

SCREEN[®] Sperm Concentration Rapid Test Cassette (Semen)

Package Insert

REF OSC-902	English
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For professional *in vitro* diagnostic use only.

【INTENDED USE】

The Sperm Concentration Rapid Test 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 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 0.5µm 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.

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.

【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.
- 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 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.
- When adding specimens, staining solution and washing solution, try to avoid any bubbles as this could adversely affect the test results.
- Please correctly follow the "time" instructions 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.
- Do **NOT** remove the light-yellow liquefying powder from the bottom of the sample cup. It is supposed to be in there as it will help the semen to liquefy.

【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 the tester should 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.

【MATERIALS】

Materials Provided

- Test Cassettes
- Collection Cups
- Workstation
- Package Insert
- Staining Solution
- Procedure Card
- Droppers
- Washing Solution

Materials required but not provided

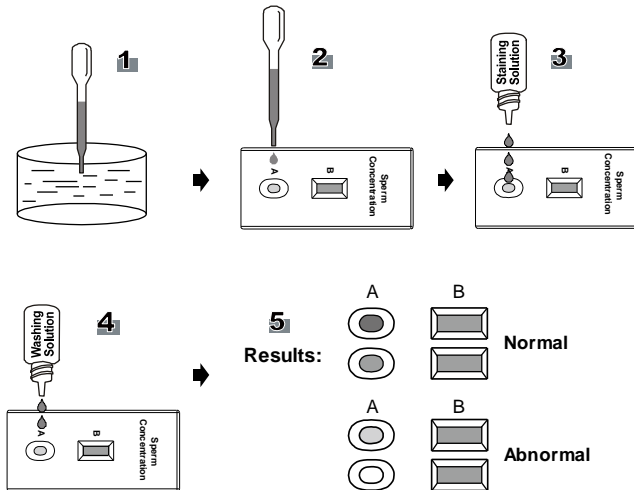
- Timer

【DIRECTIONS FOR USE】

Before testing, read the instructions completely carefully and completely.

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 **1 drop of semen** into Sample Well marked "A".

2. Once the semen is soaked into Well "A", add **3 drops of the blue staining solution to Test Well "A"**. Let it soak for **1-2 minutes**.
3. Now add **2 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 15million/ml. This is known as oligospermia. The likelihood of conception is less with this sperm concentration.

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 for any reason, the results are considered to be doubtful or inaccurate, the test should be repeated with another test.

【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.

【EXPECTED VALUES】

The Sperm Concentration Rapid Test Cassette (Semen) has been compared with a leading commercial other Sperm Concentration test, demonstrating an overall accuracy greater than or equal to 99%.

The cut-off of Sperm Concentration Rapid Test Cassette (Semen) is 15 million/ml.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The specimen correlation used a specimen number equal to 236 (52 Abnormal specimens and 184 normal specimens confirmed by Microscopic method). The results show that the relative sensitivity of the Sperm Concentration Rapid Test Cassette (Semen) is 98.1% and the relative specificity is 99.5%.

Method	Other Sperm Concentration Rapid Test			Total Results
	Results	Abnormal	Normal	
Sperm Concentration Rapid Test Cassette (semen)	Abnormal	51	1	52
	Normal	1	183	184
Total Results		52	184	236

Relative Sensitivity: 98.1% (95%CI:*89.7%-99.9%)

Interval

Relative Specificity: 99.5% (95%CI:*97.0%-99.9%)

Accuracy: 99.2% (95%CI:*97.0%-99.9%)

Precision Intra-Assay

Within-run precision has been determined by using 10 replicates of two specimens: Abnormal specimen (<12 million/ml) and normal specimen (≥16 million/ml). The abnormal specimen and normal specimen values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same two specimens: Abnormal specimen (<12 million/ml) and normal specimen (≥16 million/ml). Three different lots of the Sperm Concentration Rapid Test Cassette (Semen) have been tested over a 3-day period using abnormal specimen and normal specimen. The specimens were correctly identified >99% of the time.

【BIBLIOGRAPHY】

1. Persson BE, Ronquist G, Ekblom M. Ameliorative effect of allopurinol on nonbacterial prostatitis: a paralleldouble-blind controlled study. J Urol, 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 Technology Press, 2002
4. China Biological Products Standardization Committee of Chinese requirements of biological products 2000 ed. Beijing: Chemical Industry Press, 2000

Index of Symbols

	Consult Instructions For Use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Manufacturer		



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