

# Male Fertility Test Instructions

Please read these instructions carefully before performing the test.

## Intended Use

The OVR Y Male Fertility Test is a rapid one step assay designed for qualitative detection of Sperm SP10 Protein in semen.

The OVR Y Male Fertility Test identifies lower than normal sperm concentration in semen. The test is intended for at-home use and provides a qualitative visual result.

The OVR Y Male Fertility Test indicates if a user's sperm concentration meets the normal level of 15 million sperm per millilitre (as set by the World Health Organization). **This test alone does not prove whether or not you are fertile.** However, since sperm concentration is one of the leading indicators of male infertility, a negative result with an OVR Y Male Fertility Test (which would suggest low sperm concentration) can be valuable insight to help inform a proactive decision to visit a physician for further semen analysis.

## How does the test detect low sperm concentration?

The OVR Y Male Fertility Test is a qualitative immunoassay for the detection of sperm SP10 protein in semen. Based on anatomical, genetic and biochemical characteristics, sperm SP10 protein has been proven as an analyzer for sperm concentration detection. It is only expressed in the testis and is a differentiation marker, the last step in spermatogenesis. Sperm SP10 protein concentration and sperm concentration have a linear relationship; research has shown that when sperm concentration is more than 15 million sperm per milliliter that SP10 protein detection showed positive.

## How important is sperm concentration?

According to the World Health Organization (WHO), the main factors affecting male infertility are sperm concentration, semen volume, total sperm count, liquefaction, sperm pH, sperm motility and sperm morphology. Therefore, a definitive diagnosis for male infertility must consider many factors. Since the OVR Y Male Fertility Test only measures sperm concentration, using this test alone is not enough to determine whether or not a person is fertile. However, since lower than normal sperm concentration is an important indicator of male infertility, this test is a helpful and proactive step to identify possible obstacles for people trying to conceive.

In the test procedure, SP10 monoclonal antibody is immobilized in the test line region of the device. After a specimen is placed in the specimen well, it reacts with SP10 monoclonal antibody-coated particles that have been applied to the specimen pad. This mixture migrates chromatographically and interacts with the immobilized SP10 monoclonal antibody. This mixture binds to the SP10 monoclonal antibody in the test region (T) and produces a colored line when SP10 protein is equal to or greater than 15 million sperm per milliliter, indicating a positive result. No apparent colored line appears in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region (C) indicating that a proper volume of specimen has been added and membrane wicking has occurred.

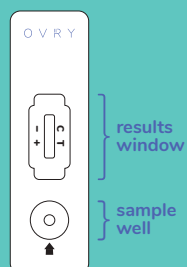
## Package Contents

Test pouch contains:

1 x Test Device

1 x Dropper

1 x Collection Tube



1 x Sample Collection Cup



Additional Materials Required (Not Provided):

- Timer (watch, clock or smartphone)

### Precautions

- Do not use after the expiration date
- Do not reuse
- Device should remain sealed in its pouch until use
- Test kit contents should be discarded after use
- For in vitro diagnostic use only
- Keep out of children's reach
- Do not use lubricants or lotions when collecting semen

## How to perform the test

Important: When and how to collect the semen sample

- 1 Use a fresh semen sample collected 2-7 days from the last ejaculation.
- 2 The Sample Collection Cup should be clean, dry, and free from any contaminants and detergents.

- 3 For the most reliable results, masturbation that is free from lubricants and lotions is the recommended method for obtaining the sample.
- 4 After the semen sample is collected, it needs to sit for 1 hour (as noted in the following step-by-step procedure) before the test can be performed. Do not perform the test more than 3 hours after the semen sample is collected.

## Step 1

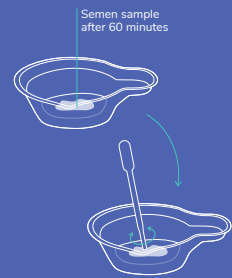
Ejaculate all semen directly into the Sample Collection Cup. All of the semen needs to make it into the cup. If some of the semen does not make it into the cup, rinse out the Sample Collection Cup with clean water only (no detergents or cleaning products) and let it air dry. Wait for at least two days to try testing again with a new, fresh semen sample.

## Step 2

On a flat surface, set aside the Sample Collection Cup for 1 hour. This allotted time allows the semen to undergo liquefaction - a process where the gel-like semen becomes more watery. The remaining steps should be completed no sooner than 1 hour after the semen was collected and no later than 3 hours after the semen was collected.

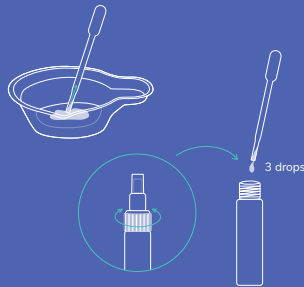
## Step 3

Once the semen sample has been standing for at least 1 hour, open the Test Pouch and remove the Dropper. Use the Dropper to gently stir the semen sample in the Sample Collection Cup about 10 times until it is well mixed.



## Step 4

Collect semen from the Sample Collection Cup using the Dropper. Unscrew the colored cap from the Collection Tube and transfer 3 drops of semen from the Dropper into the Collection Tube. Avoid drawing air bubbles into the Dropper containing the semen.



## Step 5

Tighten the colored cap of the Collection Tube and mix the contents by gently inverting the Collection Tube upside down and right side up 5 to 10 times. Do not vigorously shake the Collection Tube. If the sample still appears thick and gel-like, continue to invert and mix the Collection Tube another 10 times.

