

QUICK GUIDE TO PERFORMING THE SPERM CHECK 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 on box and insert Solution Bottle so that it stands upright.
3. Use Semen Transfer Device to gently stir and mix semen in Semen Collection Cup. Pull plunger to draw semen up to the bottom of the raised frosted line.
4. Remove purple cap from Solution Bottle.
5. Add semen from Semen Transfer Device to Solution Bottle.
6. Replace cap. Mix gently by inverting bottle several times.
7. Wait 2 minutes.
8. Unscrew tip from Solution Bottle cap.
9. Add 5 drops into oval sample-well marked "S".
10. Begin timing and wait 7 minutes.
11. Read result at exactly 7 minutes.

SpermCheck Vasectomy Helpline
 (866) 635-2308 Weekdays 8:30 AM to 5:30 PM Eastern Time
 Visit us at SpermCheckVasectomy.com

INTERPRETATION OF TEST RESULTS



High Sperm-Level Test Result
Low Sperm-Level Test Result
Invalid Test Results - Perform test again with new device

A High Sperm-Level Test Result indicates you should continue using other birth control and talk to your doctor about what to do next. We suggest you wait at least two (2) weeks before testing again with a new SpermCheck Vasectomy Device.

A Low Sperm-Level 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 two (2) SpermCheck Vasectomy tests. You should follow your doctor's instructions for when to perform the tests following vasectomy.

The results of both tests should be low. If they are not both low, then test again with another SpermCheck Vasectomy Kit until you receive two (2) consecutive low results.

- For in vitro diagnostic use. Not to be taken internally.
- Store in a dry place between 36°F - 86°F (2°C - 30°C).
- DO NOT FREEZE.
- Protect from sunlight.
- Read the instructions carefully and completely before starting the test.
- Do not use after the expiration date printed on the package.
- This test is intended for a single use only. DO NOT RE-USE.

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 SpermCheck.com

SpermCheck Vasectomy

Instructions For Use

Home Test to Confirm Success of Vasectomy

INDICATIONS FOR USE

SpermCheck Vasectomy is a rapid at-home test to detect sperm in semen following vasectomy. This simple test quickly lets 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 gives you either a high or low result. A high result does not necessarily mean that your vasectomy failed, but does indicate that additional testing is needed. A low 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 later (a year or more after your vasectomy) in order to confirm that your sperm count remains low.

IMPORTANT INFORMATION ABOUT THIS TEST

- Read these instructions carefully and completely before starting the test.
- Wait at least 48 hours after your last ejaculation to obtain your semen sample.
- 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 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 (6) months since your vasectomy, we suggest you follow your doctor's instructions about when to perform this test.

MATERIAL WARNINGS AND PRECAUTIONS

All kit components are non-toxic and safe. The Solution may cause irritation if it contacts eyes; if it does, flush 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 the following instructions.

INSTRUCTIONS FOR 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 your doctor, Customer Service at (866) 635-2308, or visit info@spermcheck.com 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 two (2) SpermCheck Vasectomy tests. Open the kit and make sure it contains the following items:



If any parts of the kit are missing or damaged, please return the kit to the place of purchase or contact Customer Service at (866) 635-2308 or info@spermcheck.com for assistance.

MATERIALS REQUIRED, BUT NOT PROVIDED

- Timer or watch

HOW TO COLLECT YOUR SEMEN SAMPLE

When collecting semen, wait at least 48 hours, but no more than seven (7) days, after your last ejaculation. Obtain your semen sample by manual stimulation (masturbation). Collect the sample in the Semen Collection Cup provided.

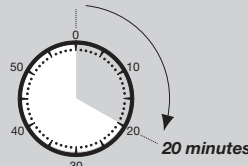
- Ejaculate directly inside the Semen Collection Cup without losing any portion of the semen. It is important to collect the entire ejaculate. Do not use any lubricants or lotions since this may interfere with the test result. Do not use a condom to collect the sample. If you do lose some of the semen, discard the sample, rinse the cup with tap water only and let it air dry before using it again. Do not use soap or detergent to wash the cup. Wait at least 48 hours, and then collect a fresh sample for testing.
- After collecting the sample, let the cup stand upright on a flat surface.
- The semen should be tested within three (3) hours after collection.
- When you are ready to test, follow the instructions in the next section, *How to Perform the Test*.

