

Quick Guide to Performing the SpermCheck® Vasectomy Test

Be sure to read "How to Perform the Test" on Page 2 of these instructions before beginning the test.

1. Let semen stand for twenty (20) minutes.

2. Punch out perforated circle and place the Solution Bottle in the Solution Bottle Stand that this makes.

3. Remove the Semen Transfer Device from its foil pouch and use it to gently stir and mix the semen in the Semen Collection Cup.

4. Fill the Semen Transfer Device to the black line with semen.

Pull plunger back to draw semen up to this line only

5. Add the semen from the Semen Transfer Device to the Solution Bottle.

6. Replace cap. Mix gently by inverting the bottle several times.

7. Wait for 2 minutes.

8. Unscrew the tip from the Solution Bottle cap.

9. Add 5 drops into the oval sample well marked "S".

10. Begin timing and wait 7 minutes.

11. Read the result at 7 minutes.



Interpretation of the Test Results



Positive Test Result



Negative Test Result



Invalid Test Results - Perform test again with new device.

A Positive Test Result indicates you should continue using other birth control and talk to your doctor about what to do next. We suggest that you wait at least two weeks before testing again with a new SpermCheck® Vasectomy kit.

A Negative Test Result indicates your sperm count is extremely low, at or below a level shown by scientific studies to present very little risk of pregnancy.

Please Note:

This SpermCheck® Vasectomy Kit contains everything you need to perform one SpermCheck® Vasectomy test. You should follow your doctor's instructions about how long to wait after your vasectomy before performing the test.

The results of your test should be negative.

If your result is not negative then test again with another SpermCheck® Vasectomy Kit. Many physicians recommend continuing other birth control after a vasectomy until two sperm tests with negative results are completed. We recommend you follow this guideline and test with SpermCheck® Vasectomy until you have obtained a negative result on two tests spaced two weeks apart.

Material Warnings and Precautions

All kit components are non-toxic and safe. The Solution may cause irritation if it contacts the eyes. Flush the eyes with plenty of water. Dispose of any unused kit components in normal household waste when no longer needed.

- For in vitro diagnostic use.
- Not to be taken internally. Do not re-use.
- Store in a dry place between 36 - 86°F (2 - 30°C).
- Do not freeze. Protect from sunlight.

Use only in accordance with these instructions.

To place an order for SpermCheck® Vasectomy:

Order online at www.spermchecktest.com or call (866) 683-7340 weekdays 8:00 a.m. to 6:00 p.m. ET.



Indications for Use:

SpermCheck® Vasectomy is a rapid test for use at home to detect sperm in semen following a vasectomy. This simple test will quickly let you or your doctor know when the number of sperm has dropped to a very low level and it is safe to stop other methods of birth control.

SpermCheck® Vasectomy is a quick screening test that will give you either a positive or negative result. A positive result does not necessarily mean that your vasectomy failed, but does indicate that additional testing is needed. A negative result means your sperm count is extremely low, at or below a level shown by scientific studies to present very little risk of pregnancy. However, it is important that you talk to your doctor and fully understand the meaning of the results before you decide to stop using other birth control methods. SpermCheck® Vasectomy can also be used at later times (a year or more after your vasectomy) in order to confirm that your sperm count is still close to zero.

Important Information About This Test:

- Read these instructions carefully and completely before starting the test.
- Do not use after the expiration date printed on the package.
- This test should be performed at room temperature 64-86°F (18-30°C).
- Keep out of the reach of children.
- This kit does not prevent pregnancy.
- This test does not protect against sexually transmitted diseases.
- Poor vision and/or improper lighting may affect interpretation of the results.
- Each test is intended for a single use only.
- If it has been less than six months since your vasectomy, we suggest that you:
 - Follow your doctor's instructions about when to perform this test, and
 - Discuss the test results and what to do next with your doctor.

Instructions and Use:

For accurate results, you must follow the steps below as described in this instruction pamphlet.

1. Read and understand the entire instruction pamphlet.
2. Check the kit contents.
3. Collect a semen sample.
4. Perform the test.
5. Read the result.
6. Call Technical Support at (866) 942-0030 if you are not sure how to perform the test, how to read the result, or if you don't understand the meaning of your test result.

