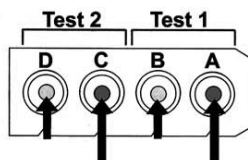


Home Diagnostic Screening Test for Male Infertility (FertiMARQ)

Package Insert Ref: BSMIT - English For Self Testing



Results Form

Fill out this form completely for each test. If you decide to consult a doctor after testing you should take this form.

Name: _____

TEST 1

Date of First Test: _____

Positive: Colour in Test Well B is equal to or darker than Reference Colour A.

Negative: Colour in Test Well B is lighter than Reference Colour A.

TEST 2

Date of Second Test: _____

Positive: Colour in Test Well D is equal to or darker than Reference Colour C.

Negative: Colour in Test Well D is lighter than Reference Colour C.

Note to doctor: A positive test result indicates a sperm concentration of 20million/ml or greater. A negative test result 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 before testing.

babystart™ products are manufactured by;

Med-Direct International Ltd,
Summit Point, Summit Crescent,
Smethwick, B66 1BT,
United Kingdom



Index of Symbols

	Attention, see instructions for use		Tests per kit		Manufacturer
	Store between 2-30°C		Use by		Do not reuse
	For in-vitro diagnostic use only		Lot Number		Catalog #

Version Number: bsmi04

Effective date: 2005-07-07

Indications for Use: The FertiMARQ Home Diagnostic Screening Test for Male Infertility is a rapid test of your semen for sperm concentration. It will measure sperm either as above or below the cut-off of 20 million sperm cells per millilitre (mL). Two test results of less than 20 million cells/mL are an indicator of male infertility.*

Instructions

Please read all the information in this leaflet before performing the test. Colour 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. For self-testing

How the FertiMARQ Test Works

The FertiMARQ 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 millilitre (millions/mL). Two test results with sperm concentration less than 20 million/mL may indicate male infertility.*

The FertiMARQ Test works by staining the cells in the sperm sample to produce a colour. The intensity of this colour is then compared to a colour reference on the FertiMARQ test cassette. The colour 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 FertiMARQ 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 FertiMARQ Test kit contains everything you need to collect and test two separate semen samples.

Sperm concentration is one of the factors used by doctors to help determine male infertility. However, since many additional factors play a role in male infertility, a positive test is also not a guarantee of fertility. 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 fertilisation, or other factors. Medical or physical conditions including stress, high fever experienced within two months prior to testing, exercise, travelling, and changes in diet. Your doctor 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 doctor to aid in determining whether you may be infertile.

Important Note When you use this kit there is a possibility that you may get false results. This is because you may make an error and also the kit is not 100% accurate. This is why it is important that you consult your doctor before making decisions of any medical relevance.

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

Facts about Semen Collection and Preparation

1) When to Collect Your Semen: You must wait three days after your last ejaculation before you collect a sample for testing.
2) How to Collect Your Semen: Your semen sample should be collected by masturbation, directly into the Liquefaction Cup provided.

Note: 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.

The kit contains two Liquefaction Cups 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.

Kit Contents

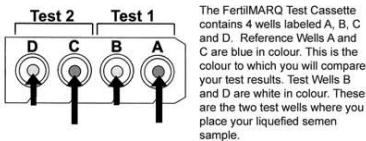
When you open the FertiMARQ Test Kit, you should find the following items:

One Foil Pouch containing:
One FertiMARQ Test Cassette
One Bottle of Blue Solution
One Bottle of Clear Solution
Two Plastic Droppers
Two Liquefaction Cups with lids

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 the normal waste. If any of the components are missing, return the kit to the supplier.

The FertiMARQ Test Cassette

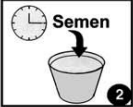


Directions for Performing the Test:

- Read ALL Instructions before You Begin the Test
- Wash hands before and after using 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 in the Questions and Answers section.



Collect Semen:
Semen should be collected by masturbation directly into the Liquefaction Cup provided. Avoid touching the inside of the Liquefaction Cup.



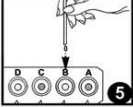
Place the lid on the Liquefaction Cup and swirl gently at least 10 times. Wait at least 15 minutes but not longer than 12 hours to begin testing. Swirl the Liquefaction Cup before you begin testing.



