

EXPLANATION OF THE TEST

Ovulation is the release of an egg from the ovary. The egg then passes into the fallopian tube where it is ready to be fertilized. In order for pregnancy to occur, the egg must be fertilized by sperm within 24 hours after its release. Immediately prior to ovulation, the body produces a large amount of luteinizing hormone (LH) which triggers the release of a ripened egg from the ovary. This "LH surge" usually takes place in the middle of the menstrual cycle.

Asan EasyTest LH kit is a rapid chromatographic immunoassay for the detection of luteinizing hormone (LH) in urine to aid in the early detection of ovulation. And EasyTest LH is a complete system to help you predict the time of ovulation, and peak fertility. It is during this fertile time that pregnancy is most likely to occur.

MATERIALS PROVIDED

Asan EasyTest LH kit contains the following components:

1. Test devices individually foil-pouched with a desiccant
2. Dropper
3. Instruction manual for use

PRECAUTIONS

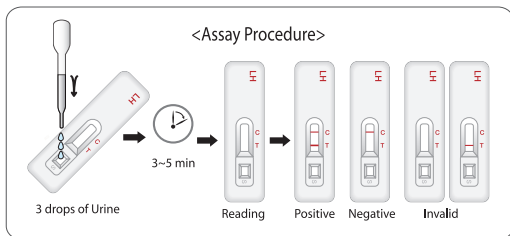
EasyTest LH should NOT be stored at freezing temperature (less than 2 °C). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date. Handle carefully all specimens as potentially infectious agent.

SPECIMEN COLLECTION AND STORAGE

1. The test should be performed using urine.
2. Specimens can be collected at any time of the day, but the FIRST MORNING URINE is best one for this test because it usually contains the highest concentration of LH hormone.
3. If specimens are not immediately tested, they should be refrigerated at 2~8 °C. For storage periods greater than three days, freezing is recommended and mixed well before testing.
4. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assay.

TEST PROCEDURE

1. Place all specimens, test devices, and allow them to room temperature prior to testing (15~30 min).
2. Remove the test device from the sealed pouch, and place it on a clean and level place.
3. Transfer 100 μ l of urine into the sample well (S). If you use the dropper, squeeze 3 drops of urine into the sample well.
4. Wait for the red or purple line in the test line to appear after the test begins to work.
5. Interpret the test result in 5~10 minutes. Do not read the result after 20 minutes.



INTERPRETATION OF THE RESULTS

A color band will appear in the upper section ("C" zone) of the window to show that the test is working properly. This band is control line (C). The down section ("T" zone) of the window (from the cap) indicates the testing result named as test band. If another color band appears in the down section of the window, this band is the test line (T).

1. Negative result:

The test line is of less intensity than the control line, or the test line is not visible. It means that LH level is not elevated (LH surge is not detected).



2. Positive result:

The test line is of equal or stronger intensity than the control line. It means that LH surge is detected.



3. Invalid result:

If at 10~20 minutes, the red color band does not appear in the control line (C), even if any shade of a pink-to-red test line (T) appears, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new test device.



STORAGE & EXPIRATION

1. Asan EasyTest LH kit should be stored between 2 to 30 °C (36~86 °F).
2. Expiration date of this kit is 18 months after its manufacture date.



LIMITATIONS OF THE TEST

Asan EasyTest LH is designed for primary screening test of ovulation. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view, collectively.

REFERENCES

1. A. Varga and E. Henriksen (1963) Urinary excretion assays of pituitary luteinizing hormone (LH) related to endometrial carcinoma. *Obstet. Gynecol.* 22:129-136.
2. J.S. Kesner, E.A. Knecht, E.F. Krieg, Jr. A.J. Wilcox, and J.F. O'Connor (1998) Detecting pre-ovulatory luteinizing hormone surges in urine. *Hum. Reprod.* 13: 15-21.
3. R. Bischof, P.G. Bianchi, and A. Campana (1991) Comparison of a rapid, quantitative and automated assay for urinary luteinizing hormone (LH), with an LH detection test, for the prediction of ovulation. *Hum. Reprod.* 6:515-518.