SwimCount®

SPERM QUALITY TEST

ENGLISH VERSION

FOR HOME USE
SELF TEST DEVICE
1 SINGLE-USE TEST

2SAN
Better care. Better life.

NAME/FUNCTION OF EACH PART

Collection Cup

Transfer Syringe

INSTRUCTIONS FOR USE

Indications for Use
The SwimCount® Sperm Quality Test is a qualitative test that detects sperm concentration above or below 5,000,000 Progressive Motile Sperm Cells per mL (PMSCs/mL). The test is intended for use as an aid in the determination of a man's fertility status. For in vitro, over-the-counter use.

The number of Progressively Motile Sperm Cells is only one factor that contributes to a male's fertility status. The SwimCount® Sperm Quality Test does not provide a complete evaluation of a male's fertility status. For a comprehensive assessment of male fertility status, please consult a physician.

Device Description
The device is a home test to measure the fertility potential of a man by measuring the number of Progressive Motile Sperm Cells (named PMSCs) per mL. The cut-off value derived from WHO[1] states that above 5 M PMSCs/mL the PMSC count is NORMAL, whereas below 5 M PMSCs/mL the PMSC count is LOW (e.g., subnormal/bad sperm quality/poor sperm quality, etc.). The semen sample is loaded into the SwimCount® Sperm Quality Test device. Inside of the device, only PMSCs can swim through the filter and into a swim-up compartment. In the swim-up compartment, the PMSCs are stained. The more PMSCs, the darker the test result. Based on the color reaction and the reference color, the user can interpret if the result is Above or Below the threshold of 5 M PMSCs/mL.

The SwimCount® Sperm Quality Test provides a color chart with two possible outcomes:

- Light Purple/Blue = LOW = less than 5,000,000 PMSCs per mL
- Purple/Blue = NORMAL = more than 5,000,000 PMSCs per mL

The SwimCount® Sperm Quality Test is intended for in vitro, over-the-counter use and is a pre-screening sperm quality test that measures PMSCs per mL. The test kit includes the following components:

1. SwimCount® Sperm Quality Test
2. Semen Collection Cup
3. Semen Transfer Syringe
4. SwimCount® Sperm Quality Test Instructions for Use

Test Principle
The semen sample is loaded into the SwimCount® Sperm Quality Test device. Inside of the device, only PMSCs can swim through the filter and into a swim-up compartment. In the swim-up compartment, the PMSCs are stained. The more PMSCs, the darker the test result. The assay inside of the device stains the mitochondria of the PMSCs and works by entering into the mitochondria of the PMSCs where the assay is changed (only in living cells) by an enzyme.

1. Cooper et al. Human Reproduction Update 2010; 16(3): 231-245.

IMPORTANT INFORMATION ABOUT THIS TEST

PRECAUTIONS

Before taking the test, please ensure the following:

- Read the instructions carefully.
- Ensure that the contents of the package are at room temperature.
- Check that the package contents are intact.
- Have a watch/clock/timer available.
- Not for internal use.
- Keep out of reach of children.
- Not for contraceptive use.
- DO NOT use this product after the expiration date found on the bottom of the box.
- For in vitro diagnostic use only.

NOTE:

- SwimCount® Sperm Quality Test is for single use only and cannot be reused.
- SwimCount® Sperm Quality Test is not to be used to determine the success of a vasectomy.
- Color blindness may impact the ability to correctly read the result.

BEFORE YOU BEGIN

Collect your sample AT LEAST 2 days, BUT no longer than 7 days after your last ejaculation.

When can you test your sperm quality?

Take your test during this period

Days since last ejaculation	1	2	3	4	5	6	7	8
	No	No	Yes	Yes	Yes	Yes	Yes	No

COLLECT YOUR SEMEN SAMPLE

A

IMPORTANT: Have a watch/clock/timer available.

- Collect your semen sample in the included Collection Cup. Make sure that the whole sample is collected. Do not use a condom or lubricant, since this might damage the sperm cells.

B

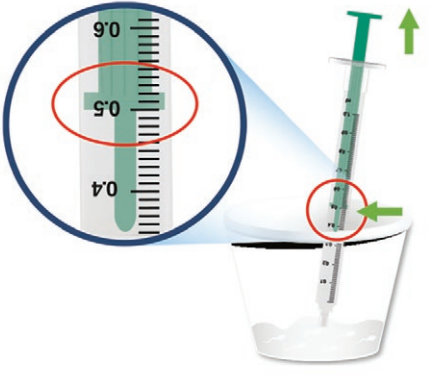
- Set a timer and leave the sample in the Collection Cup for 30 minutes.
- It is important that you wait 30 minutes after producing the sample before you perform the next steps. The waiting time is needed for the sperm sample to liquify.

NOTE: Some samples take more than 30 minutes to liquify (to become thin and watery). You may wait longer if needed, but it is important that you wait no more than one hour after the sample has been produced.

