

# LH Ovulation Rapid Test Midstream

CE 0197

## INTENDED USE

The LH Ovulation Rapid Test Midstream is a rapid one step assay designed for qualitative detection of human luteinizing hormone (LH) in urine to predict time of ovulation.

For self-testing and in vitro diagnostic use only.

## HOW DOES IT WORK

Luteinizing hormone (LH) in elevated quantities causes ovulation (the release of the egg from the ovarian follicle). Throughout the menstrual cycle, a small amount of LH is produced, but during the middle of the cycle LH briefly and dramatically increases. This increase is called the "LH surge" and precedes ovulation. Conception is most likely to occur within 24 to 48 hours following the LH surge. The LH Ovulation Rapid Test Midstream is specifically designed to detect your LH surge - the time when you are likely to ovulate. If you receive a positive on an LH test, you are in your most fertile phase of your menstrual cycle.

The test reagent is exposed to urine, allowing urine to migrate through the absorbent test strip. The labeled antibody-dye conjugate binds to the LH in the specimen forming an antibody-antigen complex. This complex binds to the anti-LH antibody in the test region (T) and produces a color line. In the absence of LH, there is no color line in the test region (T). The reaction mixture continues flowing through the absorbent device past the test region (T) and control region (C). Unbound conjugate binds to the reagents in the control region (C), producing a color line, demonstrating that the test midstream is functioning correctly. The test midstream can accurately detect your LH surge when the concentration of LH is equal to or greater than 25mIU/ml.

## WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Please read all the information in this leaflet before performing the test.
- Do not use the kit beyond the labeled expiry date.
- Do not open the sealed foil pouch until you are ready to start the test.
- Do not touch the membrane located within the Result Window.
- As with all diagnostic tests, a final clinical diagnosis should not be based on the results of a single test, but should only be made by a physician after all clinical and lab findings have been evaluated.
- Do not reuse the test midstream. Discard it in the dustbin after testing.
- All urine specimens and used strip should be considered potentially infectious and avoided contact with skin.

## COMPOSITION

The test midstream consists of colloidal gold-monoclonal antibody against LH coated on polyester membrane, and monoclonal antibody against LH and goat-anti-mouse IgG coated on cellulose nitrate membrane. Each pouch contains one test midstream and one desiccant. Each box contains one pouch and one instruction for use.

## STORAGE AND STABILITY

- Store as packaged in the sealed pouch at room temperature (4-30 °C or 40-86 °F). The kit is stable within the expiry date printed on the labeling.
- Once open the pouch, the test midstream should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.

## WHAT ELSE DO YOU NEED

- Specimen collection container
- Timer

## SPECIMEN

First morning urine is not recommended, but any other time of day is suitable. For best results, try to collect urine at approximately the same time between 10:00 A.M. and 8:00 P.M. each day. The urine specimen must be collected in a clean, dry container either plastic or glass.

## WHEN TO START TESTING

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 length is irregular, that is, if it varies by more than a few days each month take the average number of days for the last 3 months. If your cycle is shorter than 21 days or longer than 40 days, consult a physician. If you do not know your cycle length, you may begin the test 12 days after your first period since the average cycle length is 28 days. Perform one test each day over a 5 days period, or until the LH surge has been detected.

## Cycle Chart

Length of Normal Cycle (Total days)	Day of Cycle to Begin Testing	Length of Normal Cycle (Total days)	Day of Cycle to Begin Testing
21	Day 5	31	Day 15
22	Day 6	32	Day 16
23	Day 7	33	Day 17
24	Day 8	34	Day 18
25	Day 9	35	Day 19
26	Day 10	36	Day 20
27	Day 11	37	Day 21
28	Day 12	38	Day 22
29	Day 13	39	Day 23
30	Day 14	40	Day 24

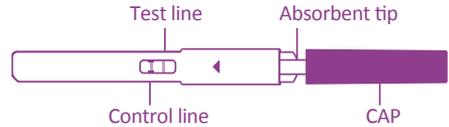
For example, if your period normally begins every 28 days, you should begin testing twelve (12) days after the beginning of your last period.

