlamydia infections are usually free of symptoms but they can also lead to inflammations in the eyes or the urinary tract or to arthritis. Untreated infections often cause infertility and they increase the risk of an ectopic (tubal) pregnancy and premature birth.

Knowing where you stand: chlamydia rapid test

The chlamydia rapid test quickly lets you know whether you are infected with the Chlamydia trachomatis bacterium. If the result is positive, you should discuss how to proceed with your doctor.

How reliable is the Veroyal[®] test?

The chlamydia rapid test was developed to make the accuracy and dependability of modern diagnostics available for private use at home. It is based on detecting the bacterium Chlamydia trachomatis (limit of detection: about 2.5 µg EB/mL) using a smear taken from the vaginal tract and therefore corresponds to the latest medical research. **A performance evaluation study confirmed an accuracy of greater than 97%.**

Is the test complicated to use?

No: All you need are clean washed hands, a clock and a flat surface. The exact test procedure is described overleaf.

Performance data:

This test achieved a diagnostic sensitivity of 85.7% and a diagnostic specificity of 98.3% compared to a method using PCR (polymerase chain reaction) in a clinical performance evaluation with 596 participants. A lay study with 56 volunteers was also carried out. Of the 56 volunteers, 54 interpreted the result correctly.

What should I pay attention to?

Storage:

• Store the self-test and all components at +4 °C to +28 °C.

Shelf life:

• The product may only be used until the printed expiry date.

Accuracy:

• Accuracy is greater than 97 %.

Application:

• **This test is not suitable for use during pregnancy, during and up to 3 days after your period or if you have a urinary tract infection.**

• You should not urinate for at least 1 hour before collecting the sample because this may distort the result.

• Do not use if the foil bag is open or the test cassette is damaged.

• The buffer is corrosive and must not be drunk.

• Only use the enclosed swab and ensure before every use that the original packaging is not damaged.

• Only use the test cassette, sample container and swab once.

• Do not dismantle the test cassette.

• Keep the test out of the reach of children.

Disposal:

• All test components can be disposed of in the household waste.

Please note:

• The test materials used that are of animal origin (e.g. antibodies) are potentially infectious materials but they do not present any danger if you use all test components as described in the instructions. For safety reasons, wash your hands after carrying out the test.

Important:

The final diagnosis should always be made together with your doctor. If you are trying to become pregnant and/or change sexual partners, it is recommended to keep the chlamydia rapid test handy so that you can regularly check for an infection.

www.veroval.en

Materials

- 1 test cassette and desiccant in a foil bag
- 1 container with buffer
- 1 swab

Puritan Medical Products Co.
31 School Street, Guilford, USA



Emergo Europe, Molenstraat 15,
2513 BH, Den Haag, NL

- 1 instruction leaflet

Explanation of symbols

Consult instruction leaflet	In-vitro diagnostic product (for use outside the body)	Expiry date (see imprint on packaging)
Store in a dry place at +4°C to +28°C. Do not freeze.	Contents sufficient for 1 test	Do not re-use
Manufacturer	Corrosive	Batch number (see imprint on packaging)
Reaction time in the test cassette	Sterilised with ethylene oxide	Rapid test for self-testing

CARE diagnostica Produktions- und Vertriebsgesellschaft m.b.H.
Römerstraße 8
AT-2513 Möllersdorf



Distributed by:
GB – PAUL HARTMANN Ltd.
Heywood OL10 2TT
office@en.hartmann.info

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Chlamydia

Rapid test for self-testing. This is how it's done:

1 • Place the test components on a flat surface in front of you.

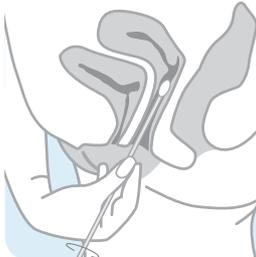
Contents:
 (1) Swab
 (2) Container with buffer
 (3) Test cassette and desiccant in a foil bag



Preparation:
 You should not urinate for at least 1 hour before collecting the sample because this may distort the result. Carry out the test in a quiet environment. Remove the swab (1) from the packaging.

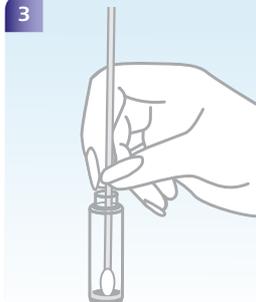
2

- Get into a comfortable position, similar to the one you would use to insert a tampon.
- Carefully insert the swab (1) up to the cervix (the end of the vaginal canal).
- Turn the swab (1) steadily for about **30 seconds** and then slowly pull the swab out.



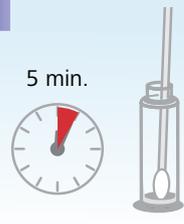
3

- The bottle with the sample dilution buffer (2) deliberately contains only a small volume of liquid. Place the swab (1) with the sample right in the bottom of the bottle.
- Turn the swab (1) in the liquid, pressing it against the wall of the bottle several times so that your sample material is well distributed in the buffer solution.



4

5 min.



- Wait **5 minutes**. Leave the swab (1) in the bottle (2) while you are waiting. You will distort the result if you wait longer or shorter.
- Before you dispose of the swab (1), thoroughly press it against the wall of the bottle (2).

5



- Dispose of the swab (1), close the bottle (2) and swirl it around again.

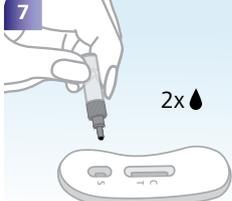
6

- Hold the bottle (2) with the cap upwards and break the tip off by bending it.



7

2x



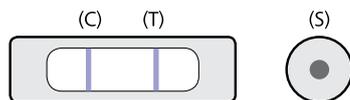
- Now place 2 drops of sample material on the 'S' sample field of the test cassette (3) as shown in the picture.
- Please ensure that no liquid ends up on the reaction field.

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- After applying the 2 drops, read the result after exactly **15 minutes**.
- After more than 20 minutes, the test result cannot be assessed with any reliability.

To assess the result, first check whether a line can be seen in the test window under (C). It does not matter how dark or light the control line is.

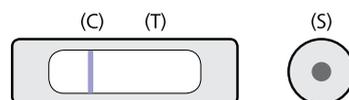
Positive result



The sample is assessed as **positive** if **two purple lines** (at 'C' and 'T') appear within 15 minutes, even if the line at 'T' is very light. A positive result can often become apparent before the 15 minute reaction time has elapsed.

If you have a **positive result**, you should contact your doctor to discuss the result with him or her. Please take this instruction leaflet with you when you visit your doctor so that he or she has a clearer idea of which test you have carried out.

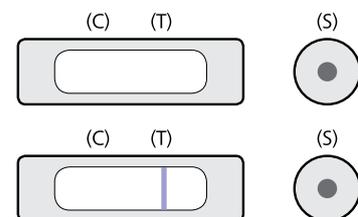
Negative result



The result is assessed as **negative** if **only one purple line appears at 'C'**. A negative result can only be reliably determined after the 15 minute reaction time has elapsed.

A **negative result** rules out an infection with Chlamydia trachomatis with a high degree of certainty but it is still recommended to be examined by a doctor at regular intervals.

Invalid result



The result is **invalid** if a **purple line does not appear at 'C' or only one line appears at 'T'** on the test field or the entire test field is evenly coloured purple. Possible reasons for an invalid result may be that the foil packaging or the swab packaging are damaged, the product may have been stored incorrectly or the test may not have been carried out properly. Please keep all test materials and contact the sales department by email.