

One Step LH Ovulation Test (Midstream) User Manual

INTENDED USE

Please read all the information in this manual before performing the test. One Step LH Test Strip is an in-vitro diagnostic test device intended for the rapid determination of human Luteinizing Hormones (LH) in urine to predict when there is a LH surge, and in turn, when you are likely to ovulate. You can easily carry out yourself. It is intended for self-testing use. For in-vitro diagnostic use only.

HOW DOES IT WORK

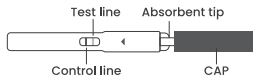
The LH (Luteinizing Hormone) which is in the urine of normal women will increase dramatically in the middle of the menstrual cycle. The LH increase triggers ovulation which is when the egg is released periodically from normal fertile women. WHO experts state that LH testing is a reliable way to detect ovulation. Ovulation will occur after 24-48 hours following a positive test. The ovulation test contains antibodies which specifically react with LH. When the sample end of the test is dipped in the urine specimen, the urine specimen is applied to the strip and migrates along the strip. A colored line will appear at the Control Zone region if the test has been performed properly. The control line also works as a reference line for you to find the LH peak time when the test line is as dark or darker than the control line.

REAGENTS

The test contains anti-LH particles and anti-LH antibody coated on the membrane.

PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test strip cannot be used more than once.
3. Do not use the test past the expiration date printed on the foil pouch.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children



STORAGE AND STABILITY

1. Store at 39°F to 86°F (4°C to 30°C) in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. DO NOT FREEZE.
4. You should perform the test soon after opening the pouch. You should keep the test in a dry environment before use.

SPECIMEN COLLECTION AND PREPARATION

1. Determine the optimal time for urine collection. For best results, collect urine at about the same time each day. Some women have found that their best specimen is after 12 noon. Do not collect the first urine specimen after waking up.
2. Reduce liquid intake approximately 2 hours prior to urine collection.
3. Record the date, cycle day and time of urine collection.

MATERIALS

Materials Provided

Test Midstream (s)	Leaflet with instructions for use.	Desiccant
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Materials Required but Not Provided

A clean, dry, plastic or glass container to collect the urine.	Timer or clock
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WHEN TO COLLECT URINE FOR TEST?

The length of the menstrual cycle is the duration from your first menstrual bleeding day to the day before the next bleeding begins. Determine the length of menstrual cycle before test. Please refer to the chart below to determine when you should start testing. If your cycle is shorter than 21 days or longer than 38 days, consult a physician. 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. Perform 1 test each day over a 5 days period, or until the LH surge has been detected.

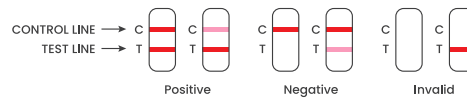
CYCLE CHART	CYCLE LENGTH		DAY OF CYCLE TO BEGIN TESTING	
	Days	Days	Day	Day
	21	days	day	5
	22	days	day	6
	23	days	day	7
	24	days	day	8
	25	days	day	9
	26	days	day	10
	27	days	day	11
	28	days	day	12
	29	days	day	13
	30	days	day	14
	31	days	day	15
	32	days	day	16
	33	days	day	17
	34	days	day	18
	35	days	day	19
	36	days	day	20
	37	days	day	21
	38	days	day	22
	39	days	day	23
	40	days	day	24

HOW TO USE

Read the entire procedure carefully before performing a test. The test midstream and urine have to be at room temperature 59°F - 86°F (15°C - 30°C) for testing.

1. Collect your urine sample in a dry and clean container.
2. Take out the LH test midstream from the foil wrapper, remove the test midstream cover.
3. Dip the absorbent tip into your urine sample and take out after 5 seconds, then lay the midstream flat on a clean dry, non-absorbent surface.
4. Read results in five minutes. Do not read results after 5 minutes.

TEST RESULT



Positive (LH Surge):

If two color bands are visible, and the test band is equal to or darker than the control band, one will probably ovulate in the next 24-48 hours. If trying to get pregnant, the best time to have intercourse is after 24 hours but before 48 hours.