Sun.	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.
1	2	3	4	5	6	7
8	9*	10	11	12	13	14
15	16	17	18	19	20(s)	21
22	23	24	25	26	27	28
29	30	31				

**Note:** If the ninth (9th) in the calendar above is the first day (day one \*) of menstrual bleeding, then the 20th, or day twelve, of your cycle is the day to begin testing (s).

## TEST PROCEDURE

- Read the entire procedure carefully before performing any tests. Allow test midstream and urine specimen to equilibrate to room temperature (20-30 °C or 68-86 °F) prior to testing.



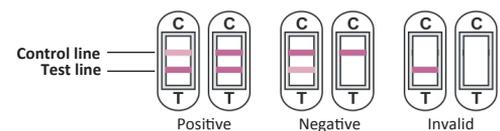
1. Remove the test midstream from the sealed pouch.
2. Remove the Cap and hold the midstream with the exposed Absorbent Tip pointing downward directly into your urine for at least 10 seconds until it is thoroughly wet.

- NOTE:** If you prefer, you can urinate into a clean and dry container, then dip only the Absorbent Tip of the midstream into the urine for at least 10 seconds.
3. After removing the midstream from your urine, immediately replace the Cap over the Absorbent Tip, lay the midstream on a flat surface, and then begin timing.
  4. Interpret the test results at 3-5 minutes.

**NOTE:** Do not read results after 10 minutes.

## INTERPRETATION OF RESULTS

To determine your result, compare the color intensity, i.e. shade of color, lightness or darkness of color, of the test line to the control line. In determining a positive or negative result, it is important to compare the color intensity, for this will indicate whether or not the LH surge (indicating ovulation) is in progress.



**Positive:** If the test line is equal to or darker than the control line, you are experiencing the hormone surge that indicates you will ovulate soon, usually within 24 to 48 hours of the surge. If you want to be pregnant, the best time to have intercourse is after 24 hours but before 48 hours.

**Negative:** Only one color line appears in the control region, or the test line appears but is lighter than the control line. This means there is no LH surge.

**Invalid:** The result is invalid if 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 the problem persists, discontinue using the lot immediately and contact your local distributor.

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

## PERFORMANCE CHARACTERISTICS

### Sensitivity and Specificity

The LH Ovulation Rapid Test Midstream will detect the concentration of LH is equal to or greater than 25mIU/ml (calibrated against WHO 2nd IS 80/552). The addition of Follicle Stimulating Hormone (FSH, 200mIU/ml, calibrated against WHO 1st IS 92/510) and Thyroid Stimulating Hormone (TSH, 250  $\mu$  IU/ml, calibrated against WHO 3rd IS 81/565) to negative specimens (0mIU/ml LH) showed that these hormones do not impact the test results.

### Cross-Reactivity

The following potentially interfering substances were added to either LH negative urine specimens or LH positive urine specimens, none of the substances at the concentration tested interfered in the assay.

Acetaminophen	20mg/dl
Acetosalicic Acid	20mg/dl
Ascorbic Acid	20mg/dl
Atropine	20mg/dl
Caffeine	20mg/dl
Gentisic Acid	20mg/dl
Glucose	2g/dl
Hemoglobin	10mg/dl
Ampicillin	20mg/dl
Tetracycline	20mg/dl
Bilirubin	2mg/dl

### Lay Person Study

60 native English-speaking females volunteers with age of 20~40, without any professional knowledge of rapid test, had participated in this experiment. They have different educational background. Questionnaire was also designed to assess the suitability of the IFU and the use of the device, concerning performing the test, reading the results, understanding the IFU, etc. The test results showed that all of the lay persons could detect the LH surge in their menstrual cycle.

