Questions and answers

Q. If there are so many factors involved in male infertility, what is the value of buying this kit?
A. Sperm concentration is still one of the most critical determinants of male infertility, as defined by the World Health Organisation. This kit allows you to collect your semen sample in the comfort and privacy of your own home, and as a screening test it offers valuable information to help you and your health practitioner diagnose male infertility.

Q. There are small flakes at the bottom of the liquefaction cup, should I still use the cup?
A. Yes, this flaking may occur due to normal shipping and handling. Do not remove these flakes. When the semen sample is added to the liquefaction cup, the flakes are absorbed and help to liquefy the sample.

Q. What could cause errors in the test results?
A. Improper collection or handling of the semen sample can cause errors, as can using a sample which has not been liquefied and does 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 semen called “high viscosity” and should be discussed with your healthcare practitioner.

Q. If I ran two tests six days apart and got one normal and one low result. Why do I need to wait 10 weeks to repeat the test?
A. Waves of sperm are produced every 70 days, so waiting 10 weeks allows time for a new batch of sperm to be produced before re-testing.

Q. Does medication affect the test results?
A. Certain medication may affect sperm concentration and viscosity. This possibility should be discussed with your healthcare practitioner.

Q. A blue colour appeared after adding the blue dye solution to the test well (T) but before the clear wash solution was added. Does this mean the test is normal?
A. Not necessarily. Complete the test using the clear solution before comparing the colours in the test (T) and reference (R) wells.

Q. How long should I wait between tests?
A. 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.

Q. I made a mistake using the first test. What should I do?
A. Restart the test using the second test cassette. After completing the test and reading the results, discard the cassette. Since you have now used both cassettes, you will not be able to perform the second test. Obtain a new test kit and test a second sample 3-7 days after the first sample was tested, or consult your healthcare practitioner. Your doctor may perform more tests.

Also Available

Fertility Test
Are you approaching menopause, have irregular periods or just unsure if you are fertile? The Babystart® Fertility Test can give a good indication. It measures the concentration of FSH (Follicle Stimulating Hormone) in urine; a high level of this hormone is associated with reduced fertility.

Ovulation Test
This simple screening test detects when you may be about to ovulate, based on increases in the LH (Luteinising Hormone) in urine. It is an invaluable tool in pregnancy planning, identifying the most fertile time in the woman’s menstrual cycle for the best possible chance of conception.

Limitations
There is the possibility that this test may produce false results. Consult your doctor or healthcare professional before making any medical decisions. Invalid results are most likely caused by not following the instructions properly. Repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact FGB Natural Products.

Precautions
Please read all the information in this instruction sheet before performing the test.
- Colour blindness and improper lighting may affect interpretation of test results.
- Store in a dry place below 30°C.
- Do not freeze.
- KEEP OUT OF REACH OF CHILDREN.
- For in-vitro diagnostic use (not for internal use).
- Do not use this product after the expiry date.
- Do not open the foil pouch or plastic bag until you are ready to start the test.
babystart® Sperm Test

A rapid diagnostic test of sperm concentration in semen. A unique home test designed to assess if a man’s sperm count is greater or less than the World Health Organisation’s cut-off point for fertility of 15 million sperm per mL of semen.

Introduction

Sperm count is widely recognised as the major indicator of fertility in men. The World Health Organisation (WHO) has defined a ‘cut-off point’ for fertility of 15 million sperm per mL of semen. A sperm count lower than this concentration can indicate male infertility. The Babystart® Sperm Test is a rapid diagnostic home test that will tell you if a man’s sperm concentration is greater or less than the WHO cut-off point. It can help you determine if you need to see your doctor for help trying to conceive.

How the Sperm Test works

The 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 test cassette. The colour comparison will tell you whether the sperm concentration in the test sample is above 15 million/mL (normal test) or below 15 million/mL (low test).

A normal test is not a guarantee of fertility

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 fertility, a normal test is also not a guarantee of fertility. There are many reasons why a man may be infertile, including 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, fever experienced within two months prior to testing, exercise, travelling and changes in diet can also be a cause. Your doctor can best explain these conditions and other factors to you.

When and how to collect semen

1. You must wait three days after your last ejaculation before you collect a sample for testing.
2. Your semen sample should be collected by masturbation, directly into the liquefaction cup provided.

Note: Freshly ejaculated sperm 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.

This kit contains a special liquefaction cup to make the semen liquefy faster. The semen sample must stay in the cup at least 15 minutes before testing starts. It can stay for up to 12 hours before you begin testing. If the semen sample has not been tested within 12 hours, it should be discarded. Wait 3 days or more then obtain a fresh sample. Do not test sperm which has not been liquefied, as the results may be incorrect.

Directions for use

Please read all the information in this instruction sheet before performing the test.
- Wash hands before and after using the test.
- Do not open foil pouch until ready to begin testing
- Add semen sample only into the white test well (T)
- If the sample or solutions take more than 5 minutes to drain through the well, the test is invalid.
- If you make a mistake using the test cassette, discard and use a new test cassette.

The test cassette contains 2 wells labelled T and R. The Reference Well (R) is blue in colour. This is the colour to which you will compare your test results. The Test Well (T) is white in colour. This is where you place your liquefied semen sample.

1. Collect semen (wait at least 3 days after your last ejaculation). Semen may be collected by masturbation directly into the liquefaction cup provided. Avoid touching the inside of the liquefaction cup.
2. Place the lid on the liquefaction cup and swirl gently at least 10 times. Wait at least 15 minutes but no longer than 12 hours to begin testing. Swirl the liquefaction cup before you begin testing.
3. Open foil pouch by tearing or cutting at notches. Remove contents. Place the test cassette on a flat surface with the wells facing up.
4. Swirl liquefaction cup before removing the lid. Hold and squeeze the plastic dropper. Place the tip into the semen sample and release the pressure slowly. Semen will be drawn up into the dropper.
5. By gentle squeezing the dropper, add ONE drop of semen to the test well (T). Let the drop soak in for at least one minute.
6. Add TWO drops of BLUE solution to the test well (T). Let the drops soak in for at least one minute.
7. Add TWO drops of CLEAR solution to the test well (T). Let the drops soak in for at least one minute. Read results within 5 minutes.

Reading the results

8. Compare the colour in the test well (T) to the colour in the reference well (R).

Normal
A blue colour as dark or darker than the Reference (R) colour is normal (sperm concentration is equal to or above 15 million/mL).

Low
A blue colour lighter than the reference colour is low (sperm concentration is less than 15 million/mL).

Keep a record of each test result noting the date.

Note: if no colour appears, you may have made an error in adding the sample or solutions. We recommend that you obtain another test kit and repeat the test.

9. After completing the first test, discard the test cassette in the normal waste, and return the 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 in the normal waste.

10. Second test: Repeat test at least 3 days but not more than 7 days after first test. Follow complete instructions, Steps 1-8, using the second test cassette provided.

Interpretation of 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 Babystart® Sperm Test.

<table>
<thead>
<tr>
<th>First Test</th>
<th>Second Test</th>
<th>Interpretation</th>
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<tbody>
<tr>
<td>Normal (+)</td>
<td>Normal (+)</td>
<td>Sperm concentration is equal to or greater than 15 million per mL.</td>
</tr>
<tr>
<td>Low (+)</td>
<td>Low (+)</td>
<td>Sperm concentration is less than 15 million per mL. Consult your doctor</td>
</tr>
<tr>
<td>Normal (+)</td>
<td>Low (+)</td>
<td>Retest in 10 weeks and consult your doctor</td>
</tr>
<tr>
<td>Low (+)</td>
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