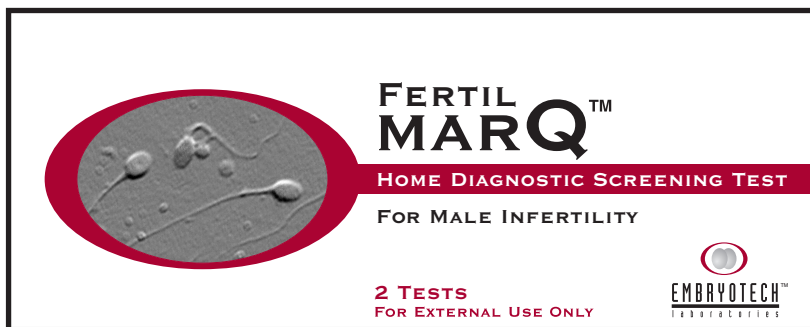


FERTIL MARQ™

**Home Diagnostic Screening Test
for Male Infertility**



Indications for Use:

The FertilMARQ™ 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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FertilMARO Home Diagnostic Screening Test Instructions
10-Sep-2001

Patents Issued: U.S. Patents 5,895,749 and 5,935,800

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 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 FertilMARQ™ Home Diagnostic Screening Test Works

The FertilMARQ™ 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 FertilMARQ™ Home Diagnostic Screening Test works by staining the cells in the sperm sample to produce a color. The intensity of this color is then compared to a color reference on the FertilMARQ™ test cassette (see Test Kit Contents on page 7). 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 FertilMARQ™ 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 FertilMARQ™ 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.

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

How the FertilMARQ™ Home Diagnostic Screening Test Works (continued)

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 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 sample 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.

IMPORTANT: Only the condoms provided with the kit should be used to collect semen. Other types of condoms could affect test results.

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 FertilMARO™ Home Diagnostic Screening Test Kit.

The kit contains two Liquefaction Cups (see Test Kit Contents on page 7) to make the semen liquefy faster. The semen sample must be added to the Liquefaction Cup for at least 15 minutes before testing starts. You may store the semen sample in the Liquefaction Cup for up to 12 hours before you begin testing.

If the semen sample is not liquefied, the test results may be incorrect. If the semen sample has not been tested within 12 hours, discard the sample, wait 3 days or more, and obtain a fresh semen sample.

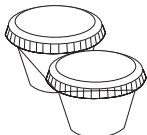
The FertilMARQ™ Home Diagnostic Screening Test Kit Contents



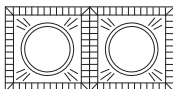
One FertilMARQ™ Test Cassette



One Bottle Blue Solution
One Bottle Clear Solution



Two Liquefaction
Cups



Two Non-spermicidal
Condoms



Two Plastic Droppers

When you open the FertilMARQ™ Home Diagnostic Screening Test Kit, you should find the following items:

One Resealable Foil Pouch containing:

- One FertilMARQ™ Test Cassette
- One Bottle of Blue Solution
- One Bottle of Clear Solution
- Two Plastic Droppers

Two Liquefaction Cups with lids

Two Non-spermicidal Condoms

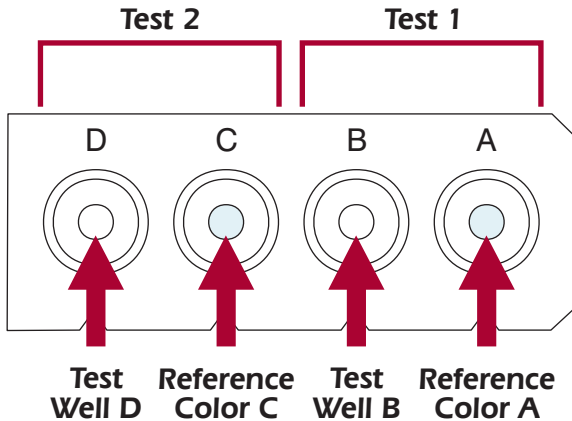
Also have on hand: a clock or a timer to do this test.

All kit materials are non-toxic. If you touch or spill either solution, wipe up with a damp cloth. Discard in regular trash.

If any of the contents are missing, return the kit to the store or contact our Hotline for technical assistance at 800-720-3055, Monday through Friday, 8:00 a.m. to 8:00 p.m EST.

