

# SpermCheck® FERTILITY

## 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 results, 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

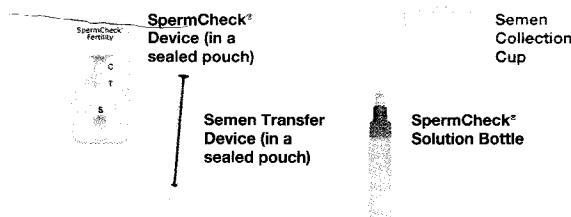
### INSTRUCTIONS AND USE

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.

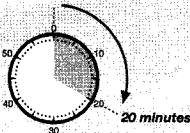
- Ejaculate directly into the Semen Collection Cup without losing any portion of the semen. Do not use any lubricants or lotions since this may interfere with the test result. Do not use a condom to collect the sample. It is important to collect the entire ejaculate. If you do lose some of the semen,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

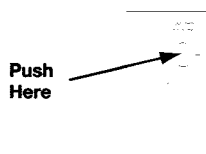
~~Place all of the test kit components on a flat surface within easy reach. Have a watch or timer ready before starting the test.~~

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

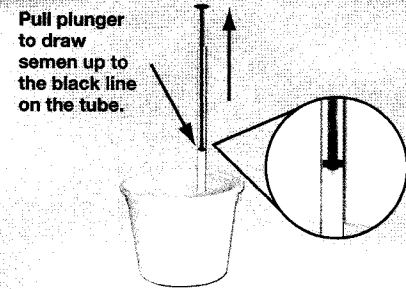
Semen is too thick to be tested immediately after ejaculation, so you must **wait at least 20 minutes** for semen to become thin (liquefied).



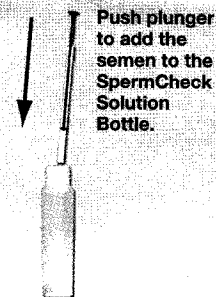
2. Remove the Semen Transfer Device from its sealed pouch and use it to gently stir the semen sample in the cup about 10 times until it is well mixed.
3. Put your finger through the round perforation area located on the side of the box. This will create a stand to hold the SpermCheck Solution Bottle. Unscrew and remove the cap on the SpermCheck Solution Bottle and place the bottle upright in the newly created stand.



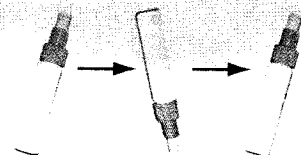
4. Insert the Semen Transfer Device into the semen sample avoiding any solid or sticky material within the semen. Slowly pull the plunger to draw your sample into the Semen Transfer Device until it reaches the black line on the tube. Avoid getting air bubbles in the Semen Transfer Device. If this happens, 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.



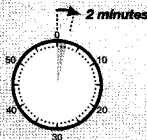
5. Insert the Semen Transfer Device with semen into the SpermCheck Solution Bottle and push the plunger gently to add all of the semen to the SpermCheck Solution.



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.



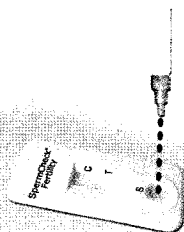
- Let the SpermCheck Solution Bottle containing the semen mixture stand for two (2) minutes before proceeding to the next step (Step 8).



- 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.

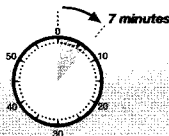


- Hold the SpermCheck Solution Bottle with the semen mixture straight up and down over the device and squeeze gently to add exactly six (6) drops of the semen mixture to the sample well (S) of the test device. The sample well is the round opening marked with an "S" near the bottom of the device. **Do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



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

- 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.

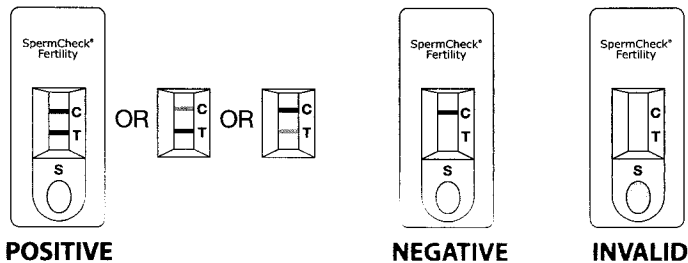


## HOW TO READ THE TEST RESULTS

**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 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

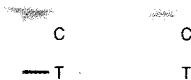
- **If you see a test line (at the T position) in the result window, your sperm count is at least 20 million per milliliter.** This “reference value” is based on the experience of many laboratories that have studied large numbers of healthy fertile men. About 90% of fertile men have sperm counts above 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

- Reading the test too soon or too late. You must read the result 7 minutes after adding the SpermCheck Solution/seminal mixture to the sample well.
- Adding sample 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 device.
- Not mixing the semen well enough in the cup before adding to the SpermCheck Solution.
- Not mixing the SpermCheck Solution/seminal mixture in the SpermCheck Solution Bottle well enough before adding it to the SpermCheck Device.
- 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.
- Adding the SpermCheck Solution/seminal mixture to the SpermCheck Device too soon. The mixture should stand for two (2) minutes after adding the semen to the SpermCheck Solution Bottle.
- Adding too much or too little of the SpermCheck Solution/seminal mixture to the SpermCheck Device sample well. You must add exactly six (6) drops from the SpermCheck Solution Bottle to the sample well.
- 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.

For technical services call 877-998-0992  
Mon - Fri 8am-8pm EST

Distributed by

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