



Intended use

One Step LH Urine Ovulation Test is a self-performing Immunochromatographic one step assay designed for in vitro qualitative determination of human Luteinizing hormone (LH) in urine to predict when there is LH surge, and in turn, when you are likely to ovulate.

One Step LH Urine Ovulation Test is designed for both professional and lay users

Safety instructions

For in vitro diagnostic use only

- Read directions for use carefully before performing this test. Pay attention to the position of the C and T line.
- Do not use beyond the labeled expiration date.
- Do not reuse the test devices. Discard it in the dustbin after single use.
- Do not use if pouch is damaged or opened.
- Do not touch the membrane on the strip.
- Once you open the pouch, the test device should be used immediately. Prolonged exposure to ambient humidity will cause product deterioration.
- Treat urine samples and used devices as if they are potentially infectious. Avoid contact with skin.
- Make sure you have a urine sample cup before beginning (not included).

Materials provided

The test contains one test stick per foil pouch. Ingredients: Test device comprised colloidal gold coated with anti β -LH antibody; NC membrane coated with mouse anti α -LH antibody and rabbit anti mouse IgG.

Each pouch contains:

- Foil pouches A foil pouch contains one test stick and one desiccant (do not eat).
- Instructions for Use

Other equipment or reagents needed:

- A clean and dry container
- Timer

When to begin testing

First, determine the length of your menstrual cycle. This is the number of days from the first day of your menstrual bleeding to the day before your next bleeding begins again. Please refer to the chart to determine when you should start testing. If your cycle is shorter than 21 days or longer than 38 days, consult your doctor. If you do not know your cycle length, you may begin the test 11 days after your first period since the average cycle length is 28 days.

It is recommended that you use One Step LH Urine Ovulation Test twice a day in the morning (after 10am) and in the evening to more effectively and accurately catch your ovulation timing.

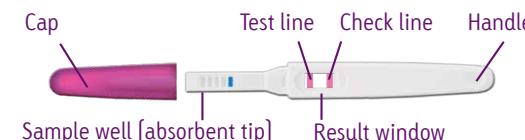
cycle length	Start to test on
21 days	Day 6
22 days	Day 6
23 days	Day 7
24 days	Day 7
25 days	Day 8
26 days	Day 9
27 days	Day 10
28 days	Day 11
29 days	Day 12
30 days	Day 13
31 days	Day 14
32 days	Day 15
33 days	Day 16
34 days	Day 17
35 days	Day 18
36 days	Day 19
37 days	Day 20
38 days	Day 21

Performing the test

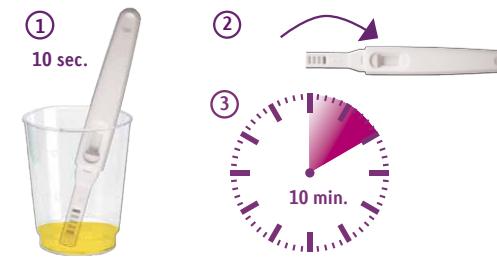
Specimen collection and handling

- Urine specimen must be collected in a clean and dry container.
- Collect urine at about the same time each day. For best results test between 10am-8pm.
- Reduce liquid intake about 2 hours before collecting your urine as a diluted urine sample may cause false negative result.
- Urine specimens exhibiting visible precipitates should be settled to obtain a clear specimen for testing.
- Bring the test pouch and urine to room temperature. To begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch and use it as soon as once opened.
- Hold the handle of the test with one hand. Use the other hand to remove the cap and expose the absorbent tip. Put the cap aside for re-cap later [See the picture].

Test procedure



1. Collect your urine into a clean container (not provided) and dip half of the absorbent pad into the urine for at least 10 seconds. You can also point the absorbent tip downward and place it in urine stream for at least 10 seconds until it is thoroughly wet.



2. Re-cap the device and wait for colored bands to appear. Read the result at 10 minutes.

3. Discard the test device after single use in the dustbin.

Do not read test result after 20 minutes.

Interpretation of results

Positive: If two color bands are visible and the test band is equal in color intensity or darker as compared to the control band, it is considered positive and you will probably ovulate within the next 24-48 hours.

Negative: Only one color band appears on the control region or the test band is lighter in color intensity as compared to the control band. There is no LH surge.

