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

<table>
<thead>
<tr>
<th>Test 2</th>
<th>Test 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td>C</td>
</tr>
<tr>
<td>C</td>
<td>B</td>
</tr>
<tr>
<td>B</td>
<td>A</td>
</tr>
</tbody>
</table>

**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 20 million/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.

**Indications for Use:** The FertiliMARQ 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 booklet before performing the test.
- Colour dilution 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 5 days after 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 85°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 FertiliMARQ Test Works**

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

The FertiliMARQ Test works by staining the cells in the semen sample to produce a colour. The intensity of this colour is then compared to a colour reference on the FertiliMARQ 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 FertiliMARQ 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 FertiliMARQ 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. 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, traveling, 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.

**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 Liquifaction 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 a thin, liquid (liquefied) should be used.

The kit contains two Liquifaction Cups to make the semen liquefy faster. The semen sample must be put into the Liquifaction Cup for at least 15 minutes before testing begins. You may store the semen sample in the Liquifaction 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 FertiliMARQ Test Kit, you should find the following items:

- One foil pouch containing:
  - One FertiliMARQ Test Cassette
  - One Bottle of Blue Solution
  - One Bottle of Clear Solution
  - Two Plastic Droppers
  - Two Liquifaction 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.

**Index of Symbols**

- CE 0088
- Index Number
- Manufacturer

**Version Number:** bsmI04  **Effective date:** 2005-07-07
The FertilMARQ Test Cassette

Test 2 Test 1

The FertilMARQ Test Cassette contains 4 wells labeled A, B, C, and D. Reference Wells A and C are blue in colour. This is the colour to which you will compare your test results. Test Wells B and D are white in colour. These are the test wells where you place your liquefied semen sample.

Directions for Performing the Test:
Read ALL instructions before you Begin the Test.
- Wash hands before and after performing the test.
- Do not open foil pouch until you are ready to begin testing.
- Add the semen sample only into a white Test well (B or D). If the sample contains no sperm, place the test in the test well before testing.
- If the sample contains no sperm, place the test well into the test well before testing.

Reading the Colour Change:
Positive Test
- 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).
- 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.

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 test with a new FertilMARQ Home Diagnostic Screening Test for male infertility.

First Test Second Test Interpretation
Positive Positive Sperm concentration is equal to or greater than 20 million/mL
Positive Negative Sperm concentration is less than 20 million/mL Consult your Doctor
Negative Positive Sperm concentration is less than 20 million/mL Consult your Doctor
Negative Negative Consult your doctor

Accuracy of the Test
Sixty-four men attending a clinic, but not undergoing active treatment for infertility, were asked to use the test kit according to the instructions. They were asked to bring the semen sample to the laboratory for estimation of sperm concentration by light microscopy. The light microscopy results showed that 46 men had sperm concentrations above 20 million/mL and 15 men had sperm concentrations below 20 million/mL.

Q1 How should the sample be collected?
A2 We recommend semen is collected by masturbation directly into the Liquifaction Cup. Care must be taken to conserve all of the semen for the test.
Q3 Why wait at least 15 minutes but not longer than 12 hours after adding the semen to the Liquifaction Cup to start the test?
A3 Sperm is very thick (gel-like) and normally takes 30 to 60 minutes to thin (liquefy). Using the specially treated Liquifaction 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 Liquifaction Cup and swirl the contents before beginning the test.
Q4 Are there any small flakelets at the bottom of the Liquifaction 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 Liquifaction Cup, the flakes are absorbed and help to liquefy the sample.
Q5 Does it really matter which 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 Can I make 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) before the Clear wash solution was added. Does this mean that the test is positive?
Q8 Not necessarily. Complete the test using the Clear solution before comparing the colours in the Test and Reference Wells.
Q9 How long should I wait for the semen to dissolve through the filter?
A8 It usually takes just seconds for 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.
Q10 How long should I wait before collecting my semen for testing?
A9 You should wait at least 3 days after ejaculation before providing semen for testing. For best results, you should wait at least 3 days and no more than 7 days between tests.
Q11 Do two positive test results indicate that I am fertile?
A10 No. 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 viewed in conjunction with other factors.
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 If I have tests 6 days apart and get one positive and one negative result, why don’t 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, smoking, stress, 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 Liquifaction Cup for at least 3 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.