C

- Use the syringe to stir the sample 10 times.

D



- Collect exactly 0.5 mL of the sample by using the included syringe.

NOTE: It is important to avoid air bubbles inside the syringe, since this will influence the sample volume.

PERFORM THE TEST — STEPS 1–5

1

- Keep the test device on a **horizontal** surface throughout the test procedure. Add the sample (0.5 mL) slowly to the Sample Well marked 1 from the syringe.

IMPORTANT: DO NOT push Slider until semen sample has been added.

2

- Push the Slider slowly, all the way forward to activate the device.

NOTE: You should hear a clicking sound. The action window will change to: .

3

- Wait another 30 minutes while keeping the test device on a **horizontal** surface.

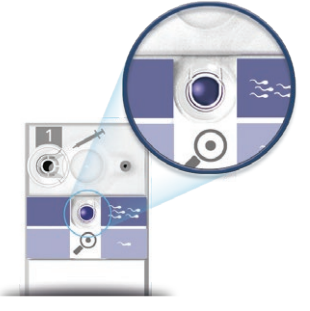
IMPORTANT: DO NOT pull Slider back to read results until 30 minutes have passed.

4

- After 30 minutes, pull the Slider all the way back as marked by the arrow.

NOTE: You should hear a clicking sound. The Action Window will change to: .

5



- The result can be read in the window marked with . The darker the color, the more PMSCs are present in the semen sample. The test result should be read **within 5 minutes** after pulling the Slider back, otherwise you might get a false positive test result.

The table below shows what the color intensity indicates.

Color Intensity Male Fertility Status*	Million (M) of Progressive Motile Sperm Cells (PMSCs)/mL	What does the result mean?
LOW	< 5	It means that your result is < 5 M PMSCs/mL and therefore below the normal level for fertile men, according to the World Health Organization (WHO)[1]. Men with a low PMSCs level/mL have been shown to have a lower chance of making their partner pregnant in a natural way compared with men with a normal PMSCs level/mL[2,3].
NORMAL	≥ 5	It means that your result is ≥ 5 M PMSCs/mL and therefore at or above the normal level for fertile men according to the World Health Organization (WHO)[1]. Men with a normal PMSCs level/mL have been shown to have a better chance of making their partner pregnant in a natural way within 12 months[2,3].

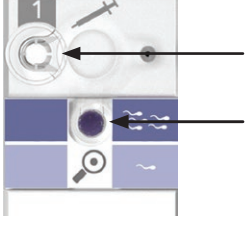
***The color intensity is correlated to the number of PMSCs/mL. The more PMSCs/mL, the darker the color.**

1. Cooper et al. Human Reproduction Update 2010; 16(3): 231-245 | 2. Larsen et al. Human Reproduction 2000; 15(7):1562-1567 | 3. Bonde et al. The Lancet 1998; 352: 1172-1177.
Not for contraceptive use.

HOW TO DETECT IF YOUR RESULT IS NORMAL OR LOW

An example of a NORMAL SwimCount® Sperm Quality Test result:
If you have followed the guidelines on How to Use the SwimCount® Sperm Quality Test in the Instructions for Use and your test result in the Result Window looks similar to the blue color in the below picture, your test result shows:

You have a NORMAL PMSC count.

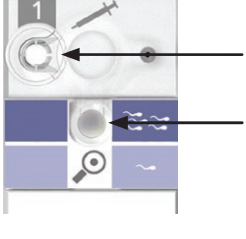


Your semen sample has been added correctly to the Sample Well

The Result Window shows a darker blue color

An example of a LOW SwimCount® Sperm Quality Test result:
If you have followed the guidelines on How to Use the SwimCount® Sperm Quality Test in the Instructions for Use and your test result in the Result Window looks similar to the light blue color in the below picture, your test result shows:

You have a LOW PMSC count.



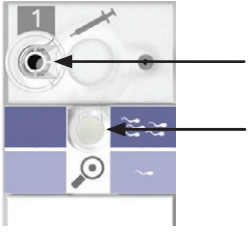
Your semen sample has been added correctly to the Sample Well

The Result Window shows a lighter blue color

HOW TO DETECT IF YOUR RESULT IS NOT VALID

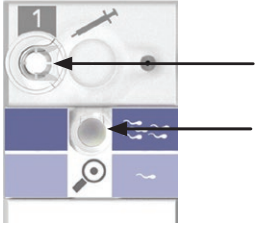
Scenario 1:
If you have not added your semen sample to the Sample Well but you have accidentally pushed the Slider forward and then pulled it all the way back, the Result Window will have a little to no change of color:

The test has been compromised and you will not obtain a valid result.



Scenario 2:
If you have added your semen sample to the Sample Well, pushed the slider forward and then pulled it all the way back after 30 minutes according to the Instructions for Use, and the Result Window has no change in color:

The device has not worked correctly and you have not obtained a valid result.
Please contact us at Helpdesk.us@2san.com.