Invalid: No visible bands at all or only one purple reactive band appears on the test region. This indicates that the test failed or the strip is invalid. In this case it is recommended to repeat the test.



Quality control

Built in Quality Control Features

When the test is complete, you will see a pink-purple colored band in the "C" area of the test window on negative samples and a pink-purple colored band in the "T" and "C" area on positive samples. The appearance of the CONTROL band indicates that the test is performing properly and serves as a procedural control.

Use with the cyclotest® cycle computers

If you are using one of the cyclotest® cycle computers, the device calculates the start of your highly fertile phase and indicates it on the display.

In order to pinpoint even more accurately the time of optimum ability to conceive, you should now use the cyclotest® LH-Sticks. This ovulation test provides reliable indications as to whether and when ovulation occurs.

If the ovulation hormone has been detected, enter this information in the cycle computer. Refer to the notes in your cycle computer's instructions for use.

cyclotest® service hotline

You have no doubt read our notes on using the cyclotest® LH-Sticks carefully and familiarised yourself with its features.

If you have any further questions, you can call our cyclotest® service hotline, which is open from Mondays to Thursdays from 8.00 am to 5.00 pm and on Fridays until 4.30 pm.

Your team of cyclotest® advisers is looking forward to taking your call.

For customers from Germany:

cyclotest® service hotline
+49 (0) 93 42 / 92 40 40
www.cyclotest.de

For customers from Switzerland:

cyclotest® service hotline
052 / 224 41 47
www.cyclotest.ch

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Summary and Explanation

cyclotest® LH-Sticks are an in-vitro diagnostic aid for self-testing to verify the presence of the ovulation hormone LH in urine. Human Luteinizing hormone [LH] is a glycoprotein hormone secreted by the anterior pituitary. This hormone is composed of α and β subunits. The amino acid sequence of α -LH is essentially identical to that of other hormones including follicle stimulating hormone [FSH], thyroid stimulating hormone [TSH] and human Chorionic Gonadotropin [HCG]. It is the β subunit of LH that confers the biological and immunochemical specificity of the hormone [1].

LH and FSH together with other steroid hormones are known to play important roles in regulating the ovulation and ovarian functions during the menstrual cycle. Maturation of an ovarian follicle and its oocyte begins during the end of the preceding menstrual cycle. In response to FSH released by the pituitary, the follicle undergoes rapid growth. As follicles develop, estradiol secretion begins to rise slowly and is followed by a rapid increase. This increase of estradiol level is generally believed as the trigger for the rapid rise and peaking of LH activity at the mid-cycle [LH surge]. Approximately 24–48 hours after the LH surge, the wall of the enlarged follicle ruptures at ovulation and the mature ovum is extruded. After ovulation, LH returns to its base line level within two days with the concomitant increase of progesterone level to initiate luteal phase. The luteal phase lasts predictably about 14 days. Unless pregnancy occurs, a new follicle begins the selection procedure for maturation in the next menstrual cycle. In view of the characteristic variation of LH during the menstrual cycle, rapid and sensitive measurement of LH is an important tool in the diagnosis and management of infertility in females [2,3].

Detection of the LH surge can aid in predicting the time of ovulation. The onset of the LH surge precedes ovulation by approximately 30 hours [4]. The analysis of LH has been used successfully to time oocyte retrieval for in vitro fertilization [5,6] and would similarly assist timing of artificial insemination.

Mode of operation

The One Step LH Urine Ovulation Test is a rapid one-step test, based on an immunochromatographic technology. A membrane with an absorbent pad overlaps the strip of fibers glass paper that is impregnated with a lyophilized colloidal conjugate of gold particles and monoclonal solid phase antibodies to LH. Other absorbent pads at the end of the assay absorb excess sample fluid. The urine sample is introduced into the device and proceeds through the absorbent pad, then laterally onto a chromatographic membrane. As it contacts the membrane, the sample dissolves the lyophilized conjugate. In a reactive sample, the LH antigen will attach to the antibodies in the colloidal solution.

As the conjugate moves forward on the membrane, anti-LH monoclonal antibody affixed on the test zone ("T") will bind the LH-gold conjugate complex, forming a pink line ("T"). All samples will cause a pink colored line to appear in the control zone ("C"). This line is formed by the binding of the polyclonal antibodies (anti-mouse IgG) affixed onto the control zone to the sample-colloidal gold conjugate. Presence of this line indicates that the test has been carried out correctly.

