

Male fertility

Rapid test for the detection of sperm concentration in the semen

7 min



Accuracy > 95 %



An important factor when wishing for a child: Sufficient sperm

Unintentionally childless couples often wonder about the cause. If it is due to the man, a below-average sperm count in the semen may be the reason why conception is not occurring.

Knowing where you stand: Male fertility rapid test

The Male fertility rapid test enables you to find out quickly and safely whether your semen contains sufficient sperm for conception. If this is not the case, you should speak with your doctor about how to proceed.

How reliable is the Veroyal[®] test?

The Male fertility rapid test was developed for the purpose of making the accuracy and dependability of modern diagnostics also available for private use at home. The rapid test determines whether or not the sperm count is in the normal range (according to WHO, handbook number 4, at least 20 million sperm/ml). **Accuracy, as evidenced by performance evaluation studies, is greater than 95 %.**

Is the test complicated to perform?

No: All you need are clean washed hands, a clock and a flat table surface. The exact test procedure is described overleaf. It is necessary to read the instruction leaflet thoroughly to understand how the result is determined and interpreted. All details should be understood before performing the test.

Performance data:

	Reference test			Total
	Positive	Negative		
Male fertility Rapid test	Positive	97	5	102
	Negative	3	89	92
	Total	100	94	194

Sensitivity: 97.00 % Specificity: 94.68 % Accuracy: 95.10 %

Important note:

This test assesses only the sperm concentration and cannot give additional information about fertility. This test is not suitable for contraception, proof of paternity or as protection from sexually transmitted diseases.

What should I pay attention to?

Warnings and important information:

- This test is intended only for use outside the body.
- Do not consume any of the test components.
- Avoid skin and eye contact with the sample dilution buffer.
- Keep the test out of the reach of children.
- Do not expose the test to direct sunlight or frost. Do not freeze. Store in a dry place between 2 °C and 30 °C.
- The test can only be used once.
- All test components can be discarded in the domestic waste.
- The product may be used only until the expiry date imprinted on the packaging.
- Poor eyesight, colour blindness or inadequate lighting can compromise the correct interpretation of the test.
- If the instruction leaflet is not correctly followed, the test may produce false results. A final diagnosis should be made by a physician.
- Do not use the test if the packaging is damaged. Do not use damaged test components.
- The test should be performed immediately or within one hour after opening the foil bag.

Test preparation:

Please note the following before you obtain semen through manual stimulation (masturbation):

- Wait at least 48 hours, but not longer than 7 days after the last ejaculation.
- Do not use any lubricants or lotions.
- Do not use a condom.

www.veroval.en

Materials

- 1 test cassette in foil bag
- 1 bottle with sample dilution buffer
- 1 syringe for drawing up the semen



- 1 beaker for collecting the semen
- 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 2–30°C. Do not freeze.	Contents sufficient for 1 test	Do not re-use
Manufacturer	Sterilisation with ethylene oxide	Batch number (see imprint on packaging)
Reaction time in the test cassette	Rapid test for self-testing	



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

1 • Lay out the test components on the table in front of you. Unpack the syringe. Do not open the foil bag with the test cassette yet!

Contents:
 (1) Beaker
 (2) Syringe
 (3) Bottle with sample dilution buffer
 (4) Test cassette in foil packaging

2

15–30 °C

- Collect the semen in the enclosed beaker (1). (If semen should go amiss, throw away the entire sample and rinse out the beaker only with tap water (1). Wait at least 48 h, but no longer than 7 days after the last ejaculation, before you obtain a new sample).
- Leave the sample standing for at least 20 minutes (but no longer than 3 hours) at room temperature (15–30 °C) on a flat surface.

3

- Stir the sample in the beaker carefully with the syringe (2) approx. 10x.
- Guide the syringe (2) in the semen so as to avoid solid or sticky material. Now pull back the syringe to the 0.1ml mark exactly and, by doing so, draw up the semen. Avoid air bubbles by frequently removing the syringe and pressing out the air and drawing up the semen again.

4

- The bottle with sample dilution buffer has a two-part cap. Open the bottle at the lower (broad) cap rim by unscrewing the whole cap.
- Now insert the syringe (2) into the bottle opening (3) and fill the entire sample amount (0.1 ml) by pressing the syringe contents into the bottle.

5

- Screw the cap closed again and carefully swirl the bottle (3).
- **Do not shake** the bottle (3), as this causes foam to be formed.

6

- Let the bottle with the sample stand for 2 minutes and make sure that everything is well mixed. Should this not be the case, swirl the bottle again.
- Now open the foil bag with the test cassette (4) and lay this on a clean and dry level surface.

7

- Screw off the upper lid of the bottle (3) and add exactly 6 drops into the round application field (S) of the test cassette (1). **Please ensure that no liquid is applied to the result window (T) or (C).** After applying the drops, do not touch or move the test cassette.
- **After adding the 6 drops, read off the result after exactly 7 minutes.**

To interpret the result, initially determine whether a line can be seen in the test window under (C). It is irrelevant how intense or faint the control line is.

Positive result

If both the control line (C) and the test line (T) can be seen, the result is positive. This result means that your sperm count is at least 20 million/ml and that you have sufficient sperm for conception.

A positive result does not yet mean that you are fertile. There is also a series of additional factors that can influence male fertility. After several months of unsuccessfully trying to conceive, you and your partner should consult a doctor for further clarification.

Negative result

The test result shows a line in the control field (C) and NO line in the test field (T), the test is negative. Your sperm count is below 20 million/ml.

A negative result on its own is not yet proof of infertility. Many men can nevertheless father children the natural way. In addition, the sperm count can vary from day to day, so that performing the test again with a new quick test can lead to a positive result. Consult your doctor for further clarification and have a full semen analysis done – especially if you and your partner have already been trying to have a child for several months without success.

Invalid result

If no line forms in the control field (C), or only a test line (T), the test has been performed incorrectly or incompletely and is invalid. The test then provides no answer to the question about your sperm count. Repeat the test with a new test cassette and be sure to wait at least 48 hours but no longer than 7 days after the last ejaculation.