SPERMSPEC

INSTRUCTIONS FOR USE

Please read this manual carefully before operation to ensure proper use.

PRODUCT NAME
SPERMSPEC Sperm Concentration Test Kit

PACKING SPECIFICATIONS
10/50/100 Tests per Kit

INTENDED USE
This product is used for the qualitative detection of sperm SP10 protein in human semen in vitro. WHO laboratory manual for the examination and processing of human semen, 5th ed. mentioned that the main factors affecting male infertility are: semen volume, total number of sperm, sperm concentration, liquefaction time, semen pH value, normal sperm morphology rate, etc, where sperm concentration is an important indicator to measure male infertility. In this manual, the normal minimum value of sperm concentration is 15×10^6/mL, and when the sperm concentration is less than 15×10^6/mL, it is considered that there is difficulty in fertility. However, male infertility needs to be combined with other indicators to make a final judgment. Based on several anatomical, genetic, and biochemical features, the SP 10 protein, which is only expressed in the testis and is a differentiation marker for the final step of the spermatogenesis process, is validated as an analyte for sperm concentration detection. According to the research data, there is a certain linear relationship between the concentration of SP10 protein and the concentration of sperm, that is, when the concentration of sperm is more than 15×10^6/mL, the detection of SP10 protein is positive. Therefore, sperm concentration can be used in the auxiliary diagnosis and curative effect observation of male infertility, and provide guidance for the reproductive planning of age-appropriate couples. This product can be used not only for the preliminary screening of sperm concentration in medical institutions, but also for consumers to test at home to preliminarily judge whether the sperm concentration level meets the standard. The colloidal gold method is currently the most commonly used detection method for sperm SP10 protein in clinic or laboratory.

TESTING PRINCIPLE
The product adopts the principle of double antibody sandwich. When the concentration of SP10 protein in the semen sample is equal to or higher than the minimum detection limit, the sperm SP10 protein in the semen reacts with the colloidal gold-labelled mouse anti-human sperm SP10 protein monoclonal antibody (SP10 mAb1) on the binding pad to form a labelled antibody-antigen complex, the complex is chromatographed upward by capillary action, captured by the detection line T-line mouse anti-human sperm SP10 protein monoclonal antibody (SP10 mAb2) coated on a nitrocellulose membrane, and a red band appears. The complex continues to be chromatographically upward, and is captured by the quality control line (C line) antibody (goat anti-mouse IgG polyclonal antibody) coated on the nitrocellulose membrane, and a red band appears. When there is no sperm SP10 protein or the concentration of sperm SP10 protein is lower than the minimum detection limit, the detection line (T line) will not show colour.

Regardless of the concentration of sperm in the sample to be tested, the quality control line (Cline) will form a red colour band visible to the naked eye, which is the standard for judging whether the sample volume is sufficient and whether the chromatography process is normal, and also serves as the internal control of this reagent.

MAIN COMPONENTS
[[GRAPHIC TABLE 1]]

Testing Schedule					
Menstrual Cycle (days)	Test Start Date	Menstrual Cycle (days)	Test Start Date	Menstrual Cycle (days)	Test Start Date
21	the 6th day	28	the 11th day	35	the 18th day
22	the 6th day	29	the 12th day	36	the 19th day
23	the 7th day	30	the 13th day	37	the 20th day
24	the 7th day	31	the 14th day	38	the 21st day
25	the 8th day	32	the 15th day	39	the 22nd day
26	the 9th day	33	the 16th day	40	the 23rd day
27	the 10th day	34	the 17th day		

The test pad (strip/card) is composed of nitrocellulose membrane, sample pad, binding pad, etc. The T line of nitrocellulose membrane is coated with mouse anti-human sperm SPI0 protein monoclonal antibody (SP10 mAb2), the C line is coated with goat anti-mouse IgG polyclonal antibody, and the binding pad contains colloidal gold-mouse IgG-mouse anti-human sperm SPI0 protein monoclonal antibody Cloned antibody (SP10 mAb1) conjugate. Sample diluent: PBS, Tween-20, PH- 7.4±0.2.

Note: The components in the kits of different batch numbers are not interchangeable.

STORAGE CONDITIONS AND VALIDITY
1. Storage conditions: The kit in the original package in a dry place protected from light at 2~30°C and the kit can be stable for 24 months, do not freeze.

2. The test pad should be used within 1 hour under the condition of 2~30°C and humidity <65% after the aluminium foil bag is unpacked, and should be used immediately under the condition of high temperature and high humidity.

3. The production date and expiration date can be seen on the label

SAMPLE REQUIREMENTS
1. The applicable sample type is male semen sample.

2. Sample collection
2.1 Semen samples should be collected in dedicated semen collection containers, or in clean, dry plastic containers.

2.2 Obtaining a semen sample by artificial stimulation (masturbation) or other methods without the use of any lubricating fluids and lotions; or semen collection using a non-toxic condom specially designed for semen collection (applicable only in cases where semen collection by masturbation is difficult), because ordinary condoms generally contain ingredients that interfere with sperm motility, which may affect the test results.

