

Artron

Sperm K

Male Fertility Sperm Test
For Professional Use
Instructions for Use

Cassette

Please read the instructions completely and carefully before starting the test.

Sperm OK

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INDICATIONS FOR USE

Artron's Sperm OK Male Fertility Sperm Test is a rapid and convenient professional use immunochromatographic assay for the qualitative detection of the standard sperm concentration in a human semen sample, which is at 15 million sperm per millilitre.

This quick screening test will give you either a positive or negative result. The section "Step 3: Interpret the Results" will provide you with an explanation on how to read and interpret your test results.

This product indicates whether your sperm concentration meets the normal levels of 15 million sperm per millilitre as set by the World Health Organization (WHO) in 2010. However, this test alone does not prove whether or not you are fertile. Thus, it is crucial that you fully understand the meaning of your test result before deciding whether or not to consult with your physician for further semen analysis. This product should be used only in accordance with the instructions provided.

SUMMARY AND PRINCIPLE OF THE ASSAY

Infertility is experienced by 10–15% of couples, and half of these cases are a result of male infertility. Since low sperm concentration is a leading cause of male infertility, an important first step in determining the cause of infertility is to test the male sperm count. However, a trip to a fertility clinic for a semen analysis might not be suitable for everyone. The World Health Organization (2010) has defined a reference value of 15 million sperm/ml or more for a normal semen analysis reading. Since the risk of male infertility and/or subfertility increases further with decreasing sperm concentration, a sperm test that provides information about sperm concentration below the WHO reference value would be convenient to the public.

Artron Sperm OK is an antigen-capture immunochromatographic assay, detecting sperm antigen in semen samples. Monoclonal antibodies specifically against sperm antigen are 1) conjugated with colloidal gold and deposited on the conjugate pad, and 2) immobilized on the test line of the nitrocellulose membrane. When sample is added, the gold-antibody conjugate is rehydrated and sperm antigens interact with the gold conjugated antibodies. The antigen-antibody-gold complex then migrates towards the test window until the Test Zone (T) where it will be captured by immobilized antibodies, forming a visible pink line (Test band), indicating a positive result. If sperm concentration is below normal limit (15

million/ml) in the sample, no pink line will appear in the Test Zone (T), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a colored control line in the Control Zone is an indication of an invalid result.

With Artron Sperm OK, you will know within minutes if your sperm concentration is within the normal range. Above 15 million sperm per millilitre ($15 \times 10^6/\text{ml}$) of semen is the accepted standard for normal sperm concentration. A **positive result** indicates that your sperm concentration is above 15 million sperm per millilitre of semen. A **negative result** indicates that the concentration is below the 15 million sperm per millilitre threshold, and that further testing by your doctor might be warranted.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not ingest.
- Keep out of children's reach.
- Do not use after the expiration date printed on the package.
- Do not use if the product seal is broken.
- Do not use this test kit with any samples other than those mentioned in the **Instructions for Use**.
- Poor vision and/or improper lighting may affect interpretation of the results.
- This test is intended for single use only. DO NOT RE-USE.
- Package contents may be disposed of in normal household waste after use.
- All package contents are non-toxic and safe when used as directed. However, irritation may occur if the Sperm OK Solution contacts the eyes. If this happens, flush eyes thoroughly with water.

STORAGE AND STABILITY

- Test device in an unopened sealed pouch can be stored in a dry place between 2°C - 30°C (36°F - 86°F) for up to the expiration date.
- Do not freeze the test device and package contents.
- Keep the test device and package contents away from direct sunlight, heat and moisture.

