

- Not collecting the entire ejaculate, especially the first drops of the ejaculate.
- Poor vision, color blindness or poor lighting may affect your ability to interpret the test correctly.
- Testing a sample obtained less than 48 hours or more than 7 days since your last ejaculation may give misleading results.

FREQUENTLY ASKED QUESTIONS

Q1. How accurate is the test?

A1. In a clinical study comparing the results of the SpermCheck® Fertility Test to the standard microscopic laboratory test, SpermCheck® Fertility was over 98% accurate in identifying if semen samples contained greater than or less than 20 million sperm per milliliter.

Q2. What does a positive test result mean?

A2. A positive result indicates that your sperm count is at least 20 million per milliliter, a level that is considered “normal” for fertile men. However, a positive SpermCheck® Fertility test result by itself does not prove that you are fertile since there are several other factors that can influence a man’s ability to father a child. If you and your partner are unable to conceive a child after several months of trying, you both should have full fertility evaluations, even if your SpermCheck® test result was positive.

Q3. What does a negative test result mean?

A3. A negative result indicates that your sperm count is less than 20 million per milliliter, which is below that of most fertile men. However, some men with sperm counts below this level are still able to father children naturally. It is also important to understand that your sperm count can vary from day to day, so it is possible that you might get a positive result if you were to wait a while and test again. However, we recommend that you talk to a doctor about your test result and have a complete semen analysis to determine just how low your sperm count is and whether you have any other sperm abnormalities that could affect your fertility status. It is particularly important to consult a physician if you and your partner have been trying to conceive a child for a year or more without success.

Q4. My semen sample did not become a thin liquid after 20 minutes. Can I still perform the test?

A4. Some semen samples will not liquefy as quickly or as fully as others. The SpermCheck® 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 at least 20 minutes and mixed it as directed, avoiding any solid material when adding semen to the SpermCheck® Solution Bottle. Letting it stand longer (up to three hours) may help it become more liquid. Keeping the semen near body temperature (but no warmer than 98°F) by carefully floating the cup containing the sample in a bowl of shallow warm water may also help the sample liquefy. DO NOT MICROWAVE. Fill the Semen Transfer Device 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 Semen Transfer Device to the black line without it clogging with solid or stringy material, you should discard the sample. Wait at least 48 hours and collect another semen sample.

If you have this problem again with the second sample, SpermCheck® 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 consider

consulting your doctor for a semen analysis and evaluation.

Q5. The test line was not visible when I looked at it at 7 minutes, but was visible when I looked at it again later. Does this mean that my test result is really positive?

A5. The correct result is the result you observe at 7 minutes after adding the semen mixture to the sample well. A Test Line that is not visible may develop some color when the SpermCheck® Device sits past the correct reading time. That is why you must read the test result at 7 minutes. Reading the test less than 7 minutes or more than 7 minutes after adding the semen mixture to the SpermCheck® Device may give an incorrect result or one that cannot be interpreted.

Q6. What else may cause errors in the test result?

A6. It is important that you carefully follow the instructions for the test in order to get an accurate result. Improper collection of the semen sample may cause errors. Testing a sample collected less than 48 hours after your last previous ejaculation may produce an incorrect result. Not collecting the entire ejaculate, especially the initial drops of the ejaculate, can affect the overall sperm concentration of the sample and lead to an incorrect result. Not adding the correct amount of semen to the SpermCheck® Solution Bottle, or the correct number of drops of semen mixture to the test device can lead to an error. Failure of the ejaculate to liquefy adequately can also affect the accuracy of the results. Poor vision, color blindness or poor lighting may affect your ability to read and interpret the test correctly. Adding the semen mixture directly to the results window instead of to the sample well can also cause an erroneous result. Although a number of drugs, disease organisms, and non-semen body fluids that might be found in the male reproductive tract have been tested and found not to interfere with the SpermCheck® Fertility test, it is possible that other substances or medical conditions that have not been tested may have an effect on the test results. Since illness can also temporarily reduce your sperm count, you should not take the test if you are (or recently have been) sick.

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Instructions For Use Home Sperm Test for Male Fertility

INDICATIONS FOR USE

SpermCheck® Fertility is a rapid test for use at home to detect the concentration of sperm in semen. This simple test will quickly let you know whether your sperm count is considered within normal limits.

SpermCheck® Fertility is a quick screening test that will give you either a positive or negative result. An explanation of how to read and interpret the test results is given in the “How To Interpret Results” Section. Regardless of the test result, it is important that you fully understand what your test means before deciding whether or not to consult your physician. Use only in accordance with the instructions provided.