2.3 Wash hands and perform other necessary cleaning measures before taking samples.

2.4 The best time for sample collection should be 2-7 days after the last ejaculation. During this period, there should be no ejaculation such as masturbation, nocturnal emission, etc. The semen obtained less than 2 days or more than 7 days will affect the accuracy of the test results.

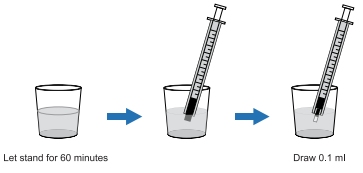
2.5 All the ejaculated semen should be collected as far as possible, without omission. If there is any omission and any doubt about the test results, the semen should be collected for testing again for the same days as possible according to the collection requirements, which is the best morning harvest. The interrupted sperm discharge method cannot be used to collect semen, because the ejaculation may be lost initially, and the sperm is usually the highest concentration, and the vaginal discharge will inevitably affect the accuracy of the test results.

2.6 Fresh semen samples (recommended within 3 hours) should be used for testing as much as possible. If they cannot be used immediately, the semen samples (airtight) should be stored at 2-8°C, but the storage time should not exceed 12 hours, longer storage should be at -20°C and below, but not repeated freezing and thawing.

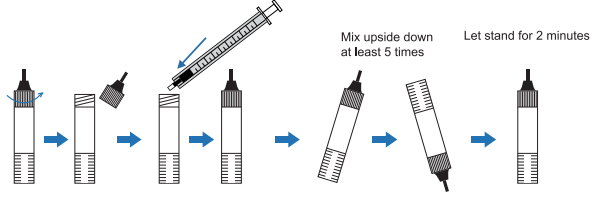
3. Sample preprocessing
3.1 The collected fresh sample quickly appears as a semi-solid gel mass in the sampling cup, which can be completely liquefied (that is, becomes homogeneous and relatively thin, which may contain gelatinous lumps that do not liquefy as normal) after being placed at room temperature for 30-60 minutes. If it is still not completely liquefied after 60 minutes, it should be regarded as abnormal. It is recommended to re-sample after 2 days and then observe. If it is still not completely liquefied after 60 minutes after another test, you should consult a specialist.
Note: Only completely liquefied semen samples can be tested with this reagent.

3.2 Take the semen transfer device and gently stir the liquefied semen sample in the sample cup for about 10 times, until the sample is fully mixed, but it can not be shaken violently.

3.3 Draw 0.1 mL of semen sample with a semen transfer (note: no bubbles, solid or viscous substances during absorption) and transfer completely to the upright disposable semen collector with sample diluent.



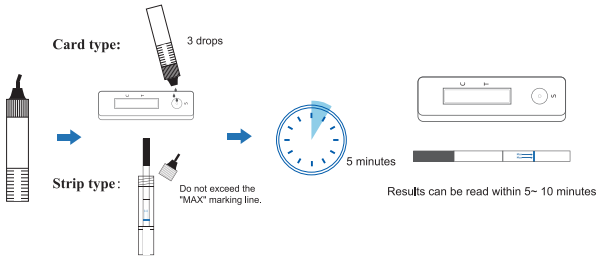
3.4 Tighten the cap of the semen collection tube and mix the semen and sample diluent thoroughly. It is recommended to rotate the semen collection tube upside down at least 5-10 times. If the sample is very thick or viscous, it should be rotated upside down again for 10 times. The sampled semen collection tubes should be allowed to stand for 2 minutes.

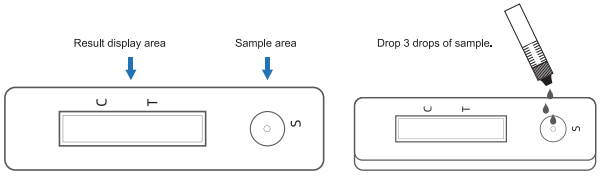


TESTING METHOD
Please read the instruction manual carefully before the test, check whether the kit is within the validity period, and check whether the kit is missing or damaged. Reagents and samples should be restored to room temperature before testing, and testing should be performed at room temperature.

1. Open the aluminium foil bag, take out the test pad (cassette). Put the test card flat, unscrew the cap of the semen collection tube, and add 3 drops (about 75 μL) to the sample hole of the test card.

2. Start the time, the test results can be observed within 5 minutes, and the results shown after 10 minutes are invalid.



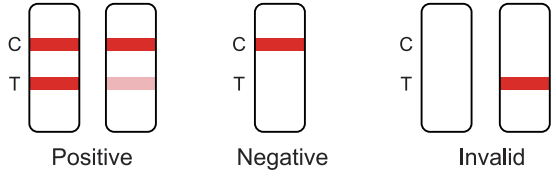


3. All used consumables, test strips/cards/pens and other waste should be put into medical waste bag and disposed of properly in accordance with local relevant regulations.

