

QUESTIONS AND ANSWERS

Question

Why does the kit contain material for two tests?

Answer

Sperm quality can vary from one sperm sample to the next in the same individual, depending on activity, diet, environment and unknown factors. Thus the result of the first test should be compared to that of a second test performed after an interval of at least one week. In most instances the two tests will be the same. If they differ it is best to obtain an evaluation of the semen in a medical laboratory.

Question

How long should I abstain prior to the test?

Answer

Avoid ejaculation for at least three days but not more than ten days before the day of the test.

Question

Thirty minutes after ejaculation the majority of the specimen is still on the funnel and it has not entered the test tube. Should I wait longer?

Answer

Yes. Wait another 10 minutes. If, at that time, the sperm sample is still on the funnel the test should be cancelled. Consult your physician. On the other hand it is normal to have a small amount of specimen remaining on the funnel. This does not interfere with the test.

Question

The top of my specimen was closest to the number 2. By mistake I added 4 drops of test liquid instead of 2 drops. Should I continue the test?

Answer

No. The result may not be valid. Discard this test and three days later do another one, using the second set of test material.

Question

What can cause a low sperm count or poor sperm movement?

Answer

Excessive heat, for example from use of hot tubs or from fevers, can depress sperm quantity and quality. High fevers may have a negative influence on the test results for up to 3 months after the illness. Illicit drugs, heavy alcohol use and cigarette smoking can all depress sperm counts or sperm movement. Sperm also can be affected adversely by a number of medications. There are many conditions that can cause low sperm quality and commonly these can be cured. If the condition can not be cured, techniques of artificial reproduction can still be successfully applied in the majority of cases.

Question

Can I collect the sperm sample in a condom?

Answer

No. The usual condoms contain a chemical that kills sperm. There are non-medicated sheaths that can be used. Ask your physician where they can be obtained. Do not collect the sperm sample by withdrawal at intercourse because the first part of the ejaculate that contains the best sperm may be lost.

Question

My sperm sample did not reach the 1 mark on the test tube. What can I do?

Answer

Try once more with a longer period (10 days) of abstinence. This may allow for building up the volume of the sperm sample. If after the second try, the sperm sample still does not reach to 1 mark, consult a physician for further investigation.

If you have other questions, contact us at service@test-point.eu.

Instructions version: 11 August 2008



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DISTRIBUTOR

OTC Medical BV
www.otc-medical.nl



TEST-POINT

TEST-POINT: THE HOME TEST SPECIALIST

THIS PACK CONTAINS:

- 1 WATER CUP WITH THERMOMETER
- 2 TEST TUBES WITH FUNNELS
- 1 COLOR CHART
- 1 BOTTLE WITH DYE
- 1 INSTRUCTIONS FOR USE

VISIT THIS WEBSITE FOR THE LATEST DEVELOPMENTS
WWW.TEST-POINT.EU

TEST-POINT MALE FERTILITY TEST

MORE QUESTIONS?

PLEASE CONTACT THE SERVICE DESK: 0031 485 - 51 99 31
IMHOTEP MEDICAL PRODUCTS
PO BOX 162, 6590 AD GENNEP, NETHERLANDS

AS SOON AS THE TEST HAS BEEN EXECUTED, YOU CAN
PUT ALL USED ITEMS BACK IN THE EMPTY FOIL AND
THAN IN THE ORIGINAL PACKAGE. AFTER THAT
YOU CAN ABOLISH IT IN THE GARBAGE.

INSTRUCTIONS VERSION: 11 - 08 - 2008 V1



TEST-POINT MALE FERTILITY TEST INSTRUCTION

SELF TEST FOR MALE FERTILITY.
FOR IN VITRO USE ONLY -
NOT TO BE TAKEN INTERNALLY.

THOROUGHLY READ THE INSTRUCTIONS FOR USE
BEFORE PERFORMING THE TEST.



TEST-POINT

WHEN TO USE IT?

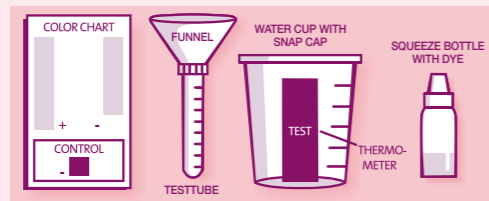
Infertility affects approximately 10-15% of couples of reproductive age and 40-50% of infertility is due to problems with sperm. The Test-Point Male Fertility Test allows you to determine if a sperm sample has normal or less than normal activity. Normal activity is associated with a better chance for pregnancy.

IMPORTANT

- Read carefully all the information in this pamphlet before performing the test.
- Store kit away from children.
- The blue color dye is not for human consumption and is toxic if swallowed.
- The blue color dye is a skin, eye and respiratory track irritant.
- First make sure you are familiar with the test
- Avoid all contact with the tip of the color dye bottle to minimize the risk of contaminating the dye.
- The Test-Point Male Fertility Test has a shelf life of 24 months from date of produce and must be stored at 2-30°C in the closed box.
- Opening the color dye bottle will not restrict the shelf life of the dye as long as all contact between the tip of the bottle or the dye is avoided.
- The test must be performed at room temperature (20-30°C). When the test is performed in a very cold room the temperature of the water in the cup will decrease too quickly, which might render false negative test results.
- The test tubes and funnels can only be used once, discard after use and use a fresh set for the second test.

