Luteinizing hormone (LH) Rapid Test Kit
(Cassette / Midstream) (Urine)

The LH Ovulation Test Device (Urine) is a rapid chromatographic immunoassay for the qualitative detection of luteinizing hormone (LH) in urine to aid in the detection of ovulation.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF	Pack Size	REF
01 Test	PLHC 01	01 Test	PLHM 01
05 Tests	PLHC 05	05 Tests	PLHM 05
10 Tests	PLHC 10	10 Tests	PLHM 10
25 Tests	PLHC 25	25 Tests	PLHM 25
50 Tests	PLHC 50		

CLINICAL SIGNIFICANCE

Ovulation is the release of an egg from the ovary. The egg 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). This is known as the "LH surge" and usually takes place in the middle of the menstrual cycle. LH triggers the release of an egg from the ovary.
The LH One Step Ovulation Test Device (Urine) 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.
The LH Ovulation Test Device (Urine) detects the LH surge in urine, signaling that ovulation is likely to occur in the next 24-36 hours.
Important: The LH surge and ovulation may not occur in all cycles.

PRINCIPLE

This LH Rapid Test is a qualitative, two site sandwich immunoassay for the determination of human luteinizing hormone in urine specimens. The membrane was precoated with LH specific antibodies on the test region. During the test, the specimen is allowed to react with the LH monoclonal antibody-colloid gold conjugate which was pre-dried on the test strip. The mixture then moves upward on the membrane chromatographically by the capillary action. For a positive specimen, the conjugate binds to the LH forming an antibody-antigen complex. This complex binds to the LH antibody as a capture regent on the test region and produces a colored band when LH concentration is equal to or greater than 25 mIU/ml. Absence of this colored band in the test region suggests a negative result. To serve as a procedural control, a colored band at control region will always appear regardless the presence of LH.

CONTENTS

Card Test	Midstream
Test Device (Cassette)	Test Device (Midstream)
Desiccant	Desiccant
Instruction for Use (IFU)	Instruction for Use (IFU)
Disposable (Dropper) sampling device	

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION & PREPARATION

1. Determine the time you will collect your urine. For best results, collect your urine at about the same time each day, for example, between 10:00AM and 8:00PM. Some women have found that their best specimen is after 12noon. Do not collect your first urine after waking up.
2. Reduce your liquid intake approximately 2 hours prior to urine collection.
3. Be sure to write down the cycle day, date and time that you collected your urine in the "Test Results Chart".
4. You can store your urine for testing later in the day. Your urine can be stored at room temperature for up to 8 hours or in the refrigerator for up to 24 hours. Do not freeze it. For best results, test your urine on the same day that it is collected. If you refrigerate your urine, let it reach room temperature before testing (about 30 minutes). Do not shake the container. If sediment forms at the bottom of the collection container, allow the sediment to settle. Use only urine from the top of the container.

WHEN TO START TESTING

Determine the Length of Your Menstrual Cycle.

Your Menstrual Cycle Length is the number of days from the first day of your period (menstrual bleeding) to the last day before your next period starts. Think back over the last few months to decide what your usual cycle length has been.

Circle your usual cycle length on the WHEN TO START CHART below. Select the number directly underneath.
Starting the first day of your last period, count ahead the selected number of days on your calendar. This is the day you should begin testing.

WHEN TO START CHART

Circle Your Usual 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

Count ahead this many days STARTING WITH THE FIRST DAY of your LAST period.

Note: If you are unsure about your cycle length, you may want to use your shortest cycle length when reading the chart. If you do this, you may need to test for more than 5 days.

Example: My usual cycle length is 28 days. My last period started on the third. The "When to Start Chart" shows that I will count ahead 11 days beginning with the third. When I count 11 days ahead on the calendar, I find that I will collect and test my urine starting on the 13th. (See "Sample Calendar" below).

Sample 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 your last period

< >--Begin testing with the LH One Step Ovulation Test Device (Urine)

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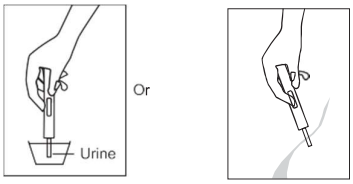
PROCEDURE
For card Test
1. Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.
2. Determine the day to begin testing. (See the above section: "WHEN TO START TESTING").
3. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
4. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 2 full drops of urine (approximately 50 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
5. Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.



For Midstream Test
1. Allow Midstream test cassette to equilibrate to room temperature (20-30°C) prior to testing.
2. Remove the midstream test from the foil pouch and test it immediately in one hour.
3. Take down the cap of the midstream, hold the midstream so as to place the absorbent tip in the urine stream or place the absorbent tip (≥2/3) in urine in a clean cup for at least 15 seconds.
4. Cover the cap on the testing midstream, then lay down the product on a clean and stable desk, start the timer immediately



INTERPRETATION OF RESULTS

POSITIVE: Coloured lines in the control region and also in the test region indicating a positive result and that the sample contains LH above the detection limit.



NEGATIVE: Only one pink colored line appears in the Control area showing negative for LH.



INVALID: Control Line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for an invalid result. Review the procedure and repeat the test with a new test device. 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 means your urine contains the level of LH that would indicate you are beginning to ovulate. You can assume that you will ovulate within 24-36 hours.
A negative result means that no LH surge has been detected and you should continue daily testing.

Not every woman ovulates mid-cycle; therefore, you may not see a positive result during the first 5 days of testing. Continue testing with the LH One Step Ovulation Test Device (Urine).

INTERFERING SUBSTANCES

The LH One Step Ovulation Test Device (Urine) has been tested with commonly known drugs and hormones including FSH (1,000 mIU/mL), TSH (1,000 µIU/mL), and hCG (10,000 mIU/mL). At the levels tested, none of these substances interfered with the expected test results.

PERFORMANCE CHARACTERISTICS

Laboratory studies have shown that the sensitivity of the LH One Step Ovulation Test Device (Urine) is 25 mIU/mL and the accuracy is 99%.

Method		Other hCG Rapid Test		Total Results
Luteinizing hormone (LH) Rapid Test Kit	Results	Positive	Negative	
	Positive	163	0	163
	Negative	0	280	280
Total Results		163	280	443

Relative Sensitivity: 100%
Relative Specificity100%
Overall Accuracy: 100%
* 95% Confidence Intervals

LIMITATIONS
1. The test works only when the test procedures are precisely followed.
2. Do not reuse the test device.
3. For professional in vitro diagnostic use only.
4. This test may not be used as a form of birth control.
5. The test results should not be affected by pain relievers, anti-biotics and other common drugs. Medication containing hCG or LH may affect the test and should be taken while using the LH One Step Ovulation Test Device (Urine). In addition, the test will not work properly if you are pregnant, menopausal, or taking birth control pills.
6. Keep out of the reach of children.

BIBLIOGRAPHY

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3. Edwards, R.G. J. Ob/Gyn 87, 737-756 (1980)
4. Collins, W.P. Int. J. Fert. 26, 196-202 (1981).
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GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

India office
BIOBOON BIOTECH INDIA LLP
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