IMPORTANT INFORMATION ABOUT THIS TEST

- 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.
- Keep out of the reach of children.
- Do not use this test as a method of birth control.
- This test does not protect against sexually transmitted diseases.
- This test cannot be used to prove paternity.
- Poor vision and/or improper lighting may affect interpretation of the results.
- This test is intended for a single use only. DO NOT RE-USE.
- This test assesses sperm concentration only. It does not detect all fertility issues.

INSTRUCTIONS AND USE

For accurate results, you must follow the instructions for each step.

1. Read and understand the entire instruction pamphlet.
2. Check the kit contents.
3. Collect a semen sample between 2 and 7 days after your last ejaculation.
4. Perform the test.
5. Read the result.
6. Call your doctor or customer service at 877-998-0992 if you are not sure that you understand the meaning of your test result.

KIT CONTENTS

In addition to these instructions, your SpermCheck® Fertility Kit contains one of each of 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 Monday - Friday, 8:00 AM to 8:00 PM EST at 877-998-0992.

MATERIALS REQUIRED, BUT NOT PROVIDED

- Timer or watch

MATERIAL WARNINGS AND PRECAUTIONS

All kit components are non-toxic and safe when used as directed. The SpermCheck® Solution may cause irritation if it contacts the eyes. If contact with the eyes occurs, flush the eyes thoroughly with water. Dispose of kit components in normal household waste after use.

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.

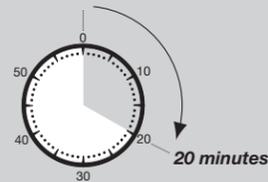
- Ejaculate directly into the Semen Collection Cup without losing any portion of the semen. Do not use any lubricants or lotions since this may interfere with the test result. Do not use a condom to collect the sample. It is important to collect the entire ejaculate. If you do lose some of the semen, 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 (but not more than seven days) after your last ejaculation 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

Place all of the test kit components on a flat surface within easy reach. Have a watch or timer ready before starting the test.

1. Let semen stand for at least twenty (20) minutes in the Semen Collection Cup before testing.

Semen is too thick to be tested immediately after ejaculation, so you must wait at least 20 minutes for semen to become thin (liquefied).

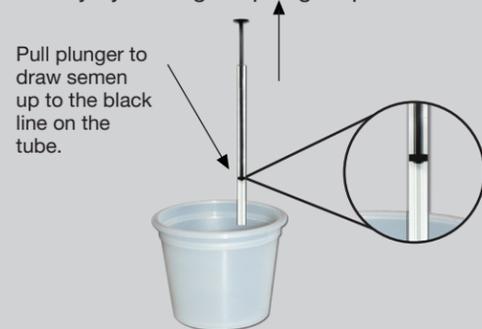


2. Remove the Semen Transfer Device from its sealed pouch and use it to gently stir the semen sample in the cup about 10 times until it is well mixed.

3. Put your finger through the round perforation area located on the side of the box. This will create a stand to hold the SpermCheck® Solution Bottle. Unscrew and remove the cap on the SpermCheck® Solution Bottle and place the bottle upright in the newly created stand.



4. Insert the Semen Transfer Device into the semen sample avoiding any solid or sticky material within the semen. Slowly pull the plunger to draw your sample into the Semen Transfer Device until it reaches the black line on the tube. Avoid getting air bubbles in the Semen Transfer Device. If this happens, push the semen back out completely and then draw semen into the Semen Transfer Device again. Make sure the semen fills the tube just to the black line on the Semen Transfer Device. Add or remove semen until it meets the line on the Semen Transfer Device exactly by moving the plunger up and down.



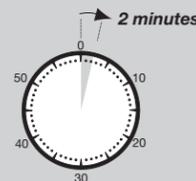
5. Insert the Semen Transfer Device with semen into the SpermCheck® Solution Bottle and push the plunger gently to add all of the semen to the SpermCheck® Solution. This creates the "semen mixture".



6. Screw the cap back onto the SpermCheck® Solution Bottle and gently mix the contents thoroughly. This is best done by turning the SpermCheck® Solution Bottle upside down at least five to ten times. If your semen is very thick or stringy, you should mix an additional ten times. Do not shake the SpermCheck® Solution Bottle too hard as this could cause foaming which in turn might make the next step difficult.



7. Let the SpermCheck® Solution Bottle containing the semen mixture stand for two (2) minutes before proceeding to the next step (Step 8).



8. Open the foil pouch containing the test device. Remove the SpermCheck® Device and lay it face up on a flat surface. Twist off the small cap on the tip of the SpermCheck® Solution Bottle cap.