Negative (No LH Surge):

Only one color band appears on the control region, or the test band appears but is lighter than the control band. This means there is no LH surge.

Invalid:

No visible band at all, or there is a visible band only in the test region and not in the control region. Repeat with a new test kit.

LIMITATIONS

1. The test works only when the test procedures are precisely followed.
2. This test may not be used as a form of birth control.
3. Consult a doctor if irregular or unusual long cycles are experienced.
4. The test results should not be affected by pain relievers, antibiotics and other common drugs. Medication containing hCG or LH may affect the test and should not be taken while using the One Step LH Ovulation Test (Midstream). In addition, the test will not work properly for subjects who are pregnant, in menopause, or are taking birth control pills.

PERFORMANCE CHARACTERISTICS

1. Sensitivity

One Step LH Test has a sensitivity of 25 mIU/ml.

2. Specificity

Cross reaction studies has been tested with known amounts of hormones. 200mIU/ml hFSH and 250uIU/ml hTSH were added to LH negative and positive specimens, no cross reaction were observed.

3. Interference Substance

The following potentially interfering substances were added to LH negative and positive specimens.

Acetaminophen, aspirin, ascorbic acid, atropine, caffeine, glucose, hemoglobin, tetracycline, ampicillin, albumin, bilirubin

4. Stability after first opening

The results of the package opened stability studies show that the product quality was stable and valid within 15 hours. Given variations in temperature and humidity that may occur, we suggest to use the test immediately after opening.

QUESTIONS & ANSWERS

1. **My cycle length is outside of the range shown in the table. How will I know when to start testing?** Simply start testing 17 days before you expect your next period.
2. **I do not know my usual cycle length. How will I know when to start testing?** If you wish to start using the test before knowing your cycle length, we recommend you to start testing on day 10.
3. **What time of day should I take the test?** You may test any time of the day, but you should test at approximately the same time each day. You should not have urinated for at least 4 hours before testing.
4. **There is much difference between the control lines of two tests. Is this a concern?** No. Variations in the color of the control band will not affect the test result. It is only effective to compare the color of the test band to that of the control band of the same device on the day the test is performed.
5. **Can test results be interpreted after more than five minutes?** No. Test results must be read at 5 minutes. Though a positive result should not change for several days, a negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading. It is always best to read the results at the 5 minute testing period and then discard the test to avoid confusion.
6. **How long should I continue to perform the test?** At least 5 days or until the LH surge has been detected.
7. **Do alcohol or common medications affect the test?** No, but you should consult your physician if you are taking any medication.
8. **Once I see a positive result, when is the best time to have intercourse?** Ovulation is likely to occur within 24-48 hours. This is your most fertile time. Sexual intercourse is advised within this time frame.
9. **Will the amount of liquid I drink affect the result?** We suggest that you limit your fluid intake for about two hours before you collect your urine. Because heavy intake of fluids prior to testing will dilute the hormone in your urine.

INDEX OF SYMBOLS

	Do not reuse		For in vitro diagnostic use only
	Store between 4-30°C		Consult instructions for use
	Manufacturer		Lot number
	Use by		Tests per kit
	Catalogue number		European Representative
	Date of Manufacture		Meet the requirements of 98/97/EC Directive
	No exposure to the sun		Keep it in a dry place

Co-Innovation Biotech Co., Ltd.
No. 9 Baihe 3 Street, Economic And Technological Development East Zone, Guangzhou 510530, Guangdong, China

Brand Holder: Lollipop Technology (Hangzhou) Co., Ltd.
8F Dongguan Building, No.618 Jiangnan Avenue, Binjiang District, 310000, Hangzhou, Zhejiang, China

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Eiffestrasse 80, 20537 Hamburg, Germany

Distributor: Biosmart Teknoloji A.Ş.