## LIMITATIONS AND POSSIBLE ERRORS

- The test works only if the instructions are followed precisely. Although the LH Ovulation Rapid Test Midstream is highly accurate and sensitive in detecting ovulation, an extremely low incidence of false results (positive when no ovulation exists or negative when ovulation exists) can occur.
- The LH Ovulation Rapid Test Midstream should not be used for contraception.
- Some prescription drugs, such as menotropins may affect the test result. Certain rare medical conditions or the onset of menopause can cause elevated levels of LH. Some women do not ovulate every cycle and they will not see any increase in the level of LH hormone during these non-ovulating cycles. Women with Poly Cystic Ovary Syndrome (PCOS) may not get reliable results from ovulation tests. Please check with your doctor if you are unsure.
- Reduce your liquid intake for 2 hours before testing, since drinking excessive amounts of liquids can dilute the LH in your urine yielding a negative result when it should be positive.
- The LH Ovulation Rapid Test Midstream only detects the hormone surge that precedes ovulation; it can't tell if you will actually release an egg during your cycle.

## QUESTIONS & ANSWERS

### How accurate is the LH Ovulation Rapid Test Midstream?

In clinical trials, the LH Ovulation Rapid Test Midstream has been shown to be >99% accurate in detecting the LH surge.

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

The shift in basal body temperature primarily indicates that ovulation has already occurred. The LH Ovulation Rapid Test Midstream indicates that ovulation is about to occur.

### Does alcohol, aspirin, paracetamol or any other common drug affect the test?

No, but some hormonal medications can interfere with test results. If such medications are being taken or are suspected, seek professional advice from a physician to confirm the test results. Drugs containing hCG or LH can affect the test results, and clomid can cause false positives if you begin testing too early in your cycles.

### Why is first morning urine not a good sample?

First morning urine is not recommended as most women experience a blood LH surge in early morning but it does not show up in the urine until later in the day.

### Can test results be interpreted after five minutes?

No. The test should be read at 3-5 minutes for best results. 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. Therefore, do not read the result after 10 minutes and discard the test midstream after reading the test.

### Today's control line is a different shade of red than yesterday's control line. Is this a concern?

No. Variations in the color of the control line will not affect the test result. Always compare the color of the test line to that of the control line of the same device on the day the test is performed. Do not compare bands from different devices.

### A pink background color and vertical streaking appeared in the result area during the testing period. Is this a concern?

No. Each urine sample will vary in its chemical makeup, as will the humidity of the air in testing chamber (room). Such variations in physical conditions can cause the vertical streaking and/or the pink-rose background color but will not affect the test results. As long as the control band appears within five minutes, the test is working properly.

### How long should I continue to perform the test?

Unless otherwise specified by a doctor, stop testing once the LH surge is detected. Five to ten days of testing may be needed to detect the LH surge, though additional testing may be required.

### If I am still uncertain when the test kit is positive, what shall I do?

If you are still uncertain when the test kit is positive, try this exercise. During one cycle, have intercourse when you think your kit shows you are ovulating, and then continue to test your urine even though ovulation has past. This will help you see the maximum darkness of your test line. Knowing that the ovulation signal (LH surge) only lasts 48-60 hours, your test line will eventually start to fade away if you continue testing after ovulation. Seeing this line fade will help you know the peak darkness of your test line and give you more confidence in pinpointing your most fertile time.

### I have received a positive result and had intercourse during these fertile days. I have not become pregnant. What shall I do?

There are many factors that can affect the ability to become pregnant. Often it may be necessary to use the test kit for 3-4 months before achieving pregnancy. A physician should be consulted if pregnancy is not achieved after 3-4 months.



### Manufacturer:

Hangzhou Bangtang Network Technology Co.,Ltd Floor 12, 92 Yueda Street, Binjiang District, Hangzhou, China

### Distributor:

Biosmart Teknoloji A.Ş., Eti mah. Ali Suavi cad. 9/A Çankaya, Ankara / TÜRKİYE

## INDEX OF SYMBOLS

	For in vitro diagnostic use only		Consult instructions for use
	Store between 4-30 C		Do not reuse
	Lot number		Use by
	Caution		Contains sufficient for <n> tests
	Keep dry		Keep away from sunlight
	Manufacturer		Do not use if package is damaged