

Package Insert

Catalogue number:	LH-101	Specimen:	Urine
Version:	C	Effective Date:	2022-12-14

For self-testing.

【INTENDED USE】

The LH One Step Ovulation Test Strip is a rapid chromatographic immunoassay for the qualitative detection of human luteinizing hormone (LH) in urine to predict time of ovulation. For self-testing and in vitro diagnostic use only.

【SUMMARY】

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.¹

The LH One Step Ovulation Test Strip is a complete system to help predict the time of ovulation, and peak fertility. It is during this fertile time that pregnancy is most likely to occur.

The LH One Step Ovulation Test Strip detects the LH surge in urine, signaling that ovulation is likely to occur in the next 24-36 hours. The test utilizes a combination of antibodies including a monoclonal LH antibody to selectively detect elevated levels of LH.

Important: The LH surge and ovulation may not occur in all cycles.

【REAGENTS】

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

【PRECAUTIONS】

- For Self Testing. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The urine specimen must be collected in a clean and dry container. 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.
- Reduce liquid intake approximately 2 hours prior to urine collection.
- Record the date, cycle day and time of urine collection. See the TEST RESULTS CHART at the end of this package insert.

【KIT CONTENTS】

● Test strip(s)	● Package insert	● Desiccant(s)
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【KIT CONTENTS】 (optional)

- Specimen collection container(s) (for specimens collection use)

【MATERIALS REQUIRED BUT NOT PROVIDED】

- Timer (for timing use)

WHEN TO START TESTING

First, determine the subject's Menstrual Cycle Length. The Menstrual Cycle Length is the number of days from the first day of the subject's period (menstrual bleeding) to the last day before the next period starts. Next, determine the Days to Count Ahead after the period to start testing. Find the subject's Menstrual Cycle Length on the first row of the chart below, and read the corresponding Days to Count Ahead in the second row. This is the number of days after the period to begin testing.

Menstrual Cycle Length

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

Days to Count Ahead

Finally, determine the day to start testing. Starting from and including the first day of the last period, count ahead the number of days indicated in the previous step. This is the day on which testing should begin. As a basic guideline, it is recommended to test once a day for five days.

Note: If uncertain about the length of the subject's menstrual cycle, use the shortest menstrual cycle length (21 days) when reading the chart. In this case, it may be necessary to test for more than 5 days.

Example: The subject's usual menstrual cycle length is 28 days. The chart indicates to count ahead 11 days from the subject's last period. The subject's last period started on the 3rd. Starting from and including the 3rd, count ahead 11 days to arrive at the 13th. Urine collection and testing should start on the 13th and proceed through the 17th. (See the Example Specimen Calendar below).

Example Specimen Calendar

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
21	22	23	24	25	26	27
28	29	30	31			

() -- First day of the last period

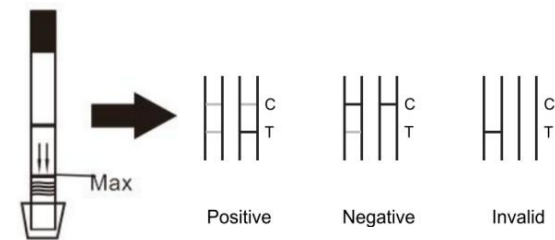
< > -- Begin testing with the LH One Step Ovulation Test

【DIRECTIONS FOR USE】

Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.

1. Determine the day to begin testing. (See the above section: “WHEN TO START TESTING”).
2. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
3. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See illustration below.
4. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear.

Read the result at 5 minutes. Do not read the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE: Two lines are visible, and the line in test line region (T) is the same as or darker than the one in the control line region (C). This indicates probable ovulation in 24-36 hours.

NEGATIVE: Two lines are visible, but the line in the test line region (T) is lighter than the one in the control line region (C), or if there is no line in the test line region (T). This indicates that no LH surge has been detected.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

A positive result indicates that the urine specimen contains the level of LH that would indicate the beginning of ovulation. Ovulation should begin in 24-36 hours.

