

INSTRUCTIONS FOR USE

For Self-testing

INTRODUCTION

FertiQUICK® is a rapid test for use at home to detect the concentration of sperm in semen. The self-test shows whether the sperm count is considered within normal limits (at least 20 million sperm/ml according to WHO). Other fertility factors are not detected by the test.

An explanation of how to read and interpret the test results is given in the "Evaluation of test result" section. It is important to fully understand the entire instruction pamphlet before performing the test.

A **step-by-step instruction** is given at the opposite side to facilitate the test performance. However, it does not replace the general instructions for use.

TEST CONTENTS

- 1 test cassette in a sealed pouch
- 1 solution bottle
- 1 semen transfer syringe
- 1 semen collection cup
- 1 instruction pamphlet



Additionally required:

- 1 timer

TEST PREPARATION

Please note the following before you obtain the semen sample by manual stimulation (masturbation):

1. Wait at least 48 hours, but not more than 7 days after the last ejaculation.
2. Do not use any lubricants or lotions.
3. Do not use a condom.
4. Place all of the test components and a timer on a flat surface. Do not yet remove the semen transfer syringe from the package.

TEST PERFORMANCE

1. Collect the semen sample into the semen collection cup. If you do lose some of the semen, discard the sample. Rinse the cup **ONLY** with tap water. Wait at least 48 hours, but not more than 7 days (see 1 above.) and collect a fresh sample.
2. Let semen stand for at least 20 minutes but not longer than 3 hours at a room temperature (15-30°C) upright on a flat surface. Semen sample become liquefied and can be easily transferred.
3. Gently stir the semen sample with the semen transfer syringe in the cup about 10 times until it is well mixed.
4. Insert the semen transfer syringe into the semen sample avoiding any solid or sticky material within the semen. Pull the plunger to draw the sample into the semen transfer syringe **until it reaches the 0,1ml on the perforation line on the tube**. Avoid getting air bubbles in the semen transfer syringe. If this happens, push the semen back out completely and then draw semen into the semen transfer syringe again.

5. Solution bottle has two caps. Open the bottle by screwing the cap at the bottom onto the solution bottle.
6. Insert the semen transfer syringe into the solution bottle and push the plunger to add the entire semen sample (0,1ml) to the solution bottle.
7. Screw the cap back and mix the content of the solution bottle by turning the solution bottle **gently upside down. Do not shake the solution bottle as this could cause foaming.**
8. Let the solution bottle stand for 2 minutes to create the semen mixture. If this does not happen, turn the solution bottle upside down again. Open the foil pouch and remove the test cassette. Lay it face up on a clean, dry and flat surface.

9. Twist off the small cap on the tip of the solution bottle cap. Hold the bottle with the semen mixture straight up and down over the test cassette and squeeze gently to add exactly 6 drops to the sample well (S). **Please note, that there should be no liquid applied to the result windows marked with the letters (T) and (C).**

Please wait exactly 7 minutes after adding 6 drops to the sample well! Then read the result.

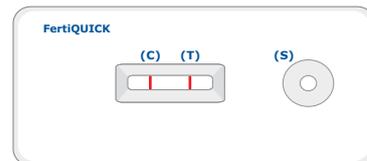
EVALUATION OF TEST RESULTS

To read the test results simply determine whether a line is present or absent at the control (C) position. It does not matter how strong or weak a Control line (C) is.

POSITIVE TEST RESULT

If there are any line at all at the **Control (C) position and the Test (T) position**, the test result is positive. The positive result means that the sperm count is at least 20 million sperm per milliliter and the sperm count level is considered normal to father a child.

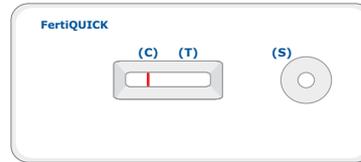
However, a positive test result alone does not prove the fertility. It is important to understand that several factors besides the sperm count could affect the ability to father a child. So if you and your partner have been trying to conceive a child without success for several months, you should both see a doctor for the comprehensive fertility evaluation.



NEGATIVE TEST RESULT

If there is **only Control line (C)** and **NO Test line (T)**, the test result is negative. The sperm count is less than 20 million per milliliter. However, a negative test result alone does not prove the infertility.

