

HEALTH-CHEM DIAGNOSTICS LLC

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MALE FERTILITY TEST

HOME DIAGNOSTIC SCREENING TEST FOR MALE INFERTILITY

INDICATIONS FOR USE:

The Male Fertility Home Diagnostic Screening Test for male infertility is a rapid test of your semen for sperm concentration; it will measure sperm as either above or below the cutoff of 20 million sperm cells per milliliter (mL). Two test results of less than 20 million cells/mL may indicate male infertility.*

*This concentration value has been recommended by the World Health Organization (WHO).

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INSTRUCTIONS AND USE

- Please read all the information in this leaflet before performing the test.
- Color blindness and improper lighting may affect interpretation of test results.
- This kit will perform two tests. Perform both tests 3-7 days apart to obtain final result.
- This kit is intended for one user only.
- Please allow 3 days since your last ejaculation before using this test kit.
- Do not use after the expiration date stamped on the side of the box.
- Store in a dry place below 86°F (30°C). Do not freeze.
- Keep out of reach of children.

- This kit cannot be used for contraception.
- This kit does not protect against sexually transmitted diseases (e.g. HIV).
- For in-vitro diagnostic use only. For external use only.

HOW THE MALE FERTILITY HOME DIAGNOSTIC SCREENING TEST WORKS

The Male Fertility Home Diagnostic Screening Test is an easy-to-use screening test to measure your sperm concentration. It determines whether your sperm concentration is above or below 20 million sperm cells per milliliter (million/mL). Two test results with sperm concentration less than 20 million/mL may indicate male infertility.*

The Male Fertility Home Diagnostic Screening Test works by staining cells in the sperm sample to produce a color. The intensity of this color is then compared to a color reference on the Male Fertility test cassette. The color comparison will tell you whether the sperm concentration in the test sample is above 20 million/mL (positive test) or below 20 million/mL (negative test).

The Male Fertility Home Diagnostic Screening Test should be performed on at least two separate semen samples. The second sample should be collected and tested at least 3 days, but not more than 7 days, after the first test was performed.

The Male Fertility Home Diagnostic Screening Test contains everything you need to collect and test two separate semen samples.

Sperm concentration is one of the factors used by physicians to help determine male infertility. However, since many additional factors play a role in male infertility, a positive test is not a guarantee of fertility.

Note: *This concentration value has been recommended by the World Health Organization (WHO).

There are many reasons why a man may be infertile, that is, unable to father a child. One important reason is a low amount of sperm in semen. Other reasons could be inactive or incompletely formed sperm cells, high levels of other cells in the semen that interfere with fertilization, or other factors. Medical or physical conditions may also interfere, including stress, high fever experienced within two months prior to testing, exercise, traveling and changes in your diet. Your physician can best explain these conditions and other factors to you.

Taking this screening test will indicate if you have a low amount of sperm in your semen. You can provide these test results to your physician to aid in determining whether you are infertile.

IMPORTANT FACTS ABOUT SEMEN COLLECTION AND PREPARATION

When to Collect Your Semen:

You must wait three days after your last ejaculation before you collect a sample for testing

How to Collect Your Semen:

Your semen may be collected in one of three ways:

- 1) by masturbation, directly into the Liquefaction Cup;
- 2) by masturbation, using the supplied condom; or
- 3) during intercourse using one of the supplied condoms to collect semen.

Semen Sample Preparation:

Freshly ejaculated semen is gel-like in consistency. Over time (normally one hour or longer), the sample thins to a liquid consistency. Only semen that is thinned (liquefied) should be used for testing with the Male Fertility Home Diagnostic Screening Test Kit.

The kit contains one Liquefaction Cup to make the semen liquefy faster. The semen sample must be added to the Liquefaction Cup at least 15 minutes before testing starts. You may store the semen sample in the Liquefaction Cup, covered, for up to 12 hours before beginning the test. If the semen sample is not liquefied, the test results may be incorrect. If the semen sample has not been tested within twelve hours, discard the sample, wait 3 days more and obtain a fresh semen sample.

