



## David Male Fertility Sperm Test For Home use

### INDICATIONS FOR USE

(Catalogue Number:RH-SP10-C, Model: CASSETTE)

For accurate results, you must follow the instructions for each step.

1. Read and understand the entire instruction pamphlet.
2. Check the package contents to ensure you have everything required.
3. **【TEST PROCEDURE】 STEP 1: Collect your Semen Sample**--Collect a semen sample between 48 hours and seven (7) days after your last ejaculation.
4. **【TEST PROCEDURE】 STEP 2. Preparation of Sample**--Let semen stand at least 20 minutes the Semen Collection Cup before testing.
5. **【TEST PROCEDURE】 STEP 3. Perform the test**
6. **【INTERPRETATION OF RESULTS】**

### 【INTENDED USE】

David Male Fertility Sperm Test is a rapid test for use at home to detect the concentration of sperm in semen. This simple test will quickly let you know whether your sperm count is considered within normal limits.

David Male Fertility Sperm Test is a quick screening test that will give you either a positive or negative result.

An explanation of how to read and interpret the test results is given in the "Interpret Results" Section. Regardless of the test result, it is important that you fully understand what your test means before deciding whether or not to consult your physician. Use only in accordance with the instructions provided.

### 【WARNINGS AND PRECAUTIONS】

1. For in vitro diagnostic use (not for internal use).
2. Do not use this test beyond the expiry date printed on the package.
3. Do not use the test device if the pouch is torn or not well sealed.
4. This test is intended for single use only. DO NOT REUSE.
5. Package contents may be disposed of in normal household waste after use.
6. Do not open the test kit foil pouch until specimen is collected and ready to be tested.
7. Incomplete semen sample can not be used for test.
8. Do not touch the result window and sample well of the cassette to avoid contaminations.
9. Do not mix different samples and dilution of different

lots.

### 【PRINCIPLE OF METHOD】

This assay is a one-step lateral flow two-site sandwich chromatographic immunoassay. The membrane is pre-coated with mouse anti-human sperm antigen monoclonal antibody on the test band region(T line) and goat anti-mouse IgG polyclonal antibody on the control band region(C line).

When sample is added, the gold-antibody conjugate is rehydrated and sperm antigens interact with the gold conjugated antibodies. The antigen-antibody-gold complex then migrates towards the test window until the Test region (T) where it will be captured by immobilized antibodies, forming a visible pink line (Test band), indicating a positive result.

### 【PACKAGE CONTENTS】

#### REAGENTS AND MATERIALS SUPPLIED

1. Each device individually sealed in a foil pouch. Each pouch contains: (1) Test device ; (2) Desiccant.
2. a Sperm Transfer Device (in a sealed pouch)
3. a Sample Dilution Tube (including dilution)

#### MATERIALS REQUIRED ,BUT NOT SUPPLIED

1. Timer or watch
2. Semen collection cup(optional)

### 【STORAGE AND STABILITY】

1. The test kit can be stored at 2°C–35°C in the sealed pouch. It is stable through the expiration date printed on the pouch label. **Do not freeze.**
2. The test s must be used immediately once the desiccated pack is opened.

### 【TEST PROCEDURE】

#### STEP1: Collect your Semen Sample

1. Semen should be collected in a special semen collection container or clean plastic container.
2. Use artificial stimulation (masturbation) or other methods to obtain semen sample without using any lubricant and lotion; or use of non-toxic condoms specifically designed for semen collection. Lubricant on ordinary condom may affect the result.

Sample collected after getting up is the best choice. Semen collected by onanism ejaculation can not be used because the first part of ejaculation which is often of the highest

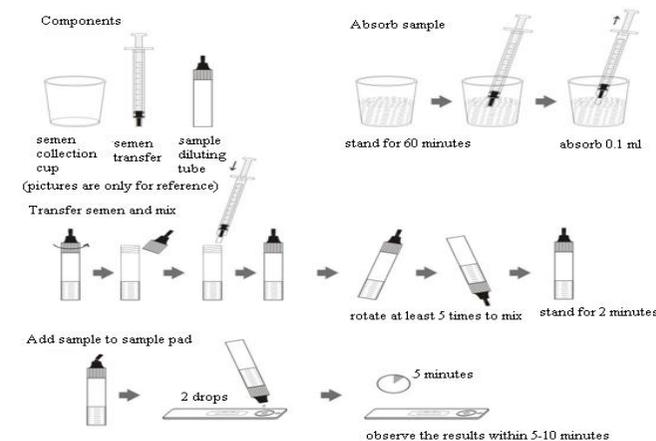
concentration may be lost and vaginal secretions inevitably mixed in will affect the accuracy of test result.

3. Semen sample collection time should be at least two(2) days after last ejaculation but not longer than seven(7) days. During this period spermiation like masturbation and nocturnal emission should not appear.

NOTE: Too short or too long period will affect the accuracy of the test.

4. Try best to collect all the semen and do not leave out. If there is semen leave out and have suspicion of the test result, a period of abstinence as long as last time is suggested before collect semen sample again.

5. Try best to use fresh semen samples for test (test within 3 hours after collection is recommended). When second time of detection is needed, store the sample (sealed) at 2~8°C for no longer than 12 hours. If longer time of storage is needed, stored at -20°C but thaw only one time.



#### STEP2. Preparation of Sample

- (1) Let semen stand the Semen Collection Cup before testing. Semen is too thick to be tested immediately after ejaculation, so you must wait at least 20 minutes for semen to become thin (liquefied).