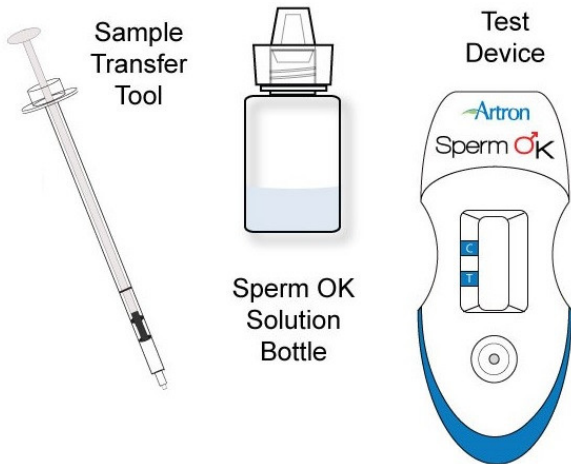
LIMITATIONS

- This test does not protect against sexually transmitted diseases.
- This test cannot be used to prove paternity.
- This test cannot be used as a method of birth control.
- This test assesses sperm concentration only. It does not detect other factors affecting male fertility.
- As with all diagnostic tests, a definitive diagnosis should not be based on the result of a single test, but should only be made by your physician after all clinical and laboratory findings have been evaluated.

- Not seeing a Test line in the results window indicates that your sperm concentration is less than 15 million per millilitre. However, a negative Sperm OK test result alone does not prove infertility. It is still possible to be fertile while having a sperm concentration below 15 million per millilitre. Please consult with your physician about further semen analysis.

PACKAGE CONTENTS

Along with these instructions, your Sperm OK Male Fertility Test kit also contains one of each of the following items:



In the case of missing or damaged items, please return the kit to your place of purchase or contact our customer service Monday to Friday from 9:00 AM to 5:00 PM PST at +1 604-415-9757.

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Sample Collection Cup
- Timer or watch

TEST PROCEDURE

For accurate results, you must follow the instructions for each step.

- Read and understand the entire instruction pamphlet.
- Check the package contents to ensure you have everything required.

Please adhere to the following steps:

1. Collect a semen sample between 48 hours and seven (7) days after your last ejaculation.
2. Carry out the test.
3. Read and interpret the result.

Contact our customer service Monday to Friday from 9:00 AM to 5:00 PM PST at +1 604-415-9757 or call your doctor if you are unsure of the meaning of your test result.

STEP 1: COLLECT YOUR SEMEN SAMPLE

Before collecting your semen sample, wait at least 48 hours, but no more than 7 days after your last ejaculation. Use manual stimulation (masturbation) to obtain your semen sample. Do not use any lubricants or lotions. Do not use a condom to collect the sample as this may interfere with the test result. Collect the sample in the Sample Collection Cup provided. Please follow the following procedures to accurately collect your semen sample:

1. Using the Sample Collection Cup, ejaculate directly into the cup. For accuracy of the test results, it is important to collect all the ejaculate without losing any portions. If some of the semen is lost, discard the sample, thoroughly rinse the cup with tap water only, and let it air dry before using it again. Do not use soap, detergent or other cleaning products to wash the cup. Wait for a minimum of 48 hours to a maximum of 7 days from your last ejaculation to collect a new sample for testing.
2. Once you have collected the semen sample, let the Sample Collection Cup stand upright on a flat surface for at least 20 minutes, but no more than 3 hours. This time period allows your semen sample to thin, as the semen sample is too thick to be tested immediately after collection.
3. When you are ready to test your semen, follow the instructions in the next step. The test should be conducted within 3 hours after sample collection.

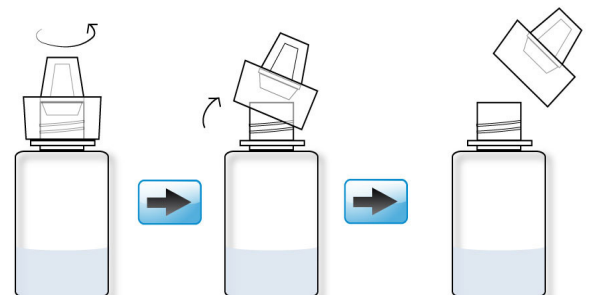
STEP 2: CARRY OUT THE TEST

Before starting the test, have all test components laid out on a flat surface within easy reach. Have a watch or timer ready as well.