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 FertilMARQ™ Test Cassette



The FertilMARQ™ Test Cassette contains 4 wells labeled A, B, C and D.

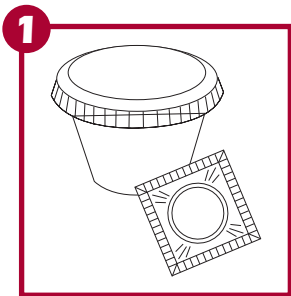
Reference Wells A and C are blue in color. You will compare your test results to the blue color in these Reference Wells.

Test Wells B and D are white in color. These are the two test wells where you place your liquefied semen sample.

The cassette contains enough wells to test 2 separate semen samples.

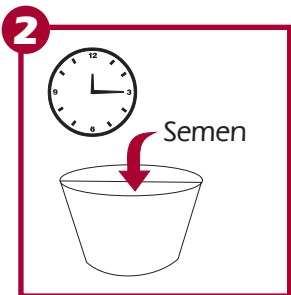
Directions for Performing the Test: Read ALL Instructions before You Begin the Test

- Wash hands before and after using the test.
- Do not open foil pouch until ready to begin testing.
- Add the semen sample only into a white Test well (B or D).
- If the sample or solutions take more than 5 minutes to drain through wells, the test is invalid.
- If you make a mistake using Test Well B, please see Q6 on page 15 in the Common Questions with Answers section.



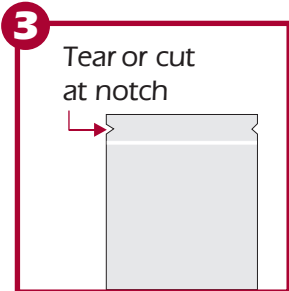
Collect Semen

Semen may be collected by masturbation directly into the Liquefaction Cup or using the provided condom. Semen may also be collected by using the condom during intercourse. (See Important Facts About Semen Collection on page 6) Avoid touching the inside of the Liquefaction Cup.



If a condom was used to collect your semen, transfer the semen from the condom to the Liquefaction Cup. Place the lid on the Liquefaction Cup and swirl gently at least 10 times.

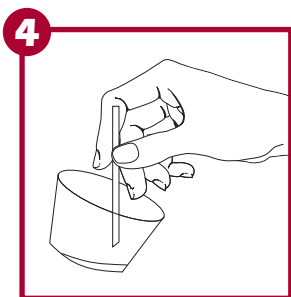
Wait at least 15 minutes but not longer than 12 hours to begin testing. Swirl the Liquefaction Cup before you begin testing.



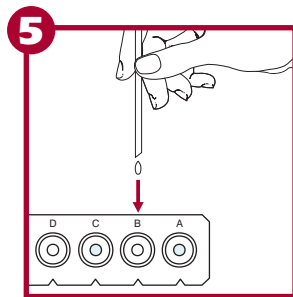
Open resealable, foil pouch by tearing or cutting at notches.

Remove contents.

Place the FertilMARO™ cassette on a flat surface with the wells facing up.

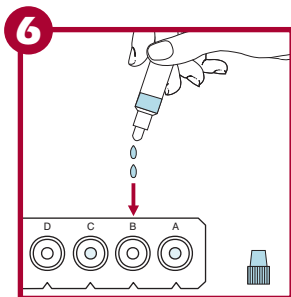


Swirl Liquefaction Cup before removing lid. Hold and squeeze the plastic dropper at its midpoint. Place the angled tip into the semen sample and release the pressure slowly. Semen will be drawn up into the dropper.



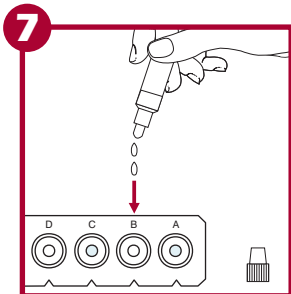
By gently squeezing the dropper, add **ONE** drop of SEMEN to the **Test Well B**.

Let the drop soak in for at least one minute.



Add **TWO** drops of BLUE solution to **Test Well B**.