Kit Contents:

Your SpermCheck® Vasectomy Kit contains everything you need to perform one SpermCheck® Vasectomy test. Open the kit and make sure that it contains the following items:

1 SpermCheck® Vasectomy Device in foil pouch

1 Semen Collection Cup

1 Semen Transfer Device in a foil pouch

1 Solution Bottle

If any parts of the kit are missing or damaged, please return the kit to the place of purchase or call (866) 683-7340 weekdays 8:00 a.m. to 6:00 p.m. ET for assistance.

Materials required, but not provided:

- Timer or watch

How to Collect Your Semen Sample:

Obtain your semen sample by manual stimulation (masturbation). Collect the sample in the Semen Collection Cup provided.

- **Ejaculate directly inside the Semen Collection Cup without losing any portion of the semen.** It is important to collect the entire ejaculate. If you do lose some of the semen, discard the sample. Wait at least 48 hours and collect a fresh sample.
- After collection, place the cap on the Semen Collection Cup and let it sit for 20 minutes.
- **Go to "How to Perform the Test" on the next page.**

SpermCheck® Vasectomy Technical Support

(866) 942-0030

Monday - Friday, 9:00 a.m. - 5:00 p.m. ET

Visit us at www.spermchecktest.com.

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How to Perform the Test

Work on a flat surface. Have a watch or other timer ready before starting the test.

1. Let the semen stand for twenty (20) minutes.

Semen is too thick to be tested immediately after ejaculation, so you must **wait at least 20 minutes** for semen to become thin (liquefy). Samples may be tested up to 3 hours after collection. Discard sample if not tested within 3 hours and wait at least 48 hours to obtain a fresh sample to test.

2. Place all of the kit components on a flat surface within easy reach.

3. Place the Solution Bottle into the Solution Bottle Stand on the box.

Push your finger through the round perforation located in the top left corner on the front of the box. This will create a stand to hold the **Solution Bottle**. Unscrew the cap on the Solution Bottle to remove it, and place the bottle into the stand so it won't tip over.



4. Fill the Semen Transfer Device to the line with semen.

Open the foil pouch labeled 'Semen Transfer Device' and take it out to use. Remove the cap from the **Semen Collection Cup** and use the Semen Transfer Device to gently stir and mix the semen sample in the Semen Collection Cup. Next, insert the **Semen Transfer Device** into the semen sample avoiding any solid or sticky material.



Slowly pull the plunger to draw semen into the Semen Transfer Device until it reaches the black line on the stem.

Avoid getting air bubbles in the Semen Transfer Device. If this occurs, push the semen back out of the Semen Transfer Device and then draw semen into the Semen Transfer Device again. Make sure the semen fills the Semen Transfer Device just to the line on the stem. Add or remove semen until it matches the line on the Semen Transfer Device exactly.

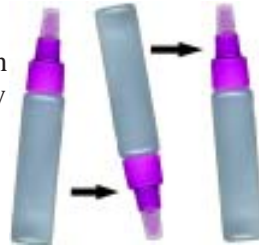
5. Add semen from the Semen Transfer Device to the Solution Bottle.

Insert the Semen Transfer Device into the Solution Bottle and press the plunger of the Semen Transfer Device gently to add the semen to the Solution Bottle.



6. Replace the cap on the Solution Bottle and mix the semen with the solution.

Screw the cap back onto the Solution Bottle and mix the contents by gently turning the Solution Bottle upside down several times. Do not shake vigorously as this will cause bubbles.



7. Wait for 2 minutes.

Place the Solution Bottle back in the Solution Bottle Stand and leave it there for two minutes before proceeding to the next step.



8. Unscrew the tip from the Solution Bottle cap.

Remove the Solution Bottle from the Solution Bottle Stand. Unscrew the tip from the Solution Bottle cap.



9. Add five (5) drops from the Solution Bottle to the Sample Well of the SpermCheck® Vasectomy Device.

Lay the SpermCheck® Vasectomy Device face up on a flat surface. Hold the Solution Bottle straight up and down over the sample well of the device and squeeze gently to add exactly five (5) drops of Solution. The sample well is marked with an "S" on the SpermCheck® Vasectomy Device.



Do not add more or less than 5 drops to the SpermCheck® Vasectomy Device sample well.

10. Begin timing and wait seven (7) minutes.

Begin timing after adding the Solution to the sample well.



11. Read the Result at 7 Minutes. See Page 3 for the details of How to Read the Results. This will explain the meaning of your test result.

Do not read the test result earlier or wait longer than 7 minutes as this may produce an incorrect result.