CONTENT

The bottle of dark blue color dye contains: water, resazurin (<1%), sodium azide (0.09%).



MATERIAL NOT INCLUDED IN THE KIT

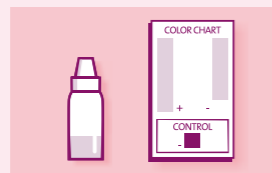
- Hot water (48°C to 50°C)
- incandescent light

PERFORMING THE TEST

The test can give a false result if the protocol is not followed strictly.

STEP 1:

The dye in the reagent bottle should be dark blue, similar to the color marked "Control" on the color chart. If the dye is clear or pink it is defective and the kit should be returned. If the color is normal continue with step 2.



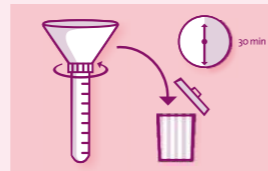
STEP 2:

Unwrap one test tube and one funnel. Remove the blue cap from the test tube and screw the funnel on in its place. Do not dispose of the blue cap because you will need it later in the test. Ejaculate by masturbation into the funnel. Place the test tube with the attached funnel in the holder opening of the box.



STEP 3:

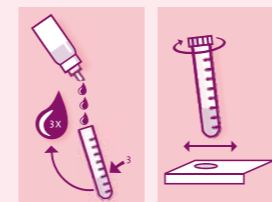
Wait 30 minutes for the sperm sample to turn liquid and to drain through the funnel into the test tube. Unscrew the funnel and discard it in the garbage.



STEP 4:

Lift the test tube from the holder and note which number on the test tube is closest to the top of the sperm sample. If the top is half way or more between two numbers note the higher one. This is the number of drops of the dye that

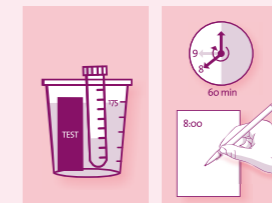
you will be adding to the sperm sample (IF THE TOP OF THE SPERM SAMPLE IS BELOW THE NUMBER 1 - WHICH IS ETCHED ON THE CONICAL PART OF THE TEST TUBE - THE SAMPLE IS TOO SMALL TO PRODUCE AN ACCURATE TEST). Invert the reagent bottle over the top of the test tube and gently squeeze out the correct number of drops of the dye onto the sperm sample. Screw the blue cap back on the test tube and shake sufficiently to mix the test liquid and the sperm sample. The sample should now appear blue or purple. Place the test tube temporarily in the test tube holder of the box.



STEP 5:

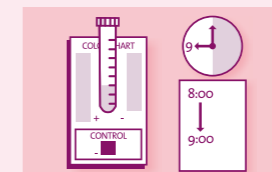
Run hot tap water until it is just too hot to touch. Quickly fill the plastic cup approximately to the "175" mark with the hot (NOT BOILING) water. If the water is at the correct temperature the word TEST will appear clearly on the thermometer strip in the cup. An arrow pointing up will appear if the water is too hot. Wait a few minutes until the word TEST appears. An arrow pointing down will appear if the water is not hot enough. Discard some of the water and add hot water. When the strip says TEST, snap the plastic cap on the cup and insert the test tube through the cap and into the water. The bottom of the test tube should touch the bottom of the cup. Write down the time and place the cup in its holder. (Note that the word TEST will be visible for only a short time after the test tube is inserted and it will be replaced by the arrow pointing down. There is no need to add hot water to maintain the

temperature). Keep the cup away from open windows or air conditioners. It is helpful to practice this step even before collecting a sperm sample.



STEP 6:

Exactly sixty (60) minutes later remove the test tube from the cup, dry the outside with a towel or tissue and shake the test tube vigorously 4 or 5 times. This should evenly distribute the color throughout the sperm sample.



STEP 7:

Using the white portion of the color chart as a background compare the color of the sperm sample with the color chart. Hold the test tube and the color chart 7 to 10 cm (3 to 4 inches) from an incandescent (NOT FLUORESCENT) light. Move the test tube along the row of colors until you come to the best match even though it may not be perfect. Note whether the best match is in the Positive (+) group (normal fertility potential)

or Negative (-) group (less than normal fertility potential). IT IS VERY IMPORTANT NOT TO HAVE ANY FLUORESCENT LIGHTS ON DURING THE READING OF THE TEST RESULTS

RESULTS OF THE TEST

Because the expected color change of the test is from dark blue to red and pink, a person with color blindness for the color red should not perform the interpretation of the results.

If the color match is in the Positive group there is an 86% chance that sperm activity is normal (20 million or more active sperm per milliliter of fluid) and fertility potential is good. This does not guarantee that a pregnancy will occur because many factors, both male and female, affect fertility. If a pregnancy does not occur in 4 months a physician should be consulted.

If the color match is in the Negative group there is an 86% chance that the sperm activity is below normal (less than 20 million active sperm per milliliter of fluid). Pregnancy is less likely but certainly not impossible. A physician should be consulted.

A NEGATIVE RESULT DOES NOT MEAN THAT A PREGNANCY CANNOT OCCUR AND IT SHOULD NOT BE USED AS A REASON FOR AVOIDING USE OF CONTRACEPTION.