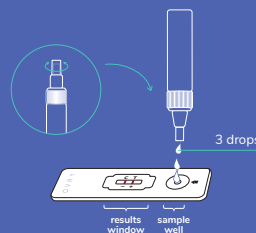


## Step 6

On a flat surface, set aside the Collection Tube for 2 minutes before proceeding.

## Step 7

Remove the Test Device from the Test Pouch and place it on a flat surface. Unscrew the small clear cap from the Collection Tube. Then holding the Collection Tube vertically above the **sample well**, transfer 3 drops of the mixture into the sample well on the Test Device. **NOTE: Do not transfer any substance directly into the results window.**

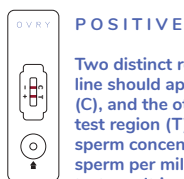


## Step 8

Read the results in 5 minutes, following instructions under the "Reading the Results" section. Do not interpret results before 5 minutes or after 10 minutes.

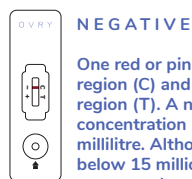
# Reading the Results

**NOTE:** The relative strength/darkness of the test line (T) and the control line (C) is irrelevant and does not matter. To read the results, determine whether the control line (C) and the test line (T) are present.



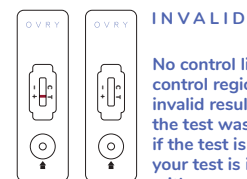
### POSITIVE

Two distinct red or pink lines appear. One line should appear in the control region (C), and the other should appear in the test region (T). A positive result indicates sperm concentration is at least 15 million sperm per millilitre. Although a positive test result is a good indicator of fertility, other factors can affect male fertility. Therefore, if you are experiencing trouble trying to conceive, it may still be prudent to see a physician for further testing.



### NEGATIVE

One red or pink line appears in the control region (C) and no line appears in the test region (T). A negative result indicates sperm concentration is below 15 million sperm per millilitre. Although sperm concentrations below 15 million sperm per millilitre suggests the possibility of infertility, other factors can affect male fertility. A negative result does not indicate certain infertility, and it is still possible to conceive. However, for those struggling to conceive, a negative test result suggests that further testing by your physician is prudent.



### INVALID

No control line (C) appears in the control region (C). This indicates an invalid result. Invalid results can occur if the test was not performed correctly or if the test is not working properly. If your test is invalid, repeat the procedure with a new OVRY Male Fertility Test. If your second test is also invalid, please contact customer support.

### Quality Control

The test includes internal procedural controls. A red or pink line should always appear in the control region (C) regardless of the positive or negative results. The appearance of a control line (C) indicates that the test has been performed correctly. It confirms sufficient specimen volume and correct procedural technique.

### Storage and Stability

- The Test Device should be stored in its sealed pouch at 2°C - 30°C (36°F - 86°F).
- The Test Device is stable until the expiration date printed on the pouch.
- Do not freeze the Test Device or any of the package contents.
- Keep the Test Device and package contents away from direct sunlight, moisture and heat.

### Limitations

- This test screens for sperm concentration by detecting SP10 protein in semen only.
- A negative test result does not prove male infertility, and a positive test result does not prove male fertility. **The results are only a reference index for male fertility; they should be combined with other clinical and laboratory analysis to produce a full evaluation of a user's fertility.**
- As with all diagnostic tests, a definitive diagnosis should not be based on the result of a single test but should instead be made by a physician after more extensive evaluation.
- This test does not protect against sexually transmitted infections.
- This test cannot be used to prove paternity.
- This test cannot be used as a form of contraception.
- This test cannot determine a quantitative value of SP10 protein in semen.
- Physical illness, medical conditions, illegal substances, certain medications and/or prescriptions may interfere with the result. If you get an unexpected result, it is recommended that you consult with a physician.
- Sperm concentration can vary from day to day, and may improve with lifestyle changes. Therefore it is possible to get different results between two testing occurrences if significant lifestyle changes have occurred in that time.

### Potential reasons for false results

- The semen sample was collected less than two (2) days or more than seven (7) days after the last ejaculation, which could cause inaccurate results.
- The entire ejaculate was not collected, including the first few drops of semen.
- The ejaculate did not liquefy between Steps 2 and 3.
- The semen in the Sample Collection Cup was not mixed well enough before it was added to the Collection Tube (Step 3).
- Too much or too little semen was added to the Collection Tube.
- Air bubbles were drawn into the Dropper during the transfer of semen from the Collection Cup to the Collection Tube (Step 4).
- The semen-solution mixture in the Collection Tube was not mixed well enough before it was added to the Test Device (Step 5).
- Step 6 was skipped and the semen-solution mixture from Step 5 was used on the Test Device too soon. The semen-solution mixture from Step 5 should stand for 2 minutes before proceeding to Step 7.
- Too much or too little semen-solution mixture was added to the sample well (Step 7). Three (3) drops from the Collection Tube should be added to the sample well on the Test Device.
- The semen-solution mixture was added to the results window on the Test Device instead of the sample well. The sample well is the round opening on the Test Device (Step 7).
- The test results were interpreted too early or too late. The test results should be read between five (5) to ten (10) minutes after the semen-solution mixture is added to the sample well (Step 8).
- Poor vision, color blindness or poor lighting may affect a person's ability to correctly interpret the result.

Questions or comments?  
We'd love to hear from you!

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visit us online at [www.myovry.com](http://www.myovry.com)

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