THE MALE FERTILITY HOME DIAGNOSTIC SCREENING TEST CONTENTS

Each Male Fertility Home Diagnostic Screening Test Kit contains enough products to perform two tests. You should find the following items:

1. Instruction Leaflet
2. Two Condoms
3. Two Liquefaction Cups with Lids

In a resealable foil pouch:

4. Two Pipettes
5. Blue Solution
6. Clear Solution
7. Two Test Cassettes



Also have on hand: a clock or timer to do this test. All kit materials are safe and non-toxic. If any of the contents are missing, return the kit to place of purchase or contact our Hotline for technical assistance at 800-482-2907

IMPORTANT: Use only the condoms provided in the kit. Do not substitute store bought condoms. Many condoms contain spermicides or lubricants that can affect test results.

THE MALE FERTILITY TEST CASSETTE



Test Well

Reference Well

The Male Fertility Test Cassette contains 2 cassettes to test 2 separate semen samples.

The Reference Wells are blue in color. You will compare your test results to the blue color in these Reference Wells.

The Test Wells are white in color. These are the two test wells where you will place your liquefied semen sample.

DIRECTIONS FOR PERFORMING THE TEST: Read ALL the Instructions before You Begin the Test

- Wash hands before and after test
- Do not open foil pouch until ready to begin test
- If you make a mistake using the Test Well in the first cassette, please restart test and use the Test Well in the second cassette (See question #6 on page 9 in the section entitled Commonly Asked Questions)

Collect Semen



1. Semen may be collected in one of three ways. (See How to Collect Your Semen)



2. Put semen in the Liquefaction Cup. Avoid touching the inside of the Liquefaction Cup. Place the lid on the Liquefaction Cup and swirl gently at least 10 times. Wait at least 15 minutes but not longer than 12 hours to begin testing. Swirl the Liquefaction Cup before you begin testing.

NOTE: Liquefaction Cup may contain small flakes. DO NOT REMOVE FLAKES. Flakes will be absorbed by the semen and will help liquefy the sample.

(Tear foil pouch at notch)



3. Open resealable, foil pouch by tearing or cutting at notches. Place one of the Male Fertility cassettes on a flat surface with the test wells facing up and the blue **Reference Well** to the right.

(Place cassette on a flat surface)





- Swirl Liquefaction Cup before removing lid. Hold and squeeze the plastic dropper at its midpoint. Place the angled tip into the semen sample and release the pressure slowly. Semen will be drawn up into the dropper.



- By gently squeezing the dropper, add **ONE** drop of **SEMEN** to the **White Test Well**. Let the drop soak in for at least one minute.

NOTE: It usually takes just seconds for either the semen or solutions to drain through the filter. If it takes longer than 5 minutes for any of the drops to drain, the semen may not have adequately liquefied and the sample is too viscous. Repeat the test using a new semen sample.

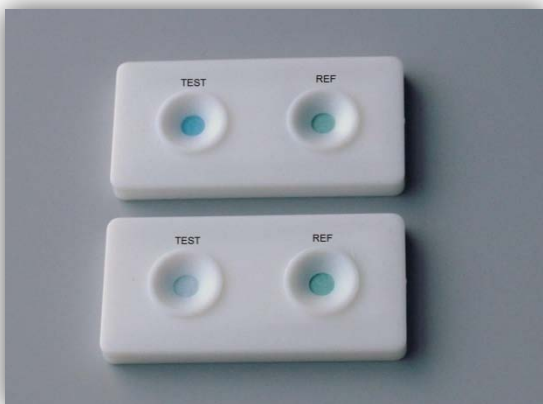


- Add **TWO** drops of **BLUE** solution to the white **Test Well**. Let the drops soak in for at least one minute.



- Add **TWO** drops of **CLEAR** solution to the same **Test Well**, as above, which now has a blue color. Let the drops soak in for at least one minute. Read results within 5 minutes according to step 8.

- Reading the Color Change:** Compare the color in the Test Well to the color in the Reference Well.



Positive Test: A blue color as dark or darker than the reference color is positive (sperm concentration is equal to or above 20 million / mL).

Negative Test: A blue color lighter than the reference color is negative (sperm concentration is less than 20 million/mL).