A negative result indicates that no LH surge has been detected and daily testing should continue.

Not every woman ovulates mid-cycle, therefore, a positive result may not appear during the selected days of testing. If you see no positive result, continue testing with the LH One Step Ovulation Test Strip for several more days. If negative results persist, test again during the next menstrual cycle.

【LIMITATIONS】

- 1. This test may not be used as a form of birth control.
- 2. 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 LH One Step Ovulation Test Strip. In addition, the test will not work properly for subjects who are pregnant, in menopause, or are taking birth control pills.
- 3. Keep out of the reach of children.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Accuracy

Laboratory studies show that the sensitivity of the LH One Step Ovulation Test Strip is 25mIU/mL and the accuracy is 99.5%

Interference Substance

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

Analyte	Concentration	Analyte	Concentration
Acetaminophen	20mg/dL	Glucose	2g/dL
Acetylsalicylic acid	20mg/dL	Hemoglobin	10mg/dL
Ascorbic acid	20mg/dL	Ampicillin	20mg/dL
Atropine	20mg/dL	Tetracycline	20mg/dL
Caffeine	20mg/dL	Bilirubin	2mg/dL
Gentisic acid	20mg/dL		

Cross Reactivity

The LH One Step Ovulation Test Strip has been tested with commonly known drugs and hormones including FSH (200 mIU/mL), TSH (250 µIU/mL).At the levels tested, none of these substances interfered with the expected test results.

【QUESTIONS & ANSWERS】

1.Q: Can the LH One Step Ovulation Test Strip be used to avoid pregnancy?

A: No, the test should not be used as a form of birth control.

2.Q: Do alcohol or common medications affect the test?

A: No, but a physician should be consulted if taking any hormonal medication. Also, recent oral contraceptive use, breastfeeding or pregnancy could affect the results.

3.Q:How long will the lines remain visible?

A: The test should be read at 5 minutes for best results. A positive (Surge) result will never disappear. The colored line(s) may become darker and a tinted background may appear after several hours. Some negative results may later display a faint second color line because of evaporation from the test line region, which prevents complete migration of the test chemicals. Therefore, do not read the result after 10minutes and discard the test after reading the test.

4.Q: Once a positive result is obtained, when is the best time to have intercourse?

A: Ovulation is likely to occur within 24-36 hours. This is the most fertile time. Sexual intercourse within this time frame is advised.

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

A: The shift in basal body temperature primarily indicates that ovulation has already occurred. The LH One Step Ovulation Test Strip indicates that ovulation is about to occur.

6.Q: Does a positive result guarantee a pregnancy after intercourse within the fertile days?

A: 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.

7.Q: How soon can pregnancy be confirmed?

A: Rapid pregnancy tests can provide results as early as the first missed period.

8.Q: What time of the day should I perform the test? Do I need to use first morning urine?

A: 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 each day.

9.Q: Will heavy intake of liquids affect the result?

A: Heavy intake of fluids prior to testing will dilute the hormone in urine. Limiting fluid intake for about two hours before collecting urine is suggested.
















TEST RESULTS CHART

Test	Date	Collection time	Result
Day 1			
Day 2			
Day 3			
Day 4			

【BIBLIOGRAPHY】

Elkind-Hirsch, K; Goldzieher, JW; Gibbons, WE and Besch, PK. Obstetrics and Gynecology, 67(3): 450-453, 1986.

Index of Symbols

	Consult instructions for use		Contains sufficient for <n> tests		Authorized representative in the European Community
	In vitro diagnostic medical device		Use-by date		Do not re-use
	Temperature limit		Batch code		Catalogue number
	Manufacturer		Date of Manufacture		Keep dry
	Keep away from sunlight		Do not use if package is damaged and consult		Meet the requirements of 98/79/EC Directive



Hangzhou Sejov Electronics& Instruments Co., Ltd.
Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China
Website: www.sejov.com



Shanghai International Holding Corp.GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