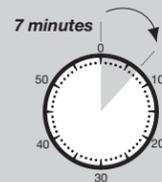


9. Hold the SpermCheck® Solution Bottle with the semen mixture straight up and down over the device and squeeze gently to add exactly six (6) drops of the semen mixture to the sample well (S) of the test device. The sample well is the round opening marked with an "S" near the bottom of the device. **Do not add more or less than 6 drops to the SpermCheck® Device sample well (S).**



10. Begin timing after adding the SpermCheck® Solution to the sample well.

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



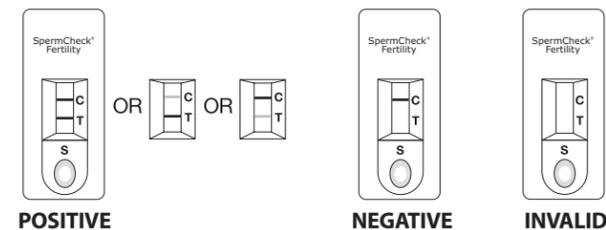
For technical services call 877-998-0992
Monday - Friday, 8 am - 8 pm EST
U.S. Patents 5,436,157, 5,602,005, and 5,605,803.
SpermCheck is a registered trademark.

HOW TO READ THE TEST RESULTS

IMPORTANT NOTE: To read your test simply determine whether a line is present or absent at the Control (C) and Test (T) positions on the device. Do not compare the lines to each other. It does not matter how strong or weak a particular line is. The Test Line may or may not be as dark as the Control Line. If you see any line at all at the Test (T) position and the Control (C) position, your test result is positive, no matter how faint the line is or how the Test Line compares to the Control Line.

Read the test in a well-lit area. First, look at the Control Line position in the results window (marked with the letter C). If the test worked properly, you should see a reddish line next to the C. **If you do not see a line at the C position, your test did not run correctly and the results are not valid.**

Next, look at the Test Line position in the result window (marked with the letter T). If you see a reddish line here, your sperm count is at least 20 million sperm per milliliter (positive). If you do not see a line at the T position, your sperm count is below 20 million sperm per milliliter (negative) and you should consult a physician about a complete fertility evaluation. Fertile men normally have 20 million sperm per milliliter or more.



WHAT THE RESULTS MEAN TO YOU

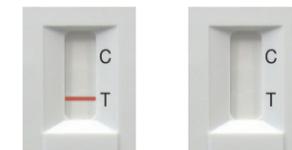
- **If you see a Test Line (at the T position) in the result window, your sperm count is at least 20 million per milliliter.** This "reference value" is based on the experience of many laboratories that have studied large numbers of healthy fertile men. About 90% of fertile men have sperm counts above 20 million per milliliter. However, a positive SpermCheck® Fertility test result alone does not prove that you are fertile. It is important to understand that several factors besides your sperm count could affect your ability to father a child. So if you and your partner have been trying to start a family without success for a year or more, you should see a doctor for a complete semen analysis and to discuss treatments that could benefit you, even if your SpermCheck® test result is positive.



- **If you do not see a Test Line (at the T position) in the results window, your sperm count is less than 20 million per milliliter.** However, a negative SpermCheck® Fertility test result alone does not prove that you are infertile. About 10% of fertile men have sperm counts below 20 million per milliliter, so you may still be able to father a child naturally. However, you should have a complete semen analysis and talk to a doctor about possible treatments for sub-fertility, especially if you and your partner have been trying to start a family without success.



- **Again, if you do not see a Control Line (at the C position) in the result window, your test did not run correctly and the results are not valid. You should test again with a new sample and a new SpermCheck® Fertility kit. Wait at least 48 hours, but not more than 7 days after your last ejaculation to retest.**



REASONS FOR INCORRECT RESULTS

- Failure of the ejaculate to liquefy
- Adding the SpermCheck® Solution/semen mixture to the SpermCheck® Device too soon. The mixture should stand for two (2) minutes after adding the semen to the SpermCheck® Solution Bottle.
- Not mixing the semen well enough in the Semen Collection Cup before adding to the SpermCheck® Solution.
- Adding too much or too little semen with the Semen Transfer Device to the SpermCheck® Solution Bottle. Be sure to fill the Semen Transfer Device with semen exactly to the black line.
- Not mixing the SpermCheck® Solution/semen mixture in the SpermCheck® Solution Bottle well enough before adding it to the SpermCheck® Device.
- Adding too much or too little of the SpermCheck® Solution/semen mixture to the SpermCheck® Device sample well. You must add exactly six (6) drops from the SpermCheck® Solution Bottle to the sample well.
- Adding semen mixture to the result window instead of the sample well. The sample well is the round opening marked with an "S" near the bottom of the SpermCheck® Device.
- Reading the test too soon or too late. You must read the result 7 minutes after adding the semen mixture to the sample well.