

ONE STEP LUTEINIZING HORMONE (LH) MIDSTREAM TEST (Urine)

FOR IN VITRO DIAGNOSTIC USE

INTENDED USE

The One Step Luteinizing Hormone (LH) Test is specifically designed to detect your LH surge - the time when you are likely to ovulate. Luteinizing hormone is always present in human urine. LH increases dramatically just before women's most fertile day of the month in a process commonly referred to as the "LH Surge". This LH increase triggers ovulation, which means an egg is released from woman's ovary. Because the egg can be fertilized only 6 to 24 hours after ovulation, detecting ovulation in advance by testing for the LH surge is very important for women seeking pregnancy.

The best times to test are between 11am and 3pm and 5pm and 10pm. If you want to make sure that you catch your surge, you may want to test twice a day, once in the earlier time frame and the other in the later time frame. Please keep in mind that while you may have the initial surge of LH earlier in the day if testing via blood tests, you will not get a positive result on the ovulation test until 4-5 hours later when the surge actually reaches your urine.

WHEN TO BEGIN TESTING

You may test at any time of the day, preferably after 10am and before 8pm. If you are testing twice a day, testing at least 8 hours apart will help catch shorter Lh surges. You should test at approximately the same time each day. Reduce your liquid intake for 2 hours before testing.

To find out when to begin testing, determine the length of your normal cycle. The length of your cycle is from the beginning of one period (the day of first bleeding) to *the day before* the beginning of the next. Count the first day of bleeding or spotting as day one (1). 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. Use the chart shown to work out the day you should begin testing. The day you begin testing is posted opposite the number of days in your normal cycle.

Length of Normal Cycle (Total days)	Start testing this many days after your last period began.	Length of Normal Cycle (Total days)	Start testing this many days after your last period began.
21	5	31	14
22	5	32	15
23	6	33	16
24	7	34	17
25	8	35	18
26	9	36	19
27	10	37	20
28	11	38	21

29	12	39	22
30	13	40	23

For example, if your period normally begins every 28 days, you should begin testing eleven (11) days after the beginning of your last period.

SUN	MON	TUES	WED	THURS	FRI	SAT
1	2	3	4	5	6	7
8	9 *	10	11	12	13	14
15	16	17	18	19 (s)	20	21
22	23	24	25	26	27	28
29	30	31				

Note in the calendar above: If the ninth (9th) in the calendar above is the first day (day one *) of menstrual bleeding, then the 19th, or day eleven, of your cycle is the day to begin testing (s).

TEST PROCEDURE

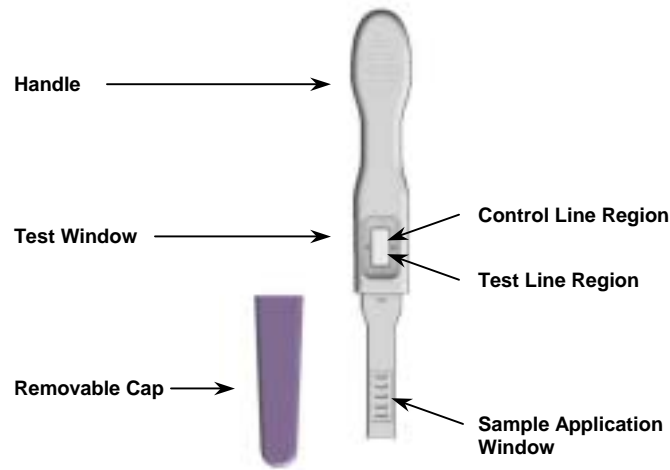
Do **not** use first morning samples as LH is synthesized in your body early in the morning. It will not show up in urine until later in the day. The best time to test urine is between 11am and 8pm. Be sure to test at the same time each day. Also, reduce your liquid intake (and try not to urinate) around 2 to 3 hours before testing as a diluted liquid sample can hinder LH detection.

1. To begin testing, open the sealed pouch by tearing along the notch. Remove test kit from the pouch.
2. Hold the round end of cover with one hand. Use the other hand to pull out the test device and expose the absorbent tip.
3. Point the absorbent tip downward. Place the absorbent tip in urine stream for at least seven to ten (10) seconds to be thoroughly wet.



4. Re-cap the device, lay flat on a table, and wait for color bands to appear. Depending on the concentration of LH, a positive result may be observed in as few as 40 seconds; however, to confirm negative results, the complete reaction time (5 minutes) is required. Do not read results after 10 minutes.

INTERPRETATION OF RESULTS

