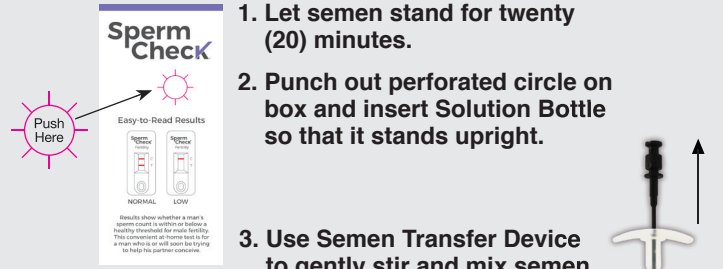


QUICK GUIDE TO PERFORMING THE
SPERM CHECK FERTILITY TEST

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 purple cap. Mix gently by inverting bottle several times.

7. Wait two (2) minutes.

8. Unscrew clear tip from Solution Bottle cap.

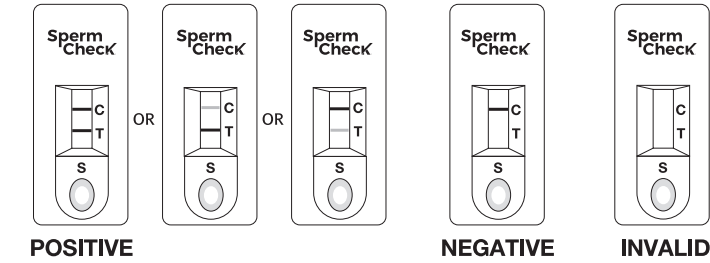
9. Add six (6) drops into oval sample well marked "S".

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

11. Read result at exactly seven (7) minutes.

SpermCheck Fertility Helpline
866.635.2308 Weekdays 8:30 AM to 5:30 PM Eastern Time
Visit us at SpermCheckFertility.com








INTERPRETATION OF TEST RESULTS



Positive (Normal): 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 at least 20 million per millileter, which is considered a healthy threshold for male fertility. **IMPORTANT:** The test line does not have to be as dark as the control line. *Even a very faint test line is a high result.*

Negative (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 less than 20 million per millileter.

Invalid: If you do not see a control line (marked as "C" on the SpermCheck Fertility Device) the test cannot be interpreted and you should test again with another SpermCheck Fertility Device.

-  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.

Manufactured by PBM
Princeton BioMeditech Corp.
4242 US Highway 1
Monmouth Junction, NJ 08852
U.S.A.

Rev. July 27, 2021

Distributed by
DDC
DNA Diagnostics Center®
1 DDC Way
Fairfield, OH 45014 U.S.A.
SpermCheck.com

SpermCheck
Fertility
Instructions For Use
Home Sperm Test for Male Fertility

INDICATIONS FOR USE

SpermCheck Fertility is a fast at-home test to detect the concentration of sperm in semen. This simple test quickly lets you know whether your sperm count is considered within the normal range for a fertile male.

SpermCheck Fertility gives you either a positive (normal sperm count) or negative (low sperm count) result. 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.

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.

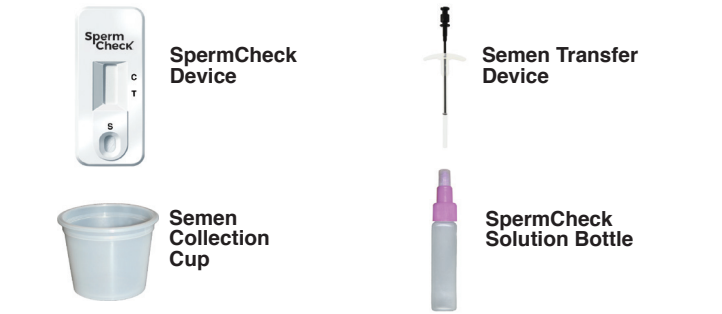
Use only in accordance with the following instructions.

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 Fertility Kit contains everything you need to perform one (1) SpermCheck Fertility test. 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.

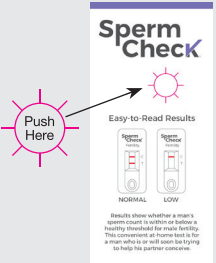
1. Let semen stand for twenty (20) minutes.

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.

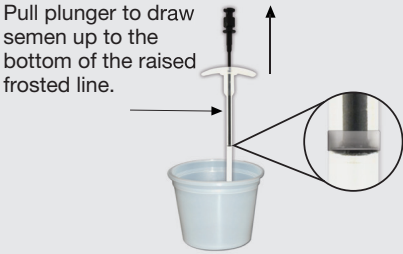
3. Carefully place Solution Bottle into Solution Bottle Stand. Punch out round perforation located in the top-right corner on the side panel of the box. This creates a stand to hold the Solution Bottle. Unscrew purple cap on the Solution Bottle to remove the clear cap, and place bottle into the stand 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.



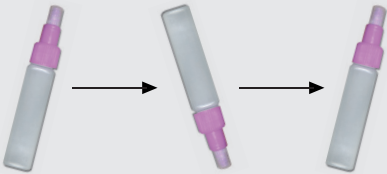
6. Add semen from Semen Transfer Device to Solution Bottle.

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 purple cap on Solution Bottle and mix semen with the solution.

Screw the purple 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 clear 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 clear tip.



10. Add six (6) drops from Solution Bottle to Sample-Well of the SpermCheck Fertility Device.

Lay the SpermCheck Fertility 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 six (6) drops of Solution. The sample-well is marked with an "S" on the SpermCheck Fertility Device.



Do not add more or fewer than six (6) drops to the SpermCheck Fertility Device sample-well.

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

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

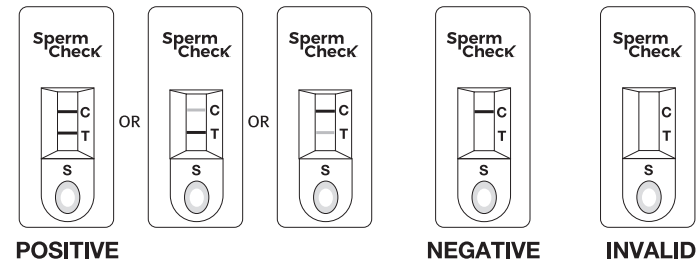
12. Read the result at precisely seven (7) minutes. See page 3 for details, under How to Read the Test Results.

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.



Positive (Normal): 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 at least 20 million per milliliter, which is considered a healthy threshold for male fertility. **IMPORTANT:** The test line does not have to be as dark as the control line. *Even a very faint test line is a positive result.*

Negative (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 less than 20 million per milliliter.

Invalid: If you do not see a control line (marked as "C" on the SpermCheck Fertility Device) the test cannot be interpreted and you should test again with another SpermCheck Fertility 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 Fertility 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 six (6) drops from the Solution Bottle to the sample-well.
- Adding the Solution/semen mixture to the 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 or failing to collect initial drops of the ejaculate. This 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.
- Using lubrication during masturbation. Both commercial and natural lubes can contaminate the semen sample.

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 more or less than 20 million sperm per milliliter.

Q2. What does a positive test result mean?

A2. A positive result indicates 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 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 is positive.

Q3. What does a negative test result mean?

A3. A negative result indicates 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. 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. 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.

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

A4. Some semen samples do 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 bottom of the raised frosted line without it clogging with solid or stringy material, you should discard the sample. Wait at least 48 hours and collect another semen sample.