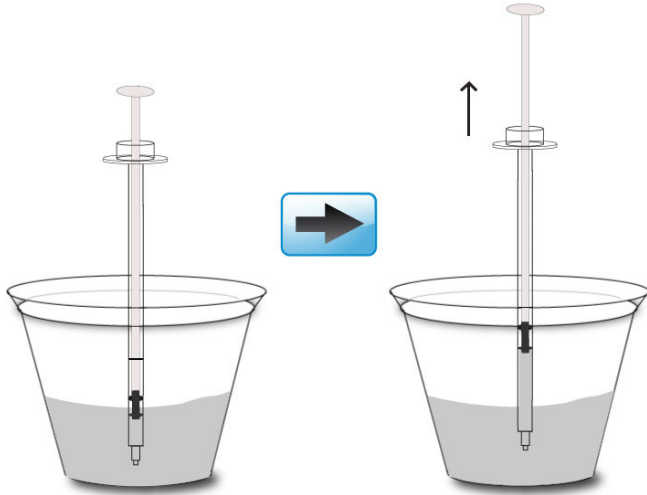
NOTE: When handling the white Sperm OK Solution Bottle, do not apply pressure to avoid squeezing out any solution.

1. Gently stir the semen sample with the Sample Transfer Tool in the Sample Collection Cup about 10 times until it is well mixed.

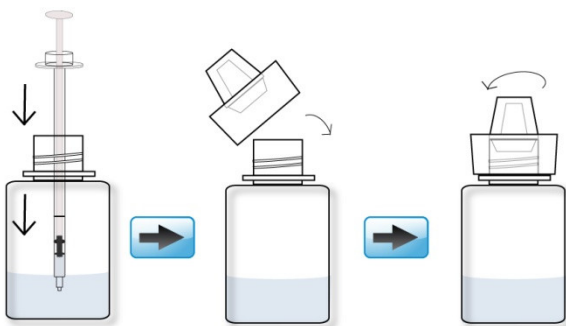
2. Completely unscrew the transparent cap on the Sperm OK Solution Bottle. Carefully **snap off** the transparent cap with the white tip in it from the bottle, ensuring that the white tip comes off with the transparent cap.



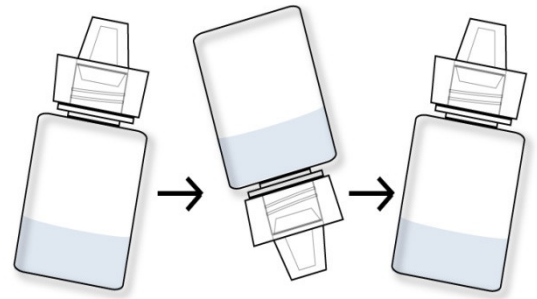
- Place the Sample Transfer Tool into the Sample Collection Cup and slowly pull up the plunger to draw the semen sample up to the black line indicated on the Sample Transfer Tool. Avoid drawing any solid or sticky material within the semen, and do not get any air bubbles into the Sample Transfer Tool. If either of these occurs, push out all the semen back into the Sample Collection Cup and redraw. Make sure the semen sample is drawn exactly to the black line, as this is crucial to the accuracy of the test result. If necessary, add or remove semen sample until you obtain the amount indicated by the black line.



- Insert the Sample Transfer Tool into the Sperm OK Solution Bottle and transfer the entire semen sample by gently pushing the plunger down. Make sure all the semen is transferred out of the Sample Transfer Tool and into the Sperm OK Solution Bottle. Securely tighten the transparent cap along with the white tip back onto the Sperm OK Solution Bottle.