Record your results on Test Results Form on the last page of this instruction booklet.

Note: If no color appears, you may have made an error in adding the Sample or Solutions. Use the second cassette, or obtain another kit if both test wells on the cassettes have been used, and repeat the test.



9. After completing the first test, return the solution bottles to the foil pouch and seal the pouch. Dispose of the used Liquefaction Cup and dropper. Second Test: Repeat test at least 3 days but not more than 7 days after first test,

Note: When performing the second test, you will be comparing the blue color in second cassette's Test Well to the blue color in its Reference Well.



10. Follow complete instructions, Steps 1-8, using the second cassette's Test Well and Reference Well.

INTERPRETING TEST RESULTS FROM BOTH TESTS

The results of the second test (performed 3-7 days after the first test) should be the same as the first test. If the results are not the same, wait 10 weeks and repeat the two tests with a new Male Fertility Home Diagnostic Screening Test Kit for Male Infertility. Once you have your test results, consult your physician.

First Test	Second Test	Interpretation
Positive	Positive	Sperm concentration is equal to or greater than 20 million/mL
Negative	Negative	Sperm concentration is less than 20 million/mL See your physician
Positive	Negative	Retest in 10 weeks and consult your physician
Negative	Positive	Retest in 10 weeks and consult your physician

ACCURACY OF TEST

Semen samples of 194 males were separately measured for sperm concentration by both home users and professionals. 87% of the results coincided between home users and professionals.

- Home users got the same results as professionals 141 out of 158 times when they reported positive results (sperm concentration equal to or more than 20 million/mL).
- Home users got the same results as professionals 27 out of 36 times when they reported negative results (sperm concentration less than 20 million/mL).

Overall accuracy of the test results is 78%. This means that 78% of the time, home users will be correct in either a positive or negative reading. Performing two tests and obtaining the same result each time (either positive or negative) will provide greater assurance of accurate results.

COMMON QUESTIONS WITH ANSWERS ABOUT THE MALE FERTILITY HOME DIAGNOSTIC SCREENING TEST

Q1- *I am aware that there are many factors other than sperm concentration in male infertility, so why should I buy this kit?*

