

Human Sperm SP10 Protein Rapid Test Cassette(Colloidal Gold)

Cassette

Instruction for Use

A lateral flow immunochromatographic assay for the qualitative detection of sperm concentration in human sperm specimen.



In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION

1T/box, 10T/box, 20T/box, 25T/box, 40T/box, 50T/box

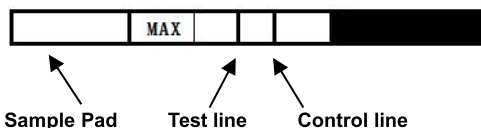
INTENDED USE

The Human Sperm SP10 Protein Rapid Test Cassette (Colloidal Gold) is a rapid test for qualitative detection of sperm concentration in human semen, as an aid in the determination of a man's fertility status.

SUMMARY

WHO "Human Semen Testing and Processing Laboratory Manual" (fifth edition) mentioned that the main factors affecting male infertility are: semen volume, total sperm, sperm concentration, liquefaction time, semen pH value, sperm normal form rate, and sperm concentration detection is an important indicator of male infertility. In this manual, the minimum normal sperm concentration is 15×10^6 sperm/mL, and when the sperm concentration is less than 15×10^6 sperm/mL, it is considered to have fertility difficulties. But male infertility needs to be combined with some other indicators to make a final judgment. Based on several anatomical, genetic, and biochemical characteristics, the SP10 protein has been shown to be an analyte of choice for sperm concentration detection. It is only expressed in the testis and is a differentiation marker for the last step in spermatogenesis. According to the research data, the concentration of SP10 protein has a certain linear relationship with the concentration of sperm, that is, when the concentration of sperm is $\geq 15 \times 10^6$ /mL, the detection of SP10 protein is positive. Therefore, the sperm concentration can be used to assist the diagnosis of male infertility and observe the curative effect, and provide guidance for the fertility planning of the appropriate age couples.

PRINCIPLE



SP10 is a protein that only expressed in testis and has been verified as an analyte for Sperm Concentration test. The concentration of SP10 is proportion to the concentration of sperm. When the sperm concentration is more than 15×10^6 /mL, the result is positive. This sperm concentration test can be used as an aid in diagnosis and treatment observation of male infertility. When the sample is added into the specimen well, capillary action carries the specimen to migrate along the membrane. When the sperm levels in specimens are at or above the target cutoff, there is a visible colored band in the Test Region(T) and indicates a positive result. Absence of this colored band in the Test region (T) suggests a negative result.

PRECAUTIONS

1. The best collection time should be 2 to 7 days from the last ejaculation, collect semen in shorter than 2 days or longer than 7 days will affect the accuracy of the test results.
2. The test cassette is disposable. Do not reuse the test cassette.
3. Do not use the test cassette beyond the expiration date.
4. Do not use the test cassette if the pouch is punctured or not well sealed.
5. Please use flesh semen sample. Do not use any lubricants or lotions, and do not collect semen from condom which may influence the test result.
6. The result can't reflect the quality of the semen if only part of semen is collected or some of the semen is spilled out.
7. The sample should be liquefied semen; the semen liquefaction process should be no more than 60 minutes. If the sample is not completely liquefied within 60 minutes, it is considered abnormal.
8. High testing temperature should be avoided.
9. The results should be interpreted by physicians along with clinical features and other laboratory test results. For any problem or suggestion, please contact the manufacturer.

MATERIAL

Material provided:

- 1) Test devices in one pouch. The test strip is sealed in a foil pouch with a package of desiccant;
- 2) Semen transfer device, one semen collection cup.
- 3) Bottle of buffer solution.

- 4) Package insert (Instruction for use).

Material needed but not provided:

Timer (It can be a clock or watch)

STORAGE AND STABILITY

1. The test kit can be stored at room temperature (4°C-30°C) in the sealed pouch to the date of expiration.
2. Test strip should be used within 1 hour after opening the pack.
3. The test kits should be kept away from direct sunlight, moisture and heat.

Do not freeze

The stability of the kit under these storage conditions is 24 months.

SPECIMEN PREPARATION

WHEN TO COLLECT SEMEN FOR THE TEST?

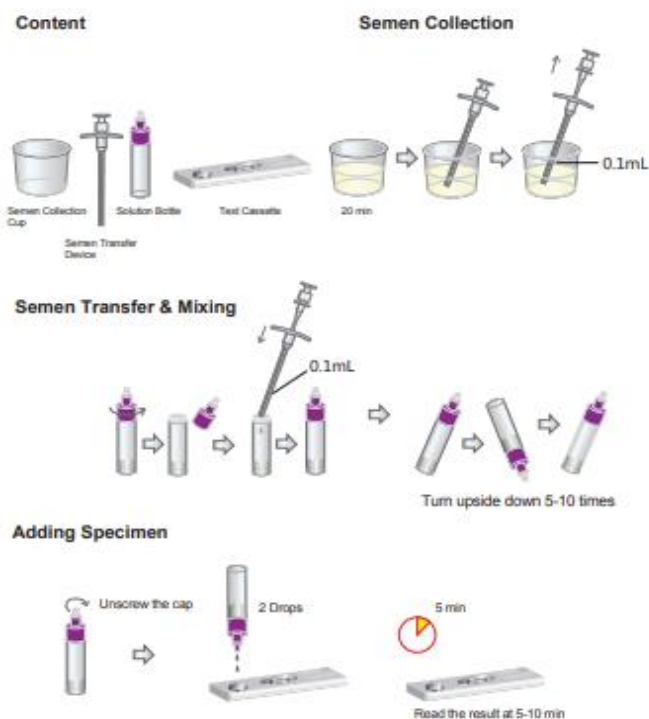
Wait at least 48 hours, but no more than seven days after your last ejaculation.

