

Instant-View® One-Step Ovulation Check

*For In Vitro Diagnostic Use (Not for Internal Use)
Store At Room Temperature*

REAGENTS AND MATERIALS SUPPLIED

Six test devices sealed in a foil pouch with a desiccant pack.

STORAGE

Store the kit at room temperature (15-30°C). Kit contents are stable for at least 2 years or until the expiration date printed on the label, whichever comes first. Do not freeze the kit as this may cause the device not to work properly. Exposing the kit to temperatures over 30°C may damage or reduce the shelf life of the components. Do not use the device if the foil pouch is broken or if the device has been exposed to air for over 30 minutes.

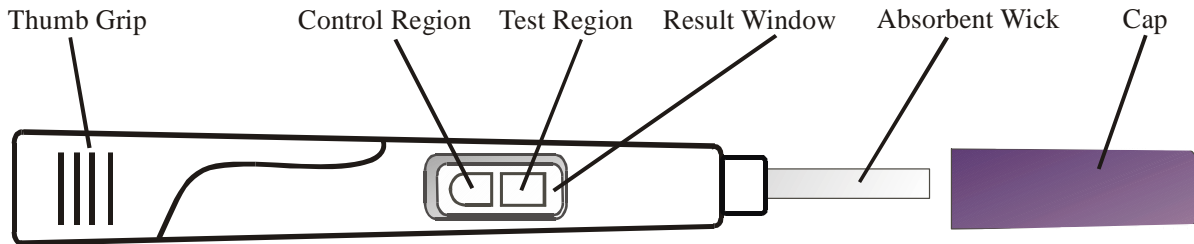
Do not freeze and/or expose the kit to temperatures over 30°C (86°F).



HOW DOES THE TEST WORK?

The detection of a woman's human luteinizing hormone (hLH) "surge" has been used successfully as an aid in ovulation predicting. Ovulation is regulated by the elevation of hLH. Usually, hLH remains at a basal level in a menstrual cycle and has a brief, significant rapid increase (LH surge) around 14 days before the next period starts. The hLH surge triggers ovulation – the release of an egg or eggs from the ovary. Then hLH returns to its basal line 2 to 3 days after ovulation. Studies have shown that conception is most likely to happen within thirty-six hours following the hLH surge. The Ovulation One-Step Check utilizes antibodies highly specific to hLH. If you obtain a positive result after this test, it indicates that you may ovulate within thirty-six hours.

THE STRUCTURE OF THE TEST:



WHEN WOULD BE THE BEST TIME OF THE DAY TO DO THE TEST?

You may perform the test any time of the day. Avoid drinking large amounts of liquid for half an hour before testing since this may dilute the LH in your urine.

WHEN SHOULD I START THE hLH TESTING?

Use the cycle chart as a reference to start testing. Cycle length is the number of days from the day your period begins to the day before your next period begins.

CYCLE LENGTH (DAYS)	
21	
22	
23	
24	
25	
26	
27	
28	
29	
30	
31	
32	
33	
34	
35	
36	
37	
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DAY OF CYCLE TO START TESTING	
5	
6	
7	
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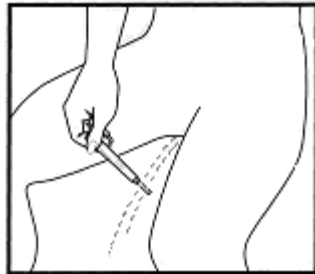
*If cycle length is more than 39 days, consult your doctor.

WHAT ARE THE LIMITATIONS OF THE TEST?

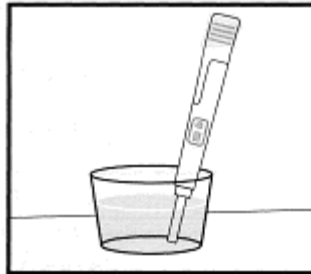
1. This test is not intended for any use other than early detection of a woman's human luteinizing hormone (hLH) surge. It is not intended for contraception.
2. Some disorders are related to the elevated levels of hLH, such as polycystic ovary syndrome.
3. Negative results may be obtained when the specimen is diluted too much.

HOW TO DO THE TEST?

1. Remove the test device from the foil pouch and uncap the device before testing.
2. **a. Midstream Method:** Simply hold the Thumb Grip and place the absorbent wick of the device into your urine stream for about 10 seconds.
b. Optional procedure: If you prefer, you may collect urine in a cup or container, then dip the absorbent wick into the urine. Make sure that at least 4/5 of the wick is submerged into the urine collected. Do not get the plastic body wet. Keep the absorbent wick in urine for about 10 seconds, and then take it out.
3. Re-cap the Test Device and place it on a flat surface. Wait for 5 minutes, then read the results displayed in the Results Window.
4. Strong positive results may be evident in 1-3 minutes. Weak positive results may take more time, up to 5 minutes, to become visible. Do not read results after 7 minutes. The device cannot be reused.



A. Midstream Method



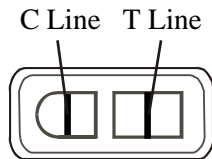
B. Optional Procedure

HOW TO READ THE RESULTS

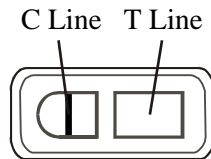
POSITIVE: If you see two lines (the **C line** in control region and the **T line** in test region) in the Results Window, hLH has been detected in your urine and you are likely to have an ovulation within thirty-six hours.

NEGATIVE: If you see only the **C line** in the control region, hLH surge has not been detected.

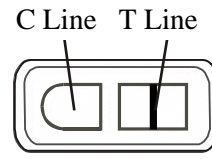
INVALID: If no band appears in the control region, the result is invalid. In this case, review the procedure carefully and repeat test with a new device.



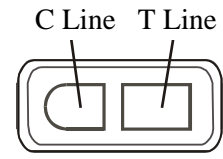
POSITIVE
(Both C Line and T Line are Visible)



NEGATIVE
(Only C Line is Visible)



(No C Line)



INVALID
(No C Line or T Line)

WHAT IS THE FUNCTION OF THE CONTROL LINE?

It is a built-in quality control feature. The appearance of the burgundy C line indicates that the test has been performed correctly. It should always appear regardless of the status of the hLH surge. If the control line does not appear within 5 minutes, the result is invalid. In this case, review the section "How to do the test" and repeat test with a new device.

IF THE T LINE IS VERY FAINT?

The intensity of T line is related to the concentration of the hLH in the urine. A faint T line indicates a low level of hLH. It is still a positive result indicating that you are likely in hLH surge or have a high baseline.

IF RESULTS NEGATIVE AND SUSPICIOUS?

Repeat the test with a new device and with fresh urine. Follow the procedure exactly when testing. If you still get uncertain results, seek advice from your doctor.

IS THIS TEST RELIABLE?

Yes, in the consumer study, over 95% of the women varying in ages and backgrounds were able to follow the package insert instructions and obtain the correct results as confirmed by professionals. This device was also compared to another commercially available ovulation test in a laboratory study. The accuracy by comparison is greater than 99%.

ASSISTANCE

Should you have any questions regarding the Instant-View® Ovulation Test, please call
1(877) 204-5071

Weekdays from 8:30 AM to 5 PM (Pacific Standard Time).