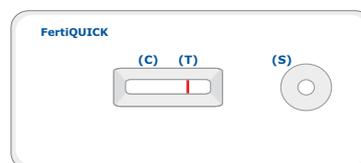
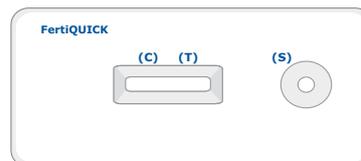
Some men have sperm counts below this range, so they still are able to father a child naturally. It is also important to understand that the sperm count can vary from day to day. So it is possible that you might get a positive result if you were to wait a while and test again. However, we recommend to talk to doctor about the test result and to have a complete semen analysis. It is particularly important to consult a doctor if you and your partner have been trying to conceive a child for several months or more without success.



INVALID TEST RESULT

If there is **no Control line (C)** or **only a Test line (T)** in the result window, the test did not run correctly and the results are not valid.

It is important that you carefully followed the instructions for the test. You should test again with a new sample and a new test. Wait at least 48 hours, but not more than 7 days after your last ejaculation to retest.



PERFORMANCE EVALUATION

		Reference Test		
Ferti-QUICK		Positive	Negative	Total
	Positive	97	5	102
	Negative	3	89	92
Total		100	94	194

Sensitivity: 97,00%

Specificity: 94,68%

Accuracy: 95,10%

WARNINGS AND IMPORTANT INFORMATION

- The test assesses sperm concentration only. It does not detect all fertility issues.
- The test is intended for use outside the body.
- Not to be taken internally.
- Keep out of the reach of children.
- Protect from sunlight, do not freeze. Store in a dry place between 2 °C and 30 °C.
- The test is intended for a single use only.
- This test cannot be used as a method of birth control, paternity proof or as a protection against sexually transmitted diseases.
- All test components can be disposed in household waste.
- Do not use after the expiration date printed on the package.
- Poor vision, color blindness or poor lighting may affect your ability to interpret the test correctly.

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Explanation of symbols:

Follow instructions	In vitro diagnostic medical devices (for external use)	Best before (See imprint on package)
Store at 2°C - 30°C DO NOT FREEZE	Sterilisation by ethylene oxide	Do not reuse
Manufacturer	Content sufficient for 1 test	Batchnumber (See imprint on package)



Instructions English
Revision from 2016-02 (Rev. 00)



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D-35037 Marburg
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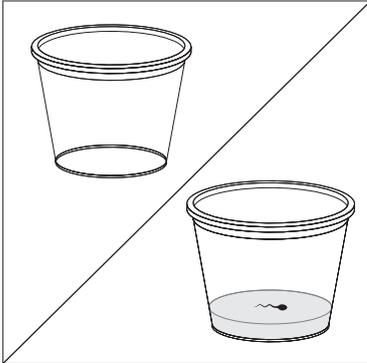


For the love of life.

STEP-BY-STEP INSTRUCTION

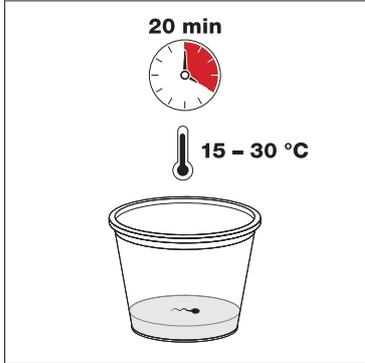
For Self-testing

STEP 1



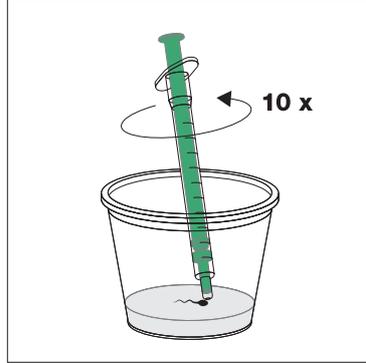
Collect the semen sample in the collection cup provided.

STEP 2



Let semen stand for **at least 20 minutes but not longer than 3 hours** at the room temperature (15°C-30°C).

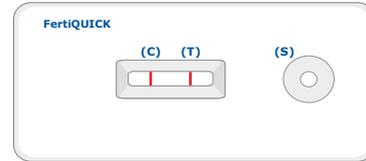
STEP 3



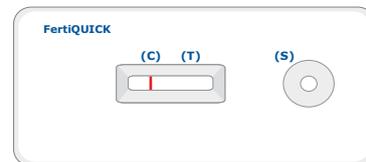
Use semen transfer syringe to gently stir the semen sample 10 times.