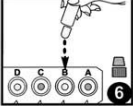
Open foil pouch by tearing or cutting at notches. Remove contents. Place the FertiMARQ cassette on a flat surface with the wells facing up.



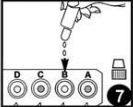
Swirl Liquefaction Cup before removing lid. Hold and squeeze the plastic dropper at its midpoint. Place the angled tip into the semen sample and release the pressure slowly. Semen will be drawn up into the dropper.



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.

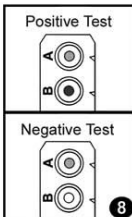


Add TWO drops of BLUE solution to Test Well B. Let the drops soak in for at least one minute.



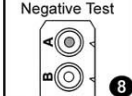
Add TWO drops of CLEAR solution to Test Well B. Let the drops soak in for at least one minute. Read results within 5 minutes.

Reading the Colour Change:



Compare the colour in the Test Well (B or D) to the colour in the Reference Well (A or C).

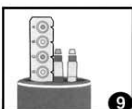
Positive Test: A blue colour as dark or darker than the Reference colour is positive (sperm concentration is equal to or above 20 million/mL).



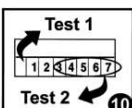
Negative Test: A blue colour lighter than the Reference colour is negative (sperm concentration is less than 20 million/mL).

Record results on Test Results Form at the back of this instruction sheet.

Note: If no colour 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 pouch. The blue solution is light sensitive and should not be left out of the pouch for prolonged periods. Dispose of the used Liquefaction Cup and dropper in the normal waste.



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 Liquefaction Cup.

Disposal: After completion of second test, dispose of the entire kit in the normal waste.

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 FertiMARQ Home Diagnostic Screening Test for Male Infertility.

First Test	Second Test	Interpretation
Positive	Positive	Sperm concentration is equal to or greater than 20 million per ml
Negative	Negative	Sperm concentration is less than 20 million per ml Consult your Doctor
Positive	Negative	Retest in 10 weeks and consult your doctor
Negative	Positive	Retest in 10 weeks and consult your doctor

Accuracy of the Test

Sixty four men attending a clinic, but not undergoing active treatment for diagnosed infertility, were asked use the test kit according to the instructions. They were also asked to bring the semen sample to the laboratory for estimation of sperm concentration by light microscopy. The light microscopy results showed that 49 men had sperm concentrations above 20 million per ml and 15 men had sperm concentrations below 20 million per ml.

Accuracy of the Test (contd)

15/15 men with low sperm counts correctly reported negative results with the test kit - showing a diagnostic specificity of 100%. 47/49 men with normal sperm counts correctly reported positive results with the test kit - showing a diagnostic sensitivity of 96%.

This study showed the overall accuracy of the test results is 97%, since 62/64 men in the study obtained the correct diagnostic result. Performing two tests and obtaining the same result each time (either positive or negative) will provide greater assurance of accurate results.

Questions and Answers

If you still have questions after reading the Questions and Answers about the FertiMARQ Test, please contact your supplier.

- 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 FertiMARQ Test Kit offers privacy and helps you 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 Organisation. As a screening test, it offers useful information to both yourself and your doctor 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?
- A2 We recommend semen is collected by masturbation 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 otherwise you may get false results.
- 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 doctor. Your doctor may perform more tests.

- Q7 A blue colour 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 colours in the Test and Reference Wells.
- 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 infertile?
- 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 doctor.
- 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 doctor if you obtain two negative results.
- Q12 Are the kit solutions safe?
- A12 Yes. However, kit solutions should be handled with care and disposed of promptly after the kit has been used.
- Q13 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?
- A13 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, travelling, 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.
- Q14 What could cause errors in test results?
- A14 It is important to follow the test procedure instructions to ensure an accurate result. Improper collection or handling of the semen sample may cause errors. It is especially important to leave the semen in the Liquefaction Cup for at least 15 minutes before 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 doctor.
- Q15 Does medication effect test results?
- A15 Certain medication may effect sperm concentration and viscosity. This possibility should be discussed with your doctor.