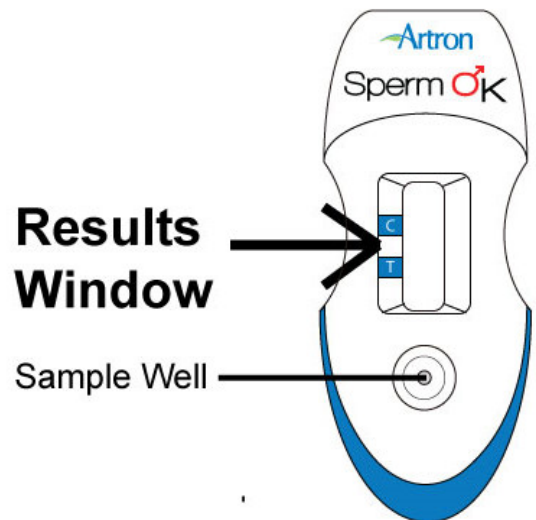


- Thoroughly mix the contents of the Sperm OK Solution Bottle by gently inverting the bottle at least five (5) to ten (10) times. If your semen is very thick or viscous, you should mix it an additional ten (10) times. Avoid vigorously shaking the Sperm OK Solution Bottle as this will create foam which may make further procedures more difficult.

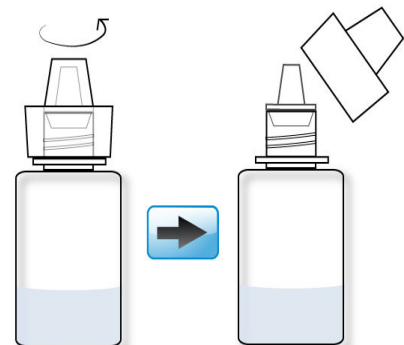


- Carefully place the Sperm OK Solution Bottle containing the semen-solution mixture upright on a flat surface. Let it stand for two (2) minutes before proceeding.

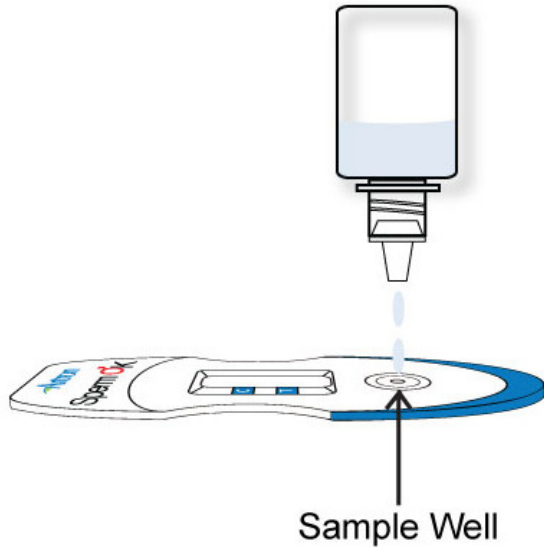
- Open the sealed pouch that contains the testing device by tearing at the notch. Remove the testing device from the pouch. Place the testing device face up on a flat surface. Do not touch the results window of the test device.



- Remove the transparent cap from the Sperm OK Solution Bottle, leaving the white tip still securely attached to the bottle.



9. Hold the Sperm OK Solution Bottle vertically above the sample well on the testing device. Gently squeeze the bottle to add three (3) full drops of the semen-solution mixture into the sample well. Make sure there are no air bubbles.



10. After you have added three (3) drops of the solution into the sample well, begin timing for five (5) to ten (10) minutes.

11. Once the five (5) to ten (10) minutes are up, read the results. Interpret results as shown under the next section, "Step 3: Interpret the Results".

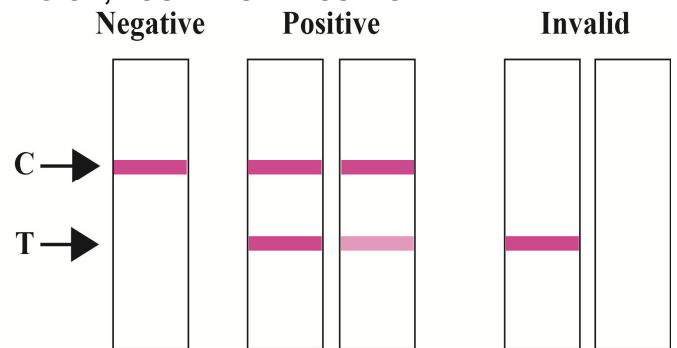


DO NOT INTERPRET RESULTS AFTER TEN (10) MINUTES.