TEST RESULT

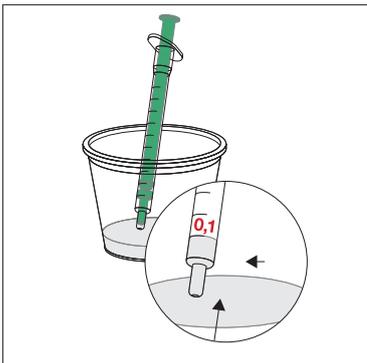
POSITIVE TEST RESULT



NEGATIVE TEST RESULT

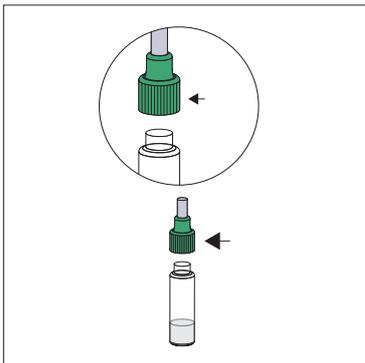


STEP 4



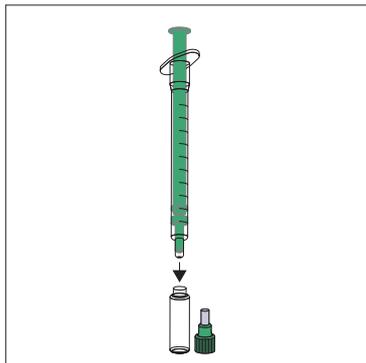
Pull plunger to draw liquified semen **exactly up to the 0,1ml** perforation line on the tube.

STEP 5



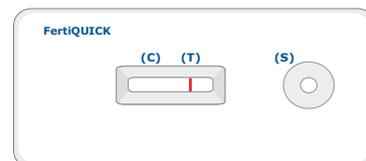
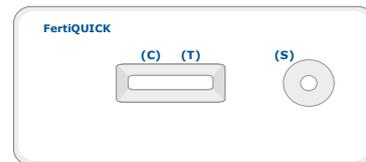
Open the solution bottle by screwing the cap at the bottom onto the solution bottle.

STEP 6

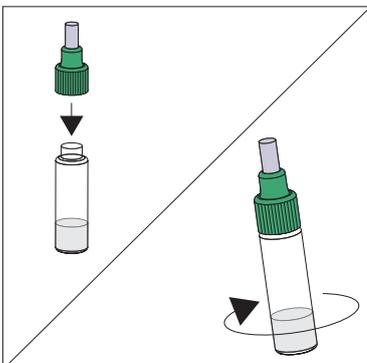


Insert the semen transfer syringe into the solution bottle and push the plunger gently to add all of the semen to the solution.

INVALID TEST RESULT

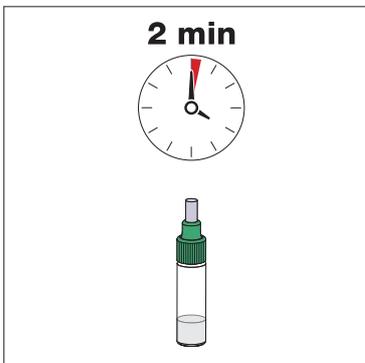


STEP 7



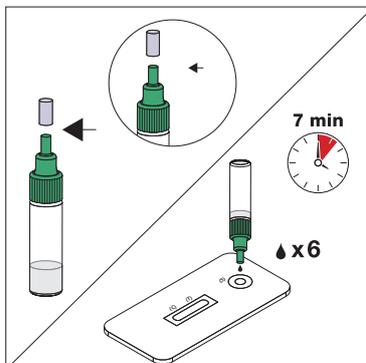
Screw the cap back onto the solution bottle and **GENTLY** mix the contents thoroughly by turning it upside down. **Do not shake!**

STEP 8



Let the solution bottle containing the semen mixture stand for 2 minutes.

STEP 9



Open the foil pouch containing the test cassette and lay it face up. Twist off the small cap on the tip of the solution bottle cap and squeeze gently to add **exactly 6 drops** of the semen mixture to the sample well (S) of the test cassette. Read the result **exactly at 7 minutes**.

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