Eti Mah. Ali Suavi Cad. 9/A 06570 Çankaya, Ankara, Türkiye

Customer Service: info@biosmart.com.tr

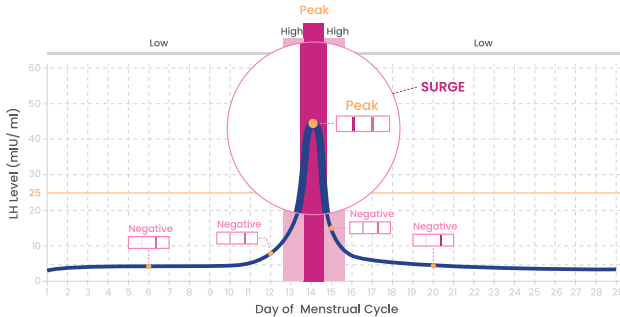
Quick Guide

please read carefully before use

How do Ovulation Test Midstream work?

Ovulation test strips detect the luteinizing hormone in urine when a surge is identified, the follicle ruptures and ovulation begins. Therefore, intercourse within 24 hours after a positive result – the test line is the same color or darker than the control line – will result in a high likelihood of conception.

Note: Some prescription drugs such as menotropins may affect the result. Certain medical conditions or the onset of menopause can cause elevated levels of LH. Some people do not ovulate every cycle and will not observe an increase of the LH hormone. Individuals with Poly Cystic Ovary Syndrome (PCOS) may not obtain dependable findings.



When to start testing?

The length of the menstrual cycle is the duration from the first day of bleeding to the day before the next one begins. Determine the length of your menstrual cycle before the test. The simplest method is by using the Femometer App. Otherwise, refer to the chart below if your cycle length varies by more than a few days, take the average of the last 3 months.

Consult a doctor if your cycle is shorter than 21 days or longer than 40 days.

It is vital to perform one test daily at a steady hour until the LH surge has been detected. When the first positive result occurs, test every four hours thereafter to capture the positive to negative moment.

LENGTH OF CYCLE	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
BEGIN TESTING	CD 5	CD 6	CD 7	CD 8	CD 9	CD 10	CD 11	CD 12	CD 13	CD 14	CD 15	CD 16	CD 17	CD 18	CD 19	CD 20	CD 21	CD 22	CD 23	CD 24

How to Use?

1. The test midstream and urine have to be at room temperature 59°F – 86°F (15°C – 30°C) for testing.
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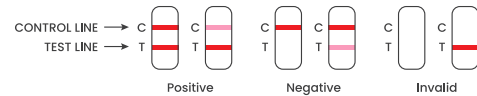
Interpretation of Results

Positive: If the test line is equal to or darker than the control line, the hormone surge indicates approaching ovulation. The ideal time for conception is after 24 hours but prior to 48 hours.

Negative: One line appears in the control region, or the test line is lighter than the control line. This indicates no LH surge.

Invalid: No color line appears in the control region (C), even if a line appears in the test region (T). In any event, repeat the test if this persists, discontinue using the lot and contact your local distributor.

NOTE: A color line appearing in the control region can be a basis for effective testing



Frequently Asked Questions

Q: When is the best time of the day to test?

A: Noon to early evening tests are the most accurate. A blood LH surge is common early in the morning, but is not presented in the urine until later in the day.

Q: Does this test replace the basal body temperature method (BBT)?

A: The LH Ovulation Rapid Test (Midstream) indicates that ovulation is about to occur. To conceive quicker, utilize both methods.

Q: How long should I continue to perform test?

A: Unless otherwise specified by a doctor, stop testing once the LH surge is detected positive to negative. To detect the LH surge, 5-10 days of testing might be required.

If you have any questions or concerns, please contact us at info@biosmart.com.tr.

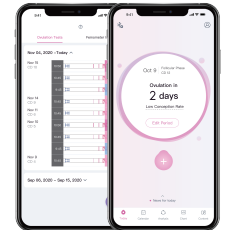
Femometer App Get pregnant quickly and naturally

- Read your test results – no more guessing!
- Visual results list, changes at a glance.
- Get your own cycle calendar and predictions.



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