STEP 3: INTERPRET THE RESULTS

PLEASE NOTE: When reading your test results, you only need to determine whether or not a line is present at the Control (C) and Test (T) regions on the testing device. **YOU DO NOT NEED TO COMPARE THE TEST LINE TO THE CONTROL LINE.** The strength (darkness) of either line does not matter. To read your results accurately, simply determine whether there is a Test line and a Control line present. Your test result will always be positive if there is a Test line and Control line present, even if the Test line is very faint compared to the Control line.

Make sure you are in a well-lit area so that your test result is clearly visible. To start, check the Control region (marked "C") to see if there is a Control line present. You should see a pink coloured line representing the Control line. **IF YOU DO NOT SEE A LINE AT THE CONTROL REGION, YOUR TEST RESULTS ARE INVALID.**



- **NO TEST LINE PRESENT at Test region (T) and only a pink colored line appears at the Control region (C)**

This indicates a **NEGATIVE** result, meaning your sperm concentration is below 15 million sperm per millilitre. A sperm concentration below 15 million sperm per millilitre indicates the possibility of infertility. However, the result of this test alone does not prove infertility, as there are other factors affecting fertility. Further testing by your physician may be warranted. The Sperm OK threshold value (15 million sperm per millilitre) is based on a 2010 publication on sperm analysis by the World Health Organization.

- **TEST LINE PRESENT at Test region (T) and a pink coloured line appears at the Control region (C)**

This indicates a **POSITIVE** result, meaning your sperm concentration is at least 15 million sperm per millilitre. A sperm concentration of at least 15 million sperm per millilitre indicates the possibility of fertility. However, a positive result does not always prove fertility, as there are other factors affecting fertility. If you received a positive test result, but you and your partner have been unable to conceive, you should see your physician for further testing.

- **NO CONTROL LINE PRESENT**

If there is no visible line at the Control region (C), this indicates an invalid result. Your test either did not run correctly and/or there was an error in your procedures. Consider repeating the test with a new Sperm OK test kit. If the test still fails, please contact the distributor with the test kit lot number.

REASONS FOR ERRONEOUS RESULTS

- The entire ejaculate was not collected – especially the first drops of the ejaculate.
- The ejaculate did not liquefy.
- The semen in the Sample Collection Cup was not mixed well enough before it was added to the Sperm OK Solution Bottle.
- Too much or too little semen was added to the Sperm OK Solution Bottle with the sample transfer tool.
- The semen-solution mixture was added too soon to the test device. The semen-solution mixture should stand for two (2) minutes after the addition of the semen sample to the Sperm OK Solution Bottle.
- Air bubbles were drawn into the Sample Transfer Tool during the transfer of semen sample from the Sample Collection Cup to the Sperm OK Solution Bottle.
- The semen-solution mixture in the Sperm OK Solution Bottle was not mixed well enough before it was added to the test device.
- Too little or too much semen-solution mixture was added to the sample well. Exactly three (3) drops from the Sperm OK Solution Bottle must be added to the sample well.
- The semen-solution mixture was added to the results window instead of the sample well. The sample well is a round opening on the test device.
- The test was read too early or too late. The test result must be read within five (5) to ten (10) minutes after the semen-solution mixture was added to the sample well.
- Poor vision, colour blindness or poor lighting may hinder your ability to correctly interpret the result.
- The semen sample was collected less than 48 hours or more than seven (7) days after your last ejaculation. This may lead to inaccurate results.

PERFORMANCE CHARACTERISTICS

The analytical sensitivity of Artron Sperm OK Male Fertility Test is the sperm concentration of 15 million sperm per millilitre ($15 \times 10^6/\text{ml}$).

