Sperm Concentration Rapid Test Cassette (Semen)
Package Insert
For Self-testing

REF OSC-902H	English

For self-testing in vitro diagnostic use only.

【INTENDED USE】

The Sperm Concentration Rapid Test Cassette is biochemical assay for *in vitro* qualitative estimation of sperm concentration in human semen as an auxiliary aid in clinical diagnosis of the infertility and/or pregnancy planning by self-evaluation of sperm concentration above or below the required concentration for successful pregnancy.

【PRINCIPLE】

This product uses the inert glass fiber membrane with high water absorption and the pore size of less than 0.5 μm to filter the semen. Sperm cells are trapped on the surface of the first layer of the membrane, and staining solution is used that can dye sperm cells. The darker the colour of well "A", the higher the sperm concentration. If the colour of test well "A" is lighter than the standard colour of reference well "B", it means that the concentration of sperm is less than 15 million/mL. If the colour of test well "A" is darker than the standard colour of reference well "B", it means that the sperm concentration is greater than 15 million/mL. Sperm concentration of 15 million/mL is the minimum expected sperm concentration level for pregnancy.[1,2]

This kit is designed to be used for *in vitro* qualitative estimation of the sperm concentration of human semen. Essentially this means the test will determine if the number of sperms is at an adequate level for conception to occur with sexual intercourse, subject to female partner's ovulation in time. A low sperm concentration would indicate less likelihood of conception.[2] It would be advisable to see your 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.

- This kit can only be used as an *in vitro* diagnostic test using human semen as specimen and cannot be used with specimens of other body fluids. Keep out of the reach of children.
- 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 doctor or medical professional. It could not replace medical advice. Always seek guidance from a qualified healthcare provider before making any health-related decisions.
- When adding specimens, staining solution and washing solution, try to avoid any bubbles as that would adversely affect the test results.
- Make sure you correctly follow the "time" instructions 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.
- **The light yellow to brown powder at the bottom of the cup is essential for liquefying the semen sample. Please do not remove it. This is a normal part of the process.**

【MATERIALS】

Materials Provided

- Test Cassette
- Package Insert
- Dropper
- Collection Cup
- Staining Solution
- Washing Solution
- Workstation
- Procedure Card

Materials Required But Not Provided

- Timer

【STORAGE AND STABILITY】

The test kit should be stored at room temperature or refrigerated (2°C-30°C) in the sealed pouch to the date of expiration. The test kits should be kept away from direct sunlight, moisture and heat. **DO NOT FREEZE.**

【SPECIMEN COLLECTION AND PREPARATION】

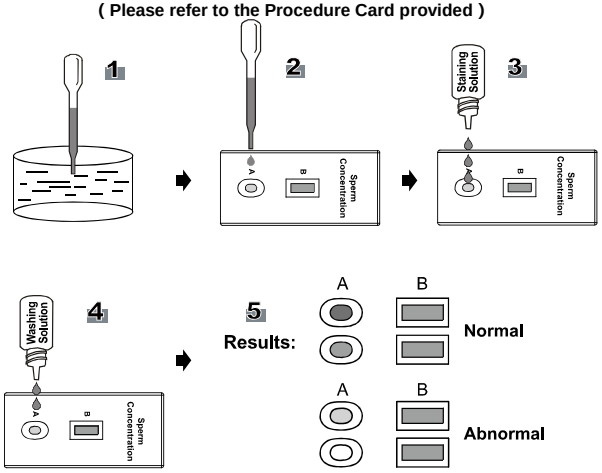
1. Before testing, it is important that you refrain from any sexual activity for 3-7 days. This ensures that the volume and quality of sperm is at its peak and the test will then be an accurate determination of sperm concentration.
2. Using masturbation, the semen should be collected directly into the 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 15 minutes at room temperature until the semen liquefy. Do not use semen stored for more than 12 hours.

【DIRECTIONS FOR USE】

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

1. Remove the test cassette from the foil pouch and lay it horizontally on a flat surface. Using the dropper provided in the foil pouch, dispense one drop of semen into sample well marked "A".
2. Once the semen is soaked into well "A", add **three drops** of the blue staining solution to test well "A". **Let it soak for 1-2 minutes.**
3. Add **two drops of the transparent washing solution** to test well "A", and **let it soak for 1-2 minutes**, and then read the results immediately.
4. Read the colour of test well "A", comparing the colour of test well "A" to reference well "B". The darker the colour of well "A", the higher the sperm concentration.

(Please refer to the Procedure Card provided)



【READING THE RESULTS】

(Compare the colour of test well "A" to reference well "B")

NORMAL

The colour of test well "A" is darker than or the same as the standard colour of reference well "B". It means that the sperm concentration is greater than or equivalent to 15 million/mL. The likelihood of conception is high with this sperm concentration, subject to other conditions, such as ovulation being favorable.

ABNORMAL

The colour of test well "A" is lighter than the standard colour of reference well "B". It means that the sperm concentration is less than 15 million/mL. This is known as oligospermia. The likelihood of conception is less with this sperm concentration and further medical consultation is recommended.

NOTE: If well "A" is colourless, it means the sperm concentration is less than 5 million/mL or zero. This condition is known as sever oligospermia or azoospermia. If you are unsure of the result or you feel the result is inaccurate, you should repeat the test using a second test but make sure you do not ejaculate through any sexual activity for 6 days before carrying out the second test. If the second test is still abnormal, you should discuss the results with your 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. 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 tests are also taken in consideration.

【EXTRA INFORMATIONS】

1. Question: Why the time is 15 minutes before the semen being taken out from the semen collecting cup for test, and the storage time after sampling does not exceed 12 hours?

Answer: The fresh semen is viscous, and normal semen needs to be incubated for 30-60 minutes at 37°C to liquefy completely.[3] Only in liquid state, the semen can be used for test, because the viscous semen cannot completely pass the membrane of the test well. The light yellow to brown powder at bottom of the semen collection cup can make the semen liquefy quickly within 15 minutes. If the storage time of sperm specimen is too long, it may cause lysis of sperms, which may affect accuracy of the results.

2. Question: How long do the semen and staining solution need to be in the test well?

Answer: In general, they may pass membrane of the test well within several seconds, if they cannot pass the membrane completely after 5 minutes, and which shows that the semen has not liquefied completely, or density of the sperm is too high, and we must repeat the test. The reasons of semen non-liquefaction may be that the enzyme in the semen collection cup becomes invalid or the user does not use the semen cup correctly or there is some other cup used for semen collection

3. Question: Is the solutions used for test safe?

Answer: The solution is safe, and which is a synthetic dye, intake of which in concentration less than 5 mg/kg does not harm to human body. The concentration of the staining fluid is less than 10 μg/mL.[4]

4. Question: Can the abnormal results show that the subject has no ability to have children?

Answer: 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.

5. Question: What is the reason that may result in wrong test results?

Answer: 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. Persson BE, RonquistG, EkblomM.Ameliorative effect of allopurinol onnonbacterial prostatitis: a paralleldouble-blind controlled study. JUro,l 1996.
2. Jianhua Yang, modern male infertility diagnosis and treatment of Shanghai:Shanghai science and Technology Literature Press, 2007.
3. Cheng liangXiong, human sperm Science Wuhan: Hubei science and TechnologyPress, 2002.
4. China Biological Products Standardization Committee of Chinese requirements ofbiological products 2000 ed. Beijing: Chemical Industry Press, 2000.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	2°C 30°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
	Caution		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer	EC REP	Authorized representative in the European Community

Hangzhou AllTest Biotech Co.,Ltd.
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