Male Fertility Test

SP-10 Male Fertility Rapid Test

CE 0123 REF OSP-902H ENGLISH

INTENDED USE

The Male Fertility Test (SP-10 male fertility rapid test cassette) is a rapid chromatographic immunoassay for *in vitro* qualitative detection of acrosomal protein SP-10 found in human semen to estimate sperm concentration above or below 15 million/mL. Sperm concentration can be used for assistant diagnosis and curative effect observation of male infertility, and provide guidance for reproductive planning for couples. For self-testing *in vitro* diagnostics use only.

SUMMARY

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 of the primary and most common reasons is an abnormally low production of viable sperm cells. Other reasons can be 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.[1]

Up to 15% of couples experience infertility, which is defined as the failure to become pregnant after one year of unprotected, well-timed intercourse. And, in 40% of couples struggling with infertility issues, male infertility is the primary cause. Because low sperm count is a leading cause of male infertility, an important first step in determining the cause of infertility is to test the sperm count.

The Male Fertility Test (SP-10 male fertility rapid test cassette) detects acrosomal protein – SP-10 found in semen. SP-10 is a protein specific to male germ cells and cannot be found in other cells. This test is very specific to sperm cells and is now being used to estimate sperm concentration in semen as an aid in identifying infertility. The Male Fertility Test (SP-10 male fertility rapid test cassette) gives a positive result when sperm concentration is above 15 million/mL in semen – a level internationally accepted as the minimum level of sperm for normal fertility.[1,2] 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.

PRINCIPLE

The Male Fertility Test (SP-10 male fertility rapid test cassette) works by detecting acrosomal protein SP-10 in sperm in the semen. During testing, SP-10, if present in the in specimen, binds with conjugated anti-SP-10 antibodies and the mixture migrates upward on the membrane by capillary action, upon adding the specimen to the sample well. The membrane is pre-coated with anti-SP-10 antibodies on the test line region (T) of the strip. The antigen-antibody complex binds with anti-SP-10 antibodies coated in test region of the test unit and produces a coloured line, if the concentration of sperm is more than or equal to 15 million/mL of semen. The coloured line thus formed indicates that sperm count in semen is equal to or more than 15 million/mL. An absence of the test line indicates that the sperm concentration is less than 15 million/mL. To serve as a procedural control, a coloured line will always appear in the control line region (C), indicating that the required volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

Please read all the information in the instructions for use before performing the test.

- For self-testing *in vitro* diagnostic use only. Keep out of the reach of children.
- This kit can only be used using human semen as a specimen and cannot be used with specimens of other body fluids.
- The sample should be collected within 3-7 days after the last ejaculation; semen obtained less than 3 days or more than 7 days will affect the accuracy.
- The collection containers should be clean, dry, waterproof and free of preservatives and detergents.
- Semen liquefaction is a process in which semen rapidly changes from jelly-like appearance to a liquefied state. Fresh samples collected are generally liquefied within 60 minutes. It would be abnormal for the semen to not liquify within 60 minutes and may indicate an infection.
- The kit should be stored at room temperature, avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use.
- Once the test cassette's package is opened, it should be used as soon as possible to avoid being exposed to the air for long periods, which could result in the test not working correctly.
- This test kit is intended to be used as a preliminary test only and repeatedly abnormal results should be discussed with a doctor or medical professional.
- The timing instructions must be followed correctly when carrying out the test and observing the results.
- The kit must not be frozen or used after the expiration date printed on the outer foil.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable until the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use after the expiration date.

MATERIALS PROVIDED

• Test cassette • Collection cup • Workstation • Semen transfer device • Sample dilution buffer • Instructions for use • Product summary

MATERIALS NOT PROVIDED

• Timer

SPECIMEN COLLECTION AND PREPARATION

Before testing, read the instructions carefully and completely. Allow the test and specimen to reach room temperature (15-30°C) prior to testing.

1. Before testing, it is important that subject refrains from ejaculation for 3-7 days prior to taking the test. 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. The semen should be collected directly into the sperm collection cup.
3. Care should be taken that collected semen is not contaminated by contact with hands, 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 after liquefaction 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 semen sample in the collection 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 up to 0.1 mL indicated on the device with the semen sample. The semen sample is then added to the vial of sample 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 µL) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration.
7. Read results at 5 minutes after dispensing the specimen. Do not read results after 10 minutes.

READING THE RESULTS

NORMAL:* 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). A normal result indicates that sperm concentration is above 15 million/mL in semen - a level internationally accepted as the minimum level of sperm for normal fertility.

***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.

ABNORMAL: One coloured line appears in the control line region (C). No line appears in the test line region (T). An abnormal result indicates that sperm concentration is below 15 million/mL in semen. A low sperm concentration would indicate less likelihood of conception.

INVALID: 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. **Note:** If for any reason, the results are considered to be doubtful or inaccurate, the test should be repeated with another test unit. However, the subject must not ejaculate through any sexual activity for 6 days before carrying out the second test. If the second test is still abnormal, the results should be discussed with a doctor or medical professional.

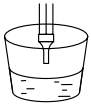
1

Remove test from pouch.

2

Collect semen sample in cup & leave to stand for 60 minutes.

3



Draw 0.1 mL of semen sample.

4

Add sample to sample dilution buffer.

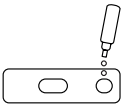
5

Mix.

6

Open cap.

7



Transfer 2 drops of diluted specimen to the well (S).

Read results at 5 minutes:

QUALITY CONTROL

A procedural control is included in the test. A coloured line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

1. For *in vitro* qualitative estimation of sperm concentration in human semen.
2. Sperm concentration is just one of the important tests for fertility. But other tests of semen like motility and morphology as well as ovulation in females are also important. For the cases of infertility, it is recommended that other factors are also taken into consideration.
3. It is recommended to use fresh samples. Any lubricants or lotions collected, and semen obtained from condoms will affect test results.

FAQs

1. How does the Male Fertility Test (SP-10 male fertility rapid test cassette) work?

SP-10 is a protein specific to male sperm cells and cannot be found in other cells. This test is very specific for sperm and is now being used for estimating sperm concentration in semen as an aid in determining causes of infertility. The Male Fertility Test (SP-10 male fertility rapid test cassette) detects SP-10, and gives a positive result when sperm concentration is above 15 million/mL in semen – a level internationally accepted as the minimum level of sperm for normal fertility.

2. When should the test be used?

It can be used for assistant diagnosis and curative effect observation of male infertility, and provide guidance for reproductive planning of the eligible couples.

3. Can the abnormal results show that the subject has no ability to have children?

Sperm concentration is one of several semen analysis tests. There are other factors that should be considered, including motility. Therefore, it is strongly recommended that you seek expert medical advice if you get an abnormal result.

4. What is the reason that may result in wrong test results?

Any mistake at any point of time from sample collection to test timing to non-compliance to abstinence may result in erroneous test results.

BIBLIOGRAPHY

1.Jianhua Yang, Modern male infertility diagnosis and treatment of Shanghai: Shanghai science and Technology Literature Press, 2007
2.Cheng liangXiong, human sperm Science Wuhan: Hubei science and Technology Press, 2002.

Index of Symbols

	Manufacturer	Σ	Tests per kit	EC REP	Authorised Representative in EU
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalogue #
	Do not use if package is damaged		Consult Instructions for Use		Non-recyclable
21	Pap 21 recyclable material	22	Pap 22 recyclable material		

CE 0123

EC REP

MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster, Germany

Number: 146720803
Revision date: 2023-01-20