HOW TO COLLECT SEMEN?

1. Wash your hands and genitals with soap.
2. Collect your semen sample by manual stimulation (masturbation), in the semen collection cup provided.
3. Ejaculate directly into the semen collection cup without losing any portion of the semen. Do not use a condom to collect the sample. (If you do lose any semen, discard the sample, rinse the cup with tap water only and let it air dry before using it again. Do not use soap or detergent to wash the cup. Wait at least 48 hours, but no more than seven days to recollect a new semen sample.)
4. After collecting the sample, let the cup stand upright on a flat surface.
5. Samples may be tested up to 3 hours after collection. Discard sample if not tested within 3 hours and wait at least 48 hours to obtain a fresh sample to test.
6. When you are ready to test, follow the instructions in the next section, 'HOW TO DO THE TEST'.

TEST PROCEDURE

1. Gently shake the collection cup with semen then let the sample standing for at least twenty(20) minutes, but no more than 60 minutes for the semen to become thin (liquefied) before testing. (The semen sample is too thick for test immediately after ejaculation).
2. Gently stir the sample in the collection cup with the semen transfer device for 10 times.
3. Unscrew the cap of the solution bottle. Pull plunger of transfer device to draw semen up to the raised frosted line (0.1mL). Transfer 0.1mL of the sample into the solution bottle, avoid any bubbles.
4. Screw the cap of solution bottle tightly and gently mix the sample thoroughly. It's recommended to turn the solution bottle upside down for 5-10 times.
5. Let the solution bottle standing for 2 minutes.
6. Remove the testing cassette from the sealed pouch by tearing at the notch and place the testing cassette on a flat surface.
7. Unscrew the smaller cap of the solution bottle, and add 2 full drops of the semen sample on the sample well of the cassette vertically.
8. Wait for 5-10 minutes and read the result. Do not read results before 5 minutes or after 10 minutes.



*The picture is only for reference; please make the object as the standard.

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INTERPRETATION OF RESULTS

(Please refer to the illustration)

Positive (+)

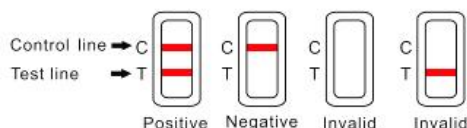
Colored bands are visible in both the control region (C) and the test region (T). It indicates a positive result (the sperm concentration $\geq 15 \times 10^6$ /mL).

Negative (-)

A colored band is visible only in the control region (C). No color band appears in the test region (T). It indicates a negative result (the sperm concentration $< 15 \times 10^6$ /mL).

Invalid

No visible band at both region, or there is a visible band only in the test region but not in the control region. Repeat with a new test cassette. Please make sure the adding sample volume is enough. If the test still fails, please contact the distributor for technical assistance.



PERFORMANCE

Detection Limit (Analytical Sensitivity): 15×10^6 /mL

Accuracy: A comparison study using 204 male semen samples, demonstrated good correlation with microscopic method.

Comparison between the Sperm Concentration Test and the microscopic method for the 204 clinical samples; the positive conformity rate is 97.95%, the negative conformity rate is 91.38%

LIMITATION OF THE PROCEDURE

1. This test is just for preliminary screening of the sperm concentration. The test result should be evaluated with other clinical and laboratory data available. If the test results do not agree with the clinical evaluation, additional tests should be performed.
2. This test is just for qualitative detection, for quantitative detection, medical professional testis suggested.
3. The test does not check the motility of the sperm, nor the morphology or genetic defects of the sperm which are additional factors that influence fertility.

FREQUENTLY ASKED QUESTIONS (FAQ)

1. What should I do if the test result is invalid?
If it is invalid, you should take a new test kit to do the test again.
2. What does it mean if the test result is positive?
Positive results show that the sperm concentration of specimens is at or above the target cutoff. It indicates that your sperm concentration is fall within the WHO reference values (i.e. > 15 million sperm/mL of semen).
3. What does it mean if the test result is negative?
Negative results show that the sperm concentration of specimens is lower than the target cutoff (15×10^6 /mL). It may indicate the oligozoospermia and male factor infertility. For further detail you should consult with your doctor. A negative result does not mean that a pregnancy cannot occur and it should not be used as a reason for avoiding use of contraception.
4. Can I read the test result before 5 minutes or more than 10 minutes?
No, test results must be read at 5-10 minutes. Though a positive result should not change for several days, but a negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading.
5. When to do this test?
Wait at least 48 hours, but no more than seven days after your last ejaculation.

BIBLIOGRAPHY

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5. Counsel M, Bellinge R, Burton P. Vitality of oligozoospermic semen samples is improved by both swim-up and density gradient centrifugation before cryopreservation. J Assist Reprod Genet. 2004;21(5):137-42.
6. Wang C, Swerdloff RS. Limitations of semen analysis as a test of male fertility and anticipated needs from newer tests. Fertil Steril.

Code:GKPD049-1 Effective date: May,28,2024

Index of Symbols

	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
	Temperature scope within which the product is reserved		Batch number
	Catalog #		Tests / box
	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Manufacturer:

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