

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. Use the Semen Transfer Device to gently stir and mix the semen in the Semen Collection Cup.

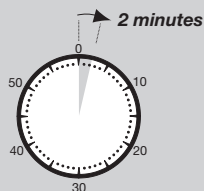
4. Fill the Semen Transfer Device to the bottom of the raised frosted line with semen.

Pull plunger to draw semen up to the bottom of the raised frosted line.

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

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

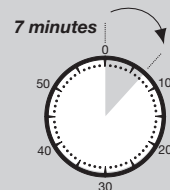
7. Wait for 2 minutes.



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 exactly 7 minutes

SpermCheck® Vasectomy Helpline

(866) 635-2308 Weekdays 8:30 AM to 5:30 PM ET

Visit us at SpermCheckVasectomy.com

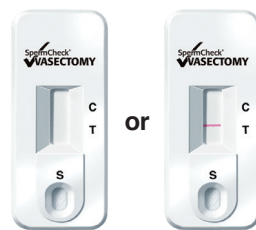
INTERPRETATION OF THE TEST RESULTS



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 Device.

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 two SpermCheck® Vasectomy tests. You should follow your doctor's instructions about how long to wait after your vasectomy before performing the tests.

The results of both tests should be negative. If they are not both negative then test again with another SpermCheck® Vasectomy Kit until you receive two consecutive negative results.

- IVD 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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U.S.A.
Printed in U.S.A.
Revised 2016-12-19

Distributed by
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1 DDC Way
Fairfield, OH 45014
U.S.A.
SpermCheckVasectomy.com

P-5192-D



Instructions For Use

Home Test to Confirm Success of Vasectomy

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.
- Wait at least 48 hours from your previous 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 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.

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 the following instructions.

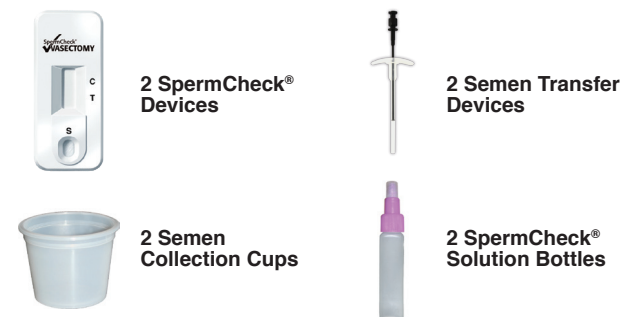
INSTRUCTIONS AND USE

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 your doctor or technical support at (866) 635-2308 or 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 SpermCheck® Vasectomy tests. Open the kit and make sure that 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 SpermCheck® at (866) 635-2308 or info@spermcheck.com for assistance.

MATERIALS REQUIRED, BUT NOT PROVIDED

- Timer or watch

HOW TO COLLECT YOUR SEMEN SAMPLE

Wait at least 48 hours, but not more than seven days after your last ejaculation. Obtain your semen sample by manual stimulation (masturbation). Collect the sample in the Semen Collection Cup provided.

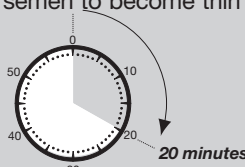
- Ejaculate directly inside the Semen Collection Cup without losing any portion of the semen. It is important to collect the entire ejaculate.** Do not use any lubricants or lotions since this may interfere with the test result. Do not use a condom to collect the sample. If you do lose some of the semen, 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 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 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

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 right corner on the side panel 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.

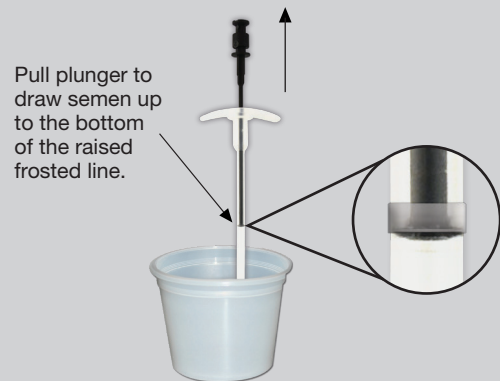


4. Fill the Semen Transfer Device to the line with semen.

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 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 matches the bottom of the raised frosted line on the Semen Transfer Device exactly.



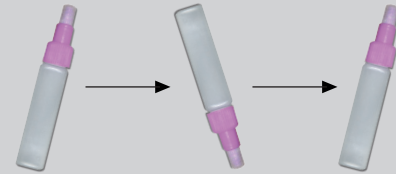
5. Add semen from the Semen Transfer Device to the Solution Bottle.

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.



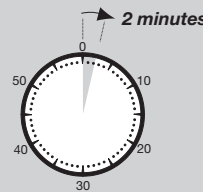
6. Replace the cap on the Solution Bottle and mix the semen with the solution.

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 small tip from the Solution Bottle cap and discard the tip.



9. Add 5 drops from the Solution Bottle to the Sample Well of the SpermiCheck Vasectomy Device.

Lay the SpermiCheck 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 SpermiCheck Vasectomy Device.

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

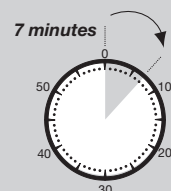


10. Begin timing and wait seven (7) minutes.

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.

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



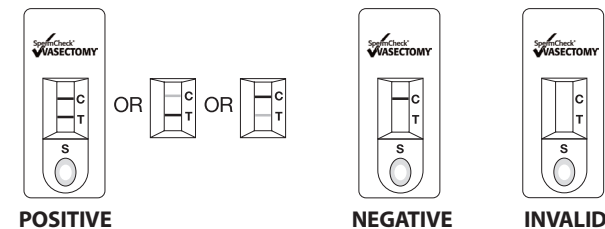
HOW TO READ THE TEST RESULTS

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.

Negative: If you see a Control Line (marked as "C" on the SpermiCheck Device) but not a Test Line (marked as "T" on the SpermiCheck 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 SpermiCheck Device) and a Test Line (marked as "T" on the SpermiCheck 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 SpermiCheck Vasectomy Device.

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

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 SpermiCheck 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 SpermiCheck 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 in the extra Semen Collection Cup included in the kit. If you have this problem again with the second sample, SpermiCheck 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.

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