FREQUENTLY ASKED QUESTIONS

1. How accurate is the Sperm OK Male Fertility Test?

Our clinical studies found the results for the Sperm OK Male Fertility Test to be over 95% agreement when compared to laboratory testing.

2. What does it mean when I have a negative test result?

A negative test result indicates that your sperm concentration is below 15 million sperm per millilitre and indicates higher possibility of infertility. Note that this result alone cannot prove that you are infertile. Sperm concentrations vary from day to day, thus it is possible for you to perform the test on another day and receive a positive result. However, we recommend that you consult with your physician for further semen analysis to get a more accurate

diagnosis of your sperm concentration levels. Other factors affecting your fertility status may also be present.

3. What does it mean when I have a positive result?

A positive result indicates that your sperm concentration is at least 15 million sperm per millilitre and indicates a higher possibility of fertility. Note that this result alone cannot prove that you are fertile as there are other factors affecting male fertility. If you and your partner have been unable to conceive even after receiving a positive Sperm OK test result, we recommend that both you and your partner consult a physician for further fertility evaluations.

4. Can I still perform the test if my semen sample did not become a thin liquid after twenty (20) minutes?

Yes. The rate and consistency at which some semen samples liquefy may differ for different individuals. Thus, you may let your semen sample stand for up to three (3) hours to allow it to become more liquid. Keeping the semen sample near body temperature can also help it liquefy. DO NOT MICROWAVE. The test device may still give an accurate result even if your sample does not completely liquefy. It is crucial that you let your semen sample stand for at least twenty (20) minutes, and then mix it as directed in “Step 2: Carry Out the Test”. Be sure to avoid any solid material when adding the semen sample to the Sperm OK Solution Bottle. The most liquefied part of the semen should be drawn into the Sample Transfer Tool.

If your semen sample did not liquefy or ended up clogging the Sample Transfer Tool, please consult with your physician and discard your semen sample and perform the test again after 48 hours, but no more than seven (7) days from your last ejaculation. Rinse the Sample Collection Cup and Sample Transfer Tool with tap water only and allow them both to air dry before using them again. Do not use soap, detergent or other cleaning products to wash the Sample Collection Cup or Sample Transfer Tool.

5. The Test line at the Test region (T) was not visible when I looked at it within the five (5) to ten (10) minute time frame. It became visible afterwards, though. Does this mean my test result is actually a positive?

No. The correct test result will appear within the five (5) to ten (10) minute time frame after the semen-solution mixture was added to the sample well. Thus, it is crucial that you read your result between those times. Any interpretation of the result before or after the five (5) to ten (10) minute time frame may give you an incorrect result.













6. What else may cause errors in the test result?

Aside from the reasons listed under the “Reasons for Erroneous Results” section, performing the test during physical illness can temporarily reduce sperm concentration. Therefore, this test should not be conducted if you are currently ill or have recently been ill. Medical conditions, use of illegal substances or prescriptions may also interfere with the result.

REFERENCES

1. National Institute for Health and Care Excellence, *NICE: Fertility: assessment and treatment for people with fertility problems. NICE CLinical Guidelines. 2013:274–.*
2. WHO: *Examination and Processing of Human Semen. Volume Edition, F; 2010:286.*
3. Cooper TG, Noonan E, von Eckardstein S, Auger J, Baker HWG, Behre HM, Haugen TB, Kruger T, Wang C, Mbizvo MT, Vogelsong KM: **World Health Organization reference values for human semen characteristics.** *Hum Reprod Update 2010, 16:231–45.*
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5. Dhar NB, Bhatt A, Jones JS: **Determining the success of vasectomy.** *BJU Int 2006, 97:773–6.*

INDEX OF SYMBOLS

 Do not reuse	 Batch code
 In vitro diagnostic medical device	 Use by
 Temperature limitation	 Contains sufficient for < n > tests
 Caution	 Catalog number
 Manufacturer	 Consult instructions for use
 Authorized representative in the European community	 CE Mark

CONTACT INFORMATION



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