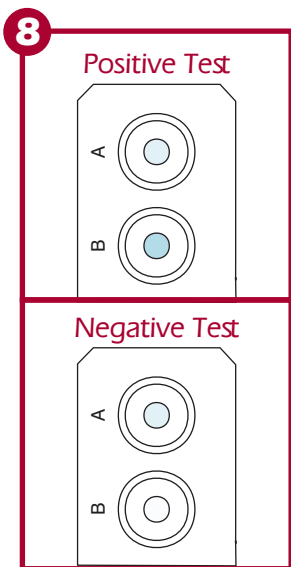
Let the drops soak in for at least one minute.



Add **TWO** drops of CLEAR solution to **Test Well B**.

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 B to the color in the Reference Well A.

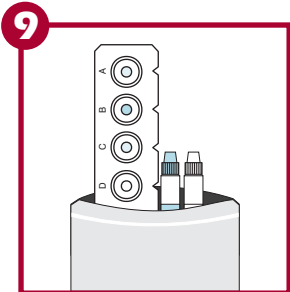
Positive Test: A blue color as dark or darker than the reference color is positive (sperm concentration is equal to or above 20 million/mL).

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

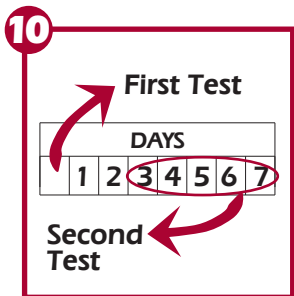
Record results on Test Results Form on page 19 of this instruction booklet.

Note: If performing the second test, you will be comparing the blue color in Test Well D to the blue color in Reference Well C.

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



After completing the first test, return the cassette and 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.

Follow complete instructions, Steps 1-8, using Test Well D and Reference Well C.

Disposal: After completion of second test, dispose of the entire kit in the regular trash.

Interpreting Test Results

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 FertilMARQ™ Home Diagnostic Screening Test Kit for Male Infertility.

Once you have your test results, consult your physician.

Interpreting Test Results (continued)

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 the 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 FertilMARO™ Home Diagnostic Screening Test

If you still have questions after reading the Common Questions and Answers about the FertilMARO™ Home Diagnostic Screening Test, please call our Hotline for technical assistance at 800-720-3055, Monday through Friday, 8:00 a.m. to 8:00 p.m EST.

- Q1** I am aware that there are many factors other than sperm concentration involved in male infertility, so why should I buy this kit?
- A1** The FertilMARO™ Home Diagnostic Screening Test Kit offers privacy and helps you avoid the embarrassment of masturbation at the doctors 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 B (or Test Well D)?
- A5 Yes. Add only the number of drops specified in the instructions.
- Q6 I made a mistake using Test Well B. What should I do?
- A6 Restart the test using Test Well D and Reference Well C. 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 (B or D) 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 liquified 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 3 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 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 on page 15 if you suspect you made an error using Test Well B). 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.

Q15 Does medication affect test results?

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

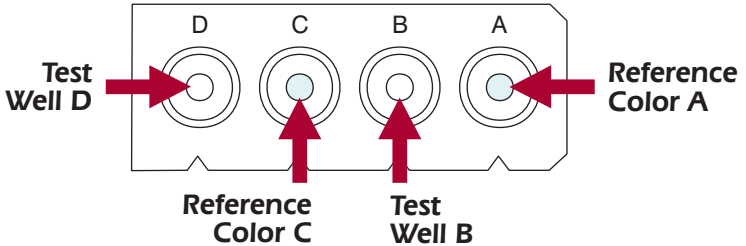


EMBRYOTECH™
l a b o r a t o r i e s

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FertilMARO™ Home Diagnostic Screening Test Results Form



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 Test Well B is equal to or darker than Reference Color A.
- Negative:** Color in Test Well B is lighter than Reference Color A.

TEST 2:

Date of Second Test: _____

Check appropriate box:

- Positive:** Color in Test Well D is equal to or darker than Reference Color C.
- Negative:** Color in Test Well D is lighter than Reference Color C.

Physicians: See note on reverse side



Note to physicians: A Positive test indicates a sperm concentration of 20 M/mL or greater. A Negative test indicates a sperm concentration of less than 20 M/mL. Time span between tests should be 3 to 7 days. Ejaculation should not occur within three days of testing.

FertilMARQ Home Diagnostic Screening Test Instructions
10-Sep-2001

Patents Issued: U.S. Patents 5,895,749 and 5,935,800



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