Instructions For Use

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 (normal sperm count) or negative (low sperm count) 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 doctor. 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 expiry 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. Speak to your doctor or email customer service at info@SpermCheck.com if you are not sure that you understand the meaning of your test result.
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.

2. Use the Semen Transfer Device 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 bottom of the raised frosted line. 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 Semen Transfer Device just to the bottom of the raised frosted line. Add or remove semen until it meets the bottom of the raised frosted 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 B).

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.

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 15 million sperm per millilitre (positive). If you do not see a line at the T position, your sperm count is below 15 million sperm per millilitre (negative) and you should consult a doctor about a complete fertility evaluation. Fertile men normally have 15 million sperm per millilitre or more.

WHAT THE RESULTS MEAN TO YOU

- If you see a Test Line (at the T position) in the results window, your sperm count is at least 15 million per millilitre. This “reference value” is based on the experience of many laboratories that have studied large numbers of healthy fertile men. About 95% of fertile men have sperm counts above 15 million per millilitre. However, a positive SpermCheck® Fertility test result alone does not prove that you are fertile. About 5% of fertile men have sperm counts below 15 million per millilitre, 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.

- If you do not see a Test Line (at the T position) in the results window, your sperm count is less than 15 million per millilitre. However, a negative SpermCheck® Fertility test result alone does not prove that you are infertile. About 5% of infertile men have sperm counts above 15 million per millilitre, so you may still be able to father a child naturally. However, 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 OR INVALID RESULTS

- When collecting your semen sample: Not collecting the entire ejaculate, especially the first drops of the ejaculate.
  - In step 1: Failure of the ejaculate to liquefy.
  - In step 2: Not mixing the semen well enough in the Semen Collection Cup before adding to the SpermCheck® Solution.
  - In step 6: Adding too much or too little semen with the Semen Transfer Device.
  - In step 7: 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.
  - In step 8: Adding too much or too little of the SpermCheck® Solution/semen mixture to the SpermCheck® Solution Bottle containing the semen mixture. The mixture should stand for two (2) minutes before adding to the SpermCheck® Device.
  - In step 9: Adding too much or too little of 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.
  - In step 10: Not mixing the semen in the Semen Collection Cup.
  - In step 11: Reading the test too soon or too late. You must read the result 7 minutes after adding the semen mixture to the sample well.
  - In step 11: Poor vision, color blindness or poor lighting may affect your ability to interpret the test correctly.
  - In general: Testing a sample obtained less than 48 hours or more than 7 days since your last ejaculation may give misleading results.