



# Male Fertility

The Male Fertility Test is a rapid self-test for the qualitative detection of sperm concentration in semen. Abnormal results will be shown if less than 15 million sperm cells/ml are detected which can be an indicator of male infertility.

The Male Fertility Test is a rapid test for the qualitative detection of acrosomal protein SP-10 found on sperms to estimate sperm concentration in human semen above or below 15 million / mL. Sperm concentration can be used to assist diagnosis of male infertility, and provide guidance for reproductive planning for the eligible couples.

Sperm concentration is one of the primary factors used by physicians to diagnose male infertility. There are many reasons why a man may be infertile and therefore unable to fertilise the female ovum during reproduction. One primary, and most common reason, is an abnormally low production of viable sperm cells. Other reasons include over production of inactive, weak, or deformed sperm cells, high levels of other cells in the semen that interfere with fertilisation, or other physiological factors. Medical or physical conditions may also interfere with normal sperm cell production, including high stress, recent high fever or illness experienced within two months prior to testing, and abrupt changes in diet. Taking this initial screening test will indicate if a low amount of sperm production exists.

The Male Fertility Test gives a positive result, when sperm concentration is above 15million/ml in semen – a level internationally accepted as the minimum level of sperm for normal fertility. A low sperm concentration would indicate less likelihood of conception. It would be advisable to see your medical professional who can advise what can be done to improve the sperm concentration.

 Accuracy  
**98.2%**

 Test type  
**Semen**

 Certifications  
**CE self-test  
| MHRA**

 Results  
**5 mins**

 Kit size  
**1 Test**

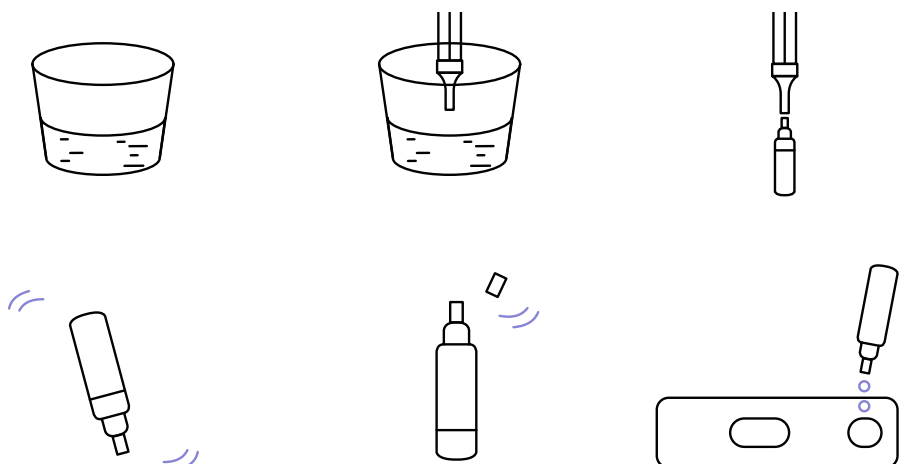
## Instructions

### Specimen collection & preparation

- 1 Before testing, it is important for the subject to refrain from any sexual activity for 3-7 days. This ensures that the volume and quality of sperm is at its peak and the test will then be an accurate determination of sperm concentration.
- 2 Using masturbation, the semen should be collected directly into the sperm collection cup.
- 3 Care should be taken that collected semen is not contaminated by touch of hands or tissues or any other materials.
- 4 Shake the semen evenly in the semen collection cup and leave it to stand for 1 hour at room temperature until the semen liquefies. Do not use semen stored for more than 12 hours.

### Procedure

- 1 Remove the test cassette from the foil pouch and lay it horizontally on a flat surface.
- 2 Collect a semen sample in the liquefaction cup provided.
- 3 The sample should then be allowed to stand for 60 minutes, until the semen is fully liquefied.
- 4 Using the semen transfer device provided, fill the semen transfer device up to 0.1ml as indicated on the device. The semen sample is then added to the vial of dilution buffer provided.
- 5 Mix the semen sample and test solution by turning the vial upside down 5-10 times.
- 6 Hold the diluted specimen buffer tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer 2 full drops of the diluted specimen (approximately 80  $\mu$ L) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
- 7 Read results at 5 minutes after dispensing the specimen. Do not read results after 10 minutes.

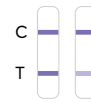


**Read the results**

**NORMAL RESULT**

Two coloured lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

NOTE: The intensity of the colour in the test line region (T) will vary depending on the concentration of SP-10 protein present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered normal.



Normal

**ABNORMAL RESULT**

One coloured line appears in the control line region (C). No line appears in the test line region (T).



Abnormal

**INVALID RESULT**

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Invalid