How to Read the Test Result:

Read the test in a well-lit area. If you know you have poor vision, you may want to have someone help you read the test.



Negative: If you see a Control Line (marked as "C" on the SpermCheck® Device) but not a Test Line (marked as "T" on the SpermCheck® Device) your sperm count is extremely low, at or below a level shown by scientific studies to present very little risk of pregnancy.



Positive: If you see both a Control Line (marked as "C" on the SpermCheck® Device) and a Test Line (marked as "T" on the SpermCheck® Device) your sperm count is above safe levels and there is still a risk of pregnancy with unprotected

intercourse. The test line does not have to be as dark as the control line. Even a very faint test line is a positive result. If you do get a positive result, you should continue using other birth control and talk to your doctor about what to do next. We suggest that you wait at least two weeks before testing again

with a new SpermCheck® Vasectomy Device.



Not Valid: If you do not see a control line (marked as "C" on the SpermCheck® Vasectomy Device) the test cannot be interpreted and you should test again with another SpermCheck® Vasectomy Device.

Things That Can Cause Incorrect Results:

- It is important that you carefully follow the instructions to get an accurate result.
- Reading the test too soon or too late. You must read the result 7 minutes after adding the Solution/semen mixture to the sample well.
- Adding Solution/semen to a part of the SpermCheck® Vasectomy Device other than the sample well.
- Adding too much or too little of the Solution/semen mixture to the sample well. You must add exactly five (5) drops from the Solution Bottle to the sample well.
- Adding the Solution/semen mixture to the SpermCheck® Vasectomy Device too soon. You must mix the semen and Solution well and let the mixture stand in the Solution Bottle for two (2) minutes after adding the semen to the Solution Bottle.
- Adding too much or too little semen to the Solution Bottle. Be sure to fill the Semen Transfer Device with semen exactly to the black line.
- Not collecting the entire ejaculate, especially the initial drops of the ejaculate, can affect the overall sperm concentration of the semen sample and lead to an incorrect result.
- Poor vision or poor lighting may affect your ability to read and interpret the test correctly.

Answers to Frequently Asked Questions:

Q1. What does a **positive test result** mean?

A1. A positive result indicates that there are still too many sperm remaining in your system. If you have recently had a vasectomy then you should continue to use other forms of birth control until a negative result is achieved on a follow up test. A positive result probably does not mean that your vasectomy failed. Although this is possible, it is more likely that your body just needs more time to get rid of the remaining sperm. If you have tested positive more than once, and you waited at least two weeks between tests, then you should talk to your doctor about what to do next.

Q2. What does a **negative test result** mean?

A2. A negative result with the test indicates that your sperm count is very low. The highest concentration of sperm that can still give a negative result with SpermCheck® Vasectomy is so low that the chance of achieving a pregnancy is extremely small. A negative result does not necessarily mean that your sperm count is zero. However, most men who get a negative result four months or more after vasectomy either already have a sperm count of zero or will soon. This is why it is important that you follow your doctor's advice about when to take the test after your vasectomy. The decision to stop using other methods of birth control is up to you, and you should be sure that you understand the risks and the meaning of your test result before you decide. We strongly recommend that you discuss this decision with your doctor.

Q3. My sample did not become a thin liquid after 20 minutes. Can I still perform the test?

A3. Some semen samples will not liquefy as quickly or as fully as others. The SpermCheck® Vasectomy Device may still give an accurate result even if your sample does not completely liquefy. It is important that you have allowed the sample to stand for 20 minutes and mixed it as directed, avoiding any solid material when performing the test. Fill the dropper with semen from the part of the sample where it is most liquid. If your sample has not liquefied at all, or if you cannot fill the dropper without it clogging with solid or stringy material, you should discard the sample. Wait at least 48 hours and collect another sample. If you have this problem again with the second sample, SpermCheck® Vasectomy may not work properly for you. If you feel that your semen did not liquefy adequately and you could not perform the test, or if you did perform the test but are concerned that this may have affected your test results, you should call your doctor for a semen analysis and evaluation.

Q4. The Test Line was not visible when I looked at it after 7 minutes, but was visible when I looked at it again later. Does this mean there are still sperm present and I need to continue to use other birth control?

A4. The Test Line may develop some color after the correct reading time period and that is why you must read the test result at 7 minutes. The right time to read the test result is 7 minutes after you add the Solution. Reading the test sooner than 7 minutes or more than 7 minutes after adding the Solution to the test device may give an incorrect result.