1. Sensitivity

cyclotest® LH-Sticks will display positive results with specimens containing LH at a level greater than 25 mIU/ml. When urine LH level is less than 25 mIU/ml but greater than 10 mIU/ml, the test line will show a faint color which is lighter than the control line in its intensity.

2. Specificity

Specificity of the test was determined from cross reaction studies with known amounts of Follicle Stimulating Hormone [FSH], thyroid Stimulating Hormone [TSH] and Chorionic Gonadotropin [HCG]. Samples containing 25 mIU/ml HCG, 200 mIU/ml FSH and 250 μ IU/ml TSH yielded negative results.

3. Diagnostic Sensitivity and Specificity

A total of 48 female and 60 menstrual cycles were followed and monitored with the test. LH urine surge was detected in 47/60 cycles which was conformed by other clinical diagnostics methods including endometrial biopsy.

Clinical Accuracy of One Step LH Urine Ovulation Test

Urine test result/ Other Clinical test result	Clinical Test Positive	Clinical Test Negative	Total
Urine test positive	47	0	47
Urine test negative	0	13	13
Total	47	13	60

Diagnostic Sensitivity [Positive agreement] = 47 / [47 + 0] = 100 %. Diagnostic Specificity [Negative agreement] = 13 / [13 + 0] = 100 %. Comparison studies on the cyclotest® LH-Sticks with a legally marketed device were performed in-house and in a clinical reference laboratory. Positive and negative results were compared and the correlation was greater than 97 %.

4. Non-cross reacting compounds:

Acetaminophen	20 mg/dl
Acetosal	20 mg/dl
Salicylic Acid	20 mg/dl
Ascorbic Acid	20 mg/dl
Caffeine	20 mg/dl
Gentisic	20 mg/dl
Ampicillin	20 mg/dl
Tetracycline	20 mg/dl
Hemoglobin	1 mg/dl
Albumin	1000 mg/dl
Glucose	2 g/dl

5. Repeatability and Reproducibility

Three lots of the test were used and 10 strips of each lot were tested in LH standard solution with different concentrations prepared at 0,25 mIU/ml and 100 mIU/ml.

LH concen- tration	20030401		20030501		20030601		Varia- bility
	P	N	P	P	P	P	
0 mIU/ml	0	10	0	10	0	10	0%
25 mIU/ml	10	0	10	0	10	0	0%
100 mIU/ml	10	0	10	0	10	0	0%

P: positive, N: negative

All samples were positive at and beyond the cut-off level. No different results were observed.

Limitation of the procedure

- Keep strictly to the instructions provided in order to get reliable test results.
- Compare the color of the test band to that of the control band of the same device on the day the test is performed. Do not compare bands from different devices.
- Do not read test result after 20 minutes.
- The results of this test cannot be used as an aid for contraception.
- The test should not be used in the following conditions:
 - During or shortly after pregnancy
 - During /after the onset of menopause
 - After or during hormone treatment
- Avoid excess liquid intake during testing since it may dilute the amount of LH in the urine cause inaccurate result.
- Some diseases [e.g. polycystic ovaries, hormonal imbalance] can falsify the results of the test. In this case, a physician should be consulted.

- As it is true with any diagnostic procedure, the user should evaluate data obtained by the use of this kit in light of other clinical information and consult the physicians for the final diagnosis before making any decision of medical relevance.

Storage and stability

The test kit can be stored at temperature [4 °C to 30 °C] in the sealed pouch to the date of expiration. The test kits should be kept away from direct sunlight, moisture and heat.

Explanation of symbols

 Consult instructions for use

 Temperature limitation

 Manufacturer

 Keep dry

 Caution, see instructions for use

 Do not reuse

 Use by

 Contains sufficient for <n> tests

 In vitro diagnostic medical device

 Catalogue number

 Batch code

 Keep away from sunlight

 Do not use if package is damaged

 This test complies with Council Directive 98/79/EC of 1998 on in-vitro diagnostics and bears the CE 0123 mark [TÜV SÜD Product Service GmbH].

References

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