Chuangxingwell

SP-10 Rapid Test Kit (Semen)
Package Insert

A rapid test for the qualitative detection of SP-10 in human semen.
For self-testing in vitro diagnostic use.

IVD

【INTENDED USE】

The SP-10 Rapid Test Kit (Semen) is a rapid chromatographic immunoassay for *in vitro* 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 for assistant diagnosis and curative effect observation of male infertility, and provide guidance for reproductive planning of the eligible couples.

【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. The most common reason 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, 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.

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 establishing the cause of infertility is to determine the sperm count

The SP-10 Male Fertility Rapid Test detects Acrosomal protein – SP-10 found on sperms. Since, SP-10 is a protein specific to male germ cells and cannot be found in other cells, it can be used for estimating sperm concentration in semen as an aid in determining causes of infertility. The SP-10 Rapid Test detects SP-10, providing a positive result, when sperm concentration is above 15 million/mL in semen – a level internationally accepted as the minimum level of sperms for normal fertility. A low sperm concentration would indicate lower likelihood of conception and It would be advisable to see a medical professional, who can advise what can be done to improve the sperm concentration.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

- For self-testing *in vitro* diagnostic use only.
- This kit can only be used as an *in vitro* diagnostic test using human semen specimen and cannot be used with 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 liquefied state. Fresh collected samples generally liquefy within 60 minutes, and if the sample does not liquefy within 60 minutes it means abnormal result.
- 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.
- "Time" instructions must be followed correctly, when carrying out the test and observing the results.
- The kit must not be frozen or used after the expiry 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 through the expiration date (for 24 months) printed on the sealed pouch. The test must remain in the sealed pouch until use. It must be used within an hour if opened.**DO NOT FREEZE**.

【MATERIALS】

Materials Provided

- Test Cassettes
- Package Insert
- Semen Transfer Device
- Sample Dilution Buffer
- Collection Cup
- Workstation

Materials Required But Not Provided

- Timer

【SPECIMEN COLLECTION AND PREPARATION】

1. Before testing, it is important that subject refrains 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 that has been left to liquefy for more than 12 hours.

【PROCEDURE】

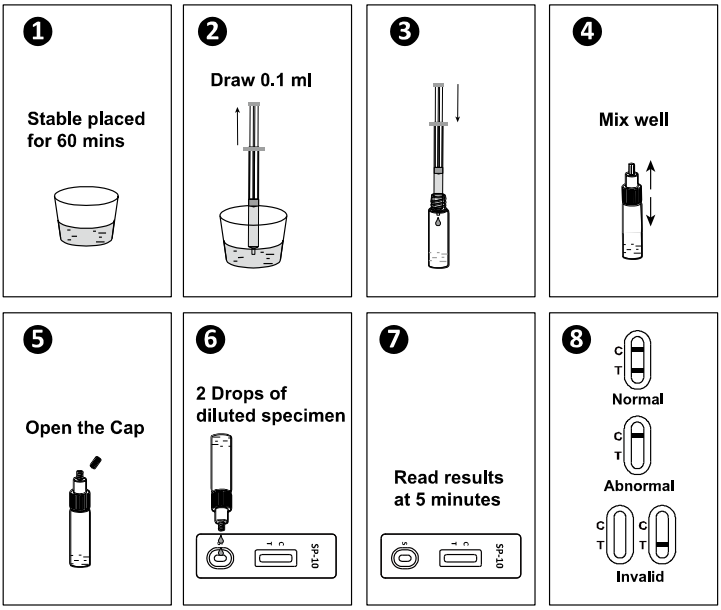
Before testing, read the instructions carefully and completely.

1. Collect a semen sample in the collection cup provided.
2. The sample should then be allowed to stand for 60 minutes, until the semen is fully liquefied.
3. Remove the test cassette from the foil pouch and lay it horizontally on a flat surface. Using the semen transfer device, draw with the collected semen to **0.1 mL** as indicated on the side of the transfer device. Add the semen sample to the sample dilution buffer provided.
4. Mix the semen sample and test solution by turning the vial upside down **5-10 times**.
5. Hold the diluted specimen buffer tube upright and open the cap. Invert the specimen collection tube and transfer **2 full drops of the diluted specimen** to the **specimen well (S)** of the test cassette, then start the timer. Try to avoid trapping air bubbles in the specimen well (S). See illustration below.
6. **Read results at 5 minutes after adding the specimen.** Do not read results after 10 minutes.

【READING THE RESULTS】

(Please refer to the illustration below)

NORMAL:* Two coloured lines appear. One coloured line should be in the control line region (C) and another 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.
ABNORMAL: **One coloured line appears in the control line region (C).** No line appears in the test line region (T).
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.



【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. Other semen tests like motility and morphology as well as ovulation tests in females are also important. For instances of infertility, it is recommended that other tests are also taken in consideration.
3. It is recommended to use fresh samples. Any lubricants or lotions collected, and semen obtained from condoms will affect test results.

【EXTRA INFORMATIONS】

1. How does the SP-10 Male Fertility test work?

Since, SP-10 is a protein specific to male germ cells and cannot be found in other cells, this test is very specific for sperms and can therefore be used for estimating sperm concentration in semen as an aid in determining causes of infertility. The SP-10 Rapid Test detects SP-10, providing a positive result when sperm concentration is above 15 million/mL in semen – a level internationally accepted as the minimum level of sperms 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.

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 obtain an abnormal result.

4. What reasons could there be for an inaccurate result?

Failure to follow the instructions from sample collection to test timing to non-compliance and abstinence, could all lead to 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

	Caution	IVD	In Vitro Diagnostic Medical Device		Do Not Use if Package is Damaged
	Manufacturer	LOT	Batch Code	Σ	Contains Sufficient for <n> Tests
CE	CE Marking	REF	Catalogue Numbe	EC REP	Authorized representative in the European Community
	Keep Dry		Use-By Date		Keep Away From Sunlight
	Temperature Limit	2	Do Not Re-use		Date of Manufacture

Manufacturer
Jinan Chuangxingwell Biotech Co., Ltd.
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