QUESTIONS & ANSWERS

1. My result is LOW, what does this mean and what should I do now?
A LOW result means that the PMSC count of your semen sample is lower than for fertile men. A LOW result does not necessarily mean that you will be unable to make a woman pregnant in a natural way, as sperm quality varies over time.

A bacterial infection may influence the semen quality, so obtaining a low PMSCs result with SwimCount® Sperm Quality Test may indicate an infection, in which case, please see your doctor.

Lifestyle changes may improve the number of PMSCs, which you can check with further SwimCount® Sperm Quality Tests or by consulting your doctor.

2. How is NORMAL defined?
A NORMAL result means that the PMSC count of your semen is ≥ 5 M PMSCs/mL[1]and therefore is at or above the normal level for fertile men.

3. My result is NORMAL but my partner is not pregnant yet despite several months of trying. What should we do?
There are factors other than the PMSC count that may affect male fertility. These factors are not assessed with this test. If you and your partner have been trying to conceive for 12 months without success, you should consult your doctor for further testing and investigation.

4. I am unsure of my result, what should I do?
If you are unsure of your test result, you can contact us at Helpdesk.us@2san.com. You can also take another test but you should wait at least 48 hours before testing with a new sample and a new kit.

1. Cooper et al. Human Reproduction Update 2010; 16(3): 231-245.

5. My sample did not become thin and watery within 30 minutes. What should I do?
Some samples take more than 30 minutes to liquify (to become thin and watery), so you should wait longer if needed. If your sample has not liquified within 1 hour after collection, then it is better not to test using this sample. Discard your sample, rinse out the Collection Cup with just water and leave to dry. Do not use soap.

Remember to wait 48 hours before you collect the next sample. If the next sample still does not liquify within 1 hour, consult your doctor.

6. The test did not seem to work or parts of the test kit were missing or damaged. What should I do?
If any part of the test kit is missing or damaged, or if the test did not seem to work, please contact us at Helpdesk.us@2san.com.

7. What may generally affect sperm quality?
There are a number of factors that can affect your sperm quality:

- If you have recently (in the last 2–3 months) been unwell, particularly if you have had a high fever, this may affect your sperm quality. It is therefore better to wait until you are well before retesting your sperm quality.

- If you have been taking anabolic steroids or other medication containing testosterone.

- Your previous medical history includes:
  — Undescended testicles as a baby
  — Varicocele (swollen veins in the testicles)
  — Groin surgery, such as hernia repair
  — Mumps in adulthood
  — Treatment for cancer

If you are concerned about any of the above factors, you should consult your doctor, who can advise you on the next steps.

8. Is there anything I can do to improve my PMSC count?

So far there is not much evidence that anything specific can improve your PMSC count; however, the following may help:

- It is always worth taking care of yourself and factors like eating healthy, regular exercise, quitting smoking and reducing alcohol consumption can improve your health.
- Take showers instead of hot baths — long hot baths may impact sperm quality.
- Stop taking anabolic steroids (do not stop taking any prescribed medication without first consulting your doctor). Male fertility often returns to normal once use of steroids is discontinued.

9. What if I want to re-test?

You can test again with a new kit as long as you wait at least 48 hours after the first test. If you want to see a possible change in your PMSC count after lifestyle changes, you should wait at least 10 weeks before testing again. It takes 10 weeks for new sperm to be produced, so changes in your lifestyle will not materialize before then.

Performance

With a sensitivity of 95.83% and specificity of 90.68%, SwimCount® Sperm Quality Test provides an excellent performance for measuring the number of PMSCs/mL.

This means that if the test shows that your semen sample has less than 5 M PMSCs/mL, it is 95.83% likely that the test result is correct. If the test shows that your semen sample has more than 5 M PMSCs/mL, it is 90.68% likely that the result is correct.

Chemical composition

SwimCount® Sperm Quality Test contains a chemical for staining the PMSCs consisting of a dye dissolved in a buffered physiological saline solution.

Interference study

Contamination of the semen sample with urine, red (RBC) and white (WBC) blood cells interfere with the result of the assay.

SYMBOL EXPLANATION

SYMBOL	EXPLANATION
	Consult instructions for use
	Manufacturer
	*In vitro* diagnostic medical device
	Do not re-use

SYMBOL	EXPLANATION
	Use-by date
	Batch number
	Temperature limit
	Catalogue number

IMPORTANT

- The test device is disposable and cannot be re-used
- Discard with normal household waste
- Do not use a device that has expired
- This device is for home use only
- For in vitro diagnostic use only

Made in Denmark by MotilityCount ApS

Distributed by:
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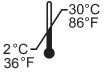
www.swimcount.com
Please contact us at
Helpdesk.us@2San.com

Call us weekdays at
1-857-328-0036
8:30am-5:00pm ET

Have LOT number available



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