HOW TO PERFORM THE TEST

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

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

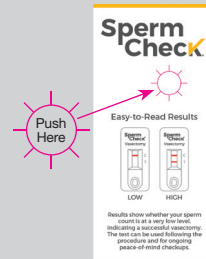
Semen is too thick to be tested immediately after ejaculation, so you must wait at least 20 minutes for semen to become thin (liquefy). Samples may be tested up to three (3) hours after collection. Discard sample if not tested within three (3) hours and wait at least 48 hours to obtain a fresh sample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



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

3. Carefully place Solution Bottle into Solution Bottle Stand.

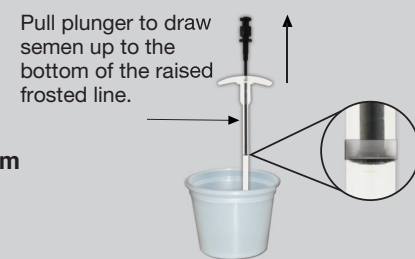
Punch out round perforation located in the top-right corner on the side panel of the box. This creates a stand to hold the Solution Bottle. Unscrew cap on the Solution Bottle to remove the cap, and place bottle into the stand so it won't tip over.



4. Fill Semen Transfer Device to the line.

Use Semen Transfer Device to gently stir and mix the semen sample in the Semen Collection Cup. Next, insert Semen Transfer Device into semen sample, avoiding any solid or sticky material. Slowly pull plunger to draw semen into Semen Transfer Device until semen level reaches the bottom of the raised frosted line.

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 bottom of the raised frosted line. Add or remove semen until it exactly matches the bottom of the raised frosted line on the Semen Transfer Device.



5. Remove purple cap from Solution Bottle.



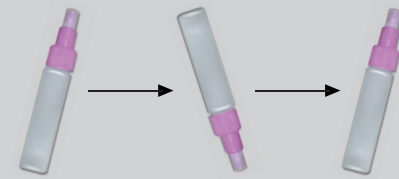
6. Add semen from Semen Transfer Device to Solution Bottle.

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



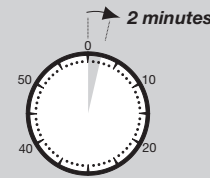
7. Replace cap on Solution Bottle and mix semen with the solution.

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.



8. Wait for two (2) minutes.

Place the Solution Bottle back in the Solution Bottle Stand. Leave it there for two (2) minutes before proceeding to the next step.



9. Unscrew tip from Solution Bottle cap.

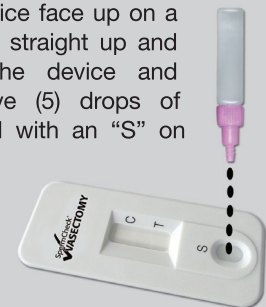
Remove the Solution Bottle from the Solution Bottle Stand, unscrew the small tip from the Solution Bottle cap, and discard the tip.



10. Add five (5) drops from Solution Bottle to 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 fewer than five (5) drops to the SpermCheck Vasectomy Device sample-well.

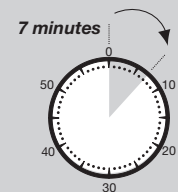


11. Begin timing and wait seven (7) minutes.

Begin timing after adding the Solution to the sample-well.

12. Read the result at precisely seven (7) minutes. See page 3 for details, under *How to Read the Test Results*.

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



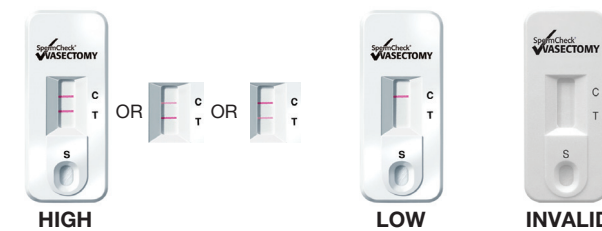
HOW TO READ THE TEST RESULTS

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.

Low: 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.

High: 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. *Even a very faint test line is a high result.* If you get a high result, you should continue using other birth control and talk to your doctor about what to do next. We suggest you wait at least two (2) weeks before testing again with a new SpermCheck Vasectomy Device.

Invalid: 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

- Not following instructions correctly.
- Reading the test too soon or too late. You must read the result seven (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 bottom of the raised frosted line.
- Not collecting the entire ejaculate. Failing to collect 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. These factors may affect your ability to read and interpret the test correctly.

FREQUENTLY ASKED QUESTIONS

Q1. What does a high test result mean?

A1. A high result indicates 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 low result is achieved on a follow-up test. A high result probably does not mean 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 high 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 low test result mean?

A2. A low result indicates your sperm count is very low. The highest concentration of sperm that can still give a low result with SpermCheck Vasectomy is so low that the chance of achieving a pregnancy is extremely small. A low result does not necessarily mean that your sperm count is zero. However, most men who get a low result four (4) 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 do 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 to allow the sample to stand for 20 minutes and mix 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 then collect another sample in the extra Semen Collection Cup included in the kit. If you have this problem again with the second sample, SpermCheck Vasectomy may not work properly for you. If you think 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 seven (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 precisely seven (7) minutes. The right time to read the test result is seven minutes after you add the Solution. Reading the test sooner or later than seven minutes after adding the Solution to the test device may give an incorrect result.

U.S. Patents 5,436,157, 5,602,005, and 5,605,803.