- A1- The Male Fertility Home Diagnostic Screening Test Kit offers privacy and helps you to avoid the embarrassment of masturbation at the doctor's office. In addition, concentration is one of the most critical determinants of male infertility, as defined by the World Health Organization. As a screening test, it offers useful information to both yourself and your physician to help diagnose male infertility. In comparison, ovulation tests (that measure hormonal surges) do not necessarily guarantee fertility either, yet the test is a very useful indicator.
- Q2- *How should the semen sample be collected? Is collection directly into the liquefaction cup or use of one of the condoms provided with the kit equally effective?*
- A2- We recommend either method. If one of the condoms provided with the kit is used, squeeze all the semen collected into the Liquefaction Cup. If semen is collected directly into the Liquefaction Cup, care must be taken to conserve all of the semen sample for the test.
- Q3- *Why wait at least 15 minutes but not longer than 12 hours after adding the semen to the Liquefaction Cup to start the test?*
- A3- Semen is very thick (gel-like) and normally takes 30 to 60 minutes to thin (liquefy). Using the specially treated Liquefaction Cup provided with the kit, the semen sample should liquefy within 15 minutes. Waiting up to 12 hours before starting the test is acceptable. Keep the provided lid on the Liquefaction Cup and swirl the contents before beginning the test.
- Q4- *There are small flakes at the bottom of the Liquefaction Cup. Should I still use the cup?*
- A4 - Yes. This flaking may occur due to normal shipping and handling. Do not remove these flakes. When the sample is added to the Liquefaction Cup, the flakes are absorbed and help to liquefy the sample.
- Q5- *Does it really matter how much semen or solution is added to the Test Well?*
- A5- Yes. Add only the number of drops specified in the instructions.
- Q6- *I made a mistake while using the Test Well of the first cassette. What should I do?*
- A6- Restart the test using the Test Well of the second cassette in the pouch. After completing the test and reading the results, discard the cassette. Since you used both Test Wells for the first sample, you will not be able to use the same cassette for testing a second sample. Obtain a new test kit and test a second sample 3-7 days after the first sample was tested or consult your physician. Your physician may perform a second sperm count in the office.
- Q7- *A blue color appeared after adding the Blue dye solution to the Test Well, but before the Clear wash solution was added. Does this mean that the test is positive?*
- A7- Not necessarily. Complete the test using the Clear solution before comparing the color in the Test Well to the Reference color.
- Q8- *How long should it take for the semen or solutions to drain through the filter?*
- A8- It usually takes just seconds for either the semen or solutions to drain through the filter. If it takes longer than 5 minutes for any of the drops to drain, the semen may not have adequately liquefied and the sample is too viscous. Repeat the test using a new semen sample.
- Q9- *How long should I wait between tests?*
- A9- You should wait at least 3 days after ejaculating before you collect semen for testing. For best results, you should wait at least three days and no more than 7 days between tests.
- Q10- *Do two positive test results indicate that I am fertile?*
- A10- Not necessarily. Besides low sperm concentration, there are other causes of infertility. Infertility could be due to high semen viscosity, a low semen volume, a high percentage of immotile sperm, presence of leukocytes in semen, antisperm antibodies, etc. Therefore, test results should be interpreted by your physician.
- Q11- *Do two negative tests indicate that I am infertile?*
- A11- Not necessarily. A low sperm concentration may be an indicator of infertility, but may also be due to a temporary or more long lasting medical condition or physical factor that does not cause infertility even if your sperm concentration is low. You should consult your physician if you obtain two negative results.
- Q12- *I ran two tests six days apart and got one positive and one negative result. Why do I need to wait 10 weeks to repeat the test (see interpreting Results)?*
- A12- Since waves of sperm are produced every 70 days, waiting 10 weeks allows time for a new batch of sperm to be produced before retesting. Sperm production is influenced by physical, emotional and psychological factors, such as the concentration of hormones in the blood, stress, high fever, exercise, traveling, surgery, medication and changes in the diet. These factors may result in a decreased sperm concentration. By waiting 10 weeks, you will test a new batch of sperm and reduce the chance that the results of both test series are affected by these factors.
- Q13- *Are the solutions safe?*
- A13- Yes. However, kit solutions should be handled with care and disposed of promptly after the kit has been used for the two semen tests.
- Q14- *What could cause errors in test results?*
- A14- It is important to follow the test procedure instructions to ensure an accurate result (see Q6 above if you suspect you made an error using the Test Well of the first cassette). Also, improper collection or handling of the semen sample may cause errors. It is especially important that the semen remains in the Liquefaction

Cup for at least 15 minutes prior to testing; otherwise, it may not drain through the filter. Some semen samples may not liquefy properly, even though you have followed all the instructions. This is a condition of the semen called 'high viscosity' and should be discussed with your physician.

A15- Certain medication may affect sperm concentration and viscosity. This possibility should be discussed with your physician.

If you still have questions after reading this brochure about the Male Fertility Home Diagnostic Screening Test, please call our HOTLINE for technical assistance at 800-482-2907.

Q15- Does medication affect test results?

MALE FERTILITY HOME DIAGNOSTIC SCREENING TEST RESULTS FORM



TEST WELL

REFERENCE WELL

Fill out this form completely for each test. If you decide to consult a physician after testing, you should bring this form.

Name: _____

Test 1:

Date of First Test: _____

Check Appropriate Box:

Positive: Color in the Test Well is equal to or darker than the Reference Color.

Negative: Color in the Test Well is lighter than the Reference Color.

Test 2:

Date of Second Test: _____

Check Appropriate Box:

Positive: Color in the Test Well is equal to or darker than the Reference Color.

Negative: Color in the Test Well is lighter than the Reference Color.

Note to Physicians:

A positive test indicates a sperm concentration of 20 million/mL or greater. A negative test indicates a sperm concentration of less than 20 million/mL. Time span between tests should be 3-7 days. Ejaculation should not occur within three days of testing.

Manufactured in the USA by:
HEALTH-CHEM DIAGNOSTICS LLC,
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