NOTE: Liquefied semen sample should be thoroughly mixed in the original container, but can not be shaken vigorously.

If semen is not fully liquefied after 3 hours, it should be regarded as an exception and collecting samples again two days later is recommended. If situation is the same, you should consult a specialist.

(2) Use a sperm transfer to absorb 0.1 ml of fully liquefied semen sample and add to a tube containing sample dilution tube.

Note: Avoid gel or viscous substances in semen.

(3) Close the cap of sample dilution tube, shake until the semen sample dilution and semen sample are thoroughly mixed, rotate the tube at least 5-10 times, if the sample is still very dense or very viscous, rotate 10 times again. Finally allow the tube containing semen to stand for 2 minutes.

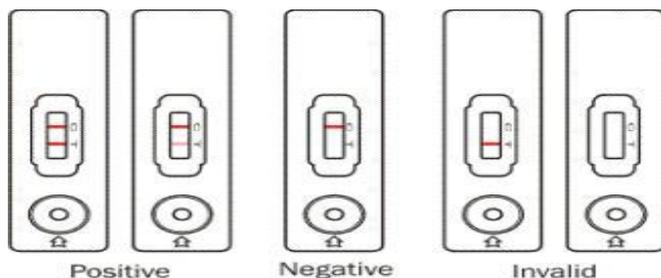
### STEP3. Perform the test

(1) Remove the test device from foil pouch. Use device as soon as possible within 1 hour after removal from pouch.

(2) Put it flat. Open the cap of dilution tube then add two drops of diluted sample directly to the sample pad of cassette, or use disposable plastic dropper supplied together with the test to absorb diluted semen specimen then add 2 drops of the sample dilution to the sample pad (should avoid air bubble).

(3) Start timing. Reaction result should be observed within 5-10 minutes. Result read after 10 minutes is invalid

### 【INTERPRETATION OF RESULTS】



**1.Negative result:** Only one red line appears in the control line (C) area, and there is no red line in the test line (T) area.

NOTE: A negative result indicates that your sperm count is less than 15 million per milliliter, which is below that of most fertile men. However, the result of this test alone does not prove infertility, as there are other factors affecting fertility. However, some men with sperm counts below this level are still able to father children naturally. It is also important to understand that your sperm count can vary from day to day. If there is any suspicion of test result, it is recommended to collect sample again after an interval of more than

seven days but less than three weeks for test again. If the result is still negative, it is recommended to consult a specialist.

**2.Positive result:** Two red lines appear. Red lines appear in test line (T) area and control line (C) area.

NOTE: Positive test result can not prove infertility but only prove that sperm concentration in the semen sample is not less than 15 million / ml because there are a variety of factors that cause infertility in addition to sperm concentration. If a couple can not conceive after a year or longer time of normal and unprotected intercourse, it is recommended to consult a specialist.

**3.Invalid result:** No visible bands appear at all, or no visible band shows at the control region even if there is colour at the test region. Repeat the test.

### 【LIMITATIONS】

1.This test kit can not be used to identify fatherhood or as indicator for contraception.

2.This test does not protect against sexually transmitted diseases.

3.This test assesses sperm concentration only. It can not determine the exact number of sperm. It does not detect all fertility issues.

4.The number of sperm varies widely so judgement can not be made after only one time of test. Once abnormal test results appear, sample should be collected again for test after an interval of 1 to 2. Usually 2 to 3 times of re-test is recommended.

5.At the test level, the following substances would not affect the test result:  $1 \times 10^7$  / mL escherichia coli,  $1 \times 10^7$  / mL neisseria gonorrhoeae,  $1 \times 10^7$  / mL chlamydia trachomatis,  $20\mu\text{g}$  / mL testosterone,  $20\mu\text{g}$  / mL of estradiol, 10% of whole blood,  $200 \times 10^6$  / ml leukocytes, 10% of saliva, 10% of urine.

6.This test kit is only used to evaluate sperm concentration through detection of sperm marker protein SP10. The lowest concentration at which hook effect appears is 423 million/mL.

7.Sperm concentration is only one factor that could impact a man's fertility status and time to pregnancy. For complete assessment of male reproductive health, the user should consult a physician.

8.The following situations may cause inaccurate results.

(1) Not collecting the entire ejaculate, especially the first drops of the ejaculate.

(2) The semen sample was collected less than 48 hours or more than seven (7) days after your last ejaculation. This may lead to inaccurate results.

(3) Failure of the ejaculate to liquefy

(4) The semen in the Sample Collection Cup was not mixed well enough before it was added to the Sperm Solution Tube.

(5) The semen-solution mixture in the Sperm solution tube was not mixed well enough before it was added to the test device.

(6) Too little or too much semen-solution mixture was added to the sample well.

### 【PERFORMANCE CHARACTERISTICS】

1.Limit of detection: When use quality control samples of company to for testing, detection limit of sperm concentration shall be  $15 \times 10^6$  / ml

2. Specificity: When test specificity control samples including 1000ng / mL prostate specific antigen (PSA), 1000ng / mL prostatic acid phosphatase (PAP), results should be negative

### 【References】

1. WHO Laboratory Manual For Human Semen (Version 5).

### 【MANUFACTURER】

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Document number : RH-JS-SP10-C,

Version 201901-C01-A

Effective Date:2019-01-16

INDEX of SYMBOLS			
	Manufacturer		Keep dry
	Date of manufacture		Temperature limit
	Use-by-Date		Do not re-use
	Batch/Lot code		Consult instructions
	Catalogue number		Caution
	Contains < n > tests		In vitro Diagnostics