4. Wash or disinfect your hands.

Note: Please interpret the results within the specified time, and reading less or more than this time may lead to wrong results.

INTERPRETATION OF TEST RESULTS



Positive: Red bands appear in both the detection area (T) and the control area (C).

Negative: There is no red band in the detection area (T), and a red band appears in the control area (C).

Invalid: There is no red band in the control area (C), no matter whether there is a red band in the detection area (T), the test strip/card is judged to be invalid, and retesting is recommended, paying special attention to whether the sample volume is sufficient.

LIMITATIONS OF TEST METHODS

1. This reagent mainly achieves the purpose of screening the sperm concentration by detecting the sperm SP10 protein, and it cannot reflect its fertility. The test results are only used as a reference index for male infertility, and they need to be comprehensively evaluated in combination with other clinical and laboratory data. If the test results are inconsistent with the clinical assessment, further examination is required.

2. This reagent is an in vitro qualitative detection reagent, which is only used to reflect whether the sperm concentration in the sample is higher or lower than the lower limit of the reference value (15×106/mL), and cannot be used to determine the exact number of sperm in the sample.

3. This reagent cannot be used to confirm the identity of the father, nor can it be used as an indicator of contraception.

4. The number of spermatozoa changes greatly, so a judgment cannot be made based on only one test result. If you have doubts about the test results, it is recommended to re-sample for testing after the same number of days of abstinence as required by the collection requirements. Generally, the test shou1d be repeated 2 to 3 times. [f the retest result is still negative, it is recommended to consult a specialist in the hospital.

5. The test result of this reagent is negative, and it cannot prove infertility, because the sperm concentration in the semen of 10% of fertile men is lower than 15×10^6/mL.

6. The test result of this reagent is positive, which cannot be inferred to have fertility, but can only reflect that the sperm concentration in the semen sample is not less than 15×106/mL, because in addition to the sperm concentration, there are many factors that can lead to infertility. If the couple have a normal sexual life and are not pregnant for a year or more without contraception, they should consult a specialist.

7. The test results of this reagent are for reference only and shall not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be combined with the final clinical diagnosis of their symptoms, medical history, other laboratory tests and treatment response.
[Performance characteristics)

1. Minimum detection limit
Test the enterprise's lowest detection limit reference product (L1-L3), the L1 result should be negative, and the L2 and L3 results should both be positive.

2. Specificity
Test specific reference substances with concentrations of 1000 ng/mL prostate-specific antigen (PSA) and 1000 ng/mL prostatic acid phosphatase (PAP) respectively, and the test results should be negative.

3. Conformity rate of positive reference products
Use the company's positive reference products (P1-P5) for testing, all should be positive, and the positive coincidence rate (+/+) should be 5/5.

4. Conformity rate of negative reference product
Use enterprise negative reference products (N1-N5) for testing, all should be negative, and the negative coincidence rate (-/-) should be 5/5.

5. Repeatability
Take the SP10 reagent of the same batch number, and use the repeatable reference products R1 and R2 of the enterprise to test, and repeat the measurement 10 times. It is required that both R1 and R2 are positive, and the test results should be consistent and the chromaticity should be uniform.

PRECAUTIONS

1. This reagent is a single-use in vitro diagnostic reagent. Do not use reagents with obvious packaging damage, and do not use expired products.

2. It is recommended to use fresh samples, use any lubricant or lotion when collecting, and obtain semen from ordinary condoms, which will affect the test results.

3. Incomplete or leaky semen samples are not suitable for testing, and the results cannot reflect the quality of semen.

4. The samples may contain hepatitis B virus, herpes virus and human immunodeficiency virus, etc., so semen samples and other wastes should be treated as potential infectious substances.

5. The final diagnosis should be made by a doctor after comprehensive testing indicators and clinical symptoms. This reagent is only used as an auxiliary diagnosis. If you have any questions or suggestions during use, please consult a professional.

(Version and update date)

Version: 1.0
Updated date: 2023.07.24

SYMBYOLOGY

Abbreviation	Explanation	Abbreviation	Explanation
IVD	In vitro diagnostic medical device	LOT	Batch code
Σ	Contains sufficient for<n>tests		Date of manufacture
	Manufacturer		Use-by date
EC REP	Authorized representative in the European Community	30℃ 2℃	Temperature limit: 2~30℃
CE	CE Marking		Keep dry
	Do not use if package damaged		Keep away from sunlight
	Consult instructions for use	2	Do not re-use
REF	Catalogue number		Biological risks

	Nanjing Synthgene Medical Technology Co., Ltd. Building B6-2, No. 9, Weidi Road, Xianlin University Town, Xianlin Subdistrict, Qixia District, Nanjing City, China
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GUARANTEE AND TECHNICAL SUPPORT

If you get repeated invalid test results, or need technical support, please contact Preggo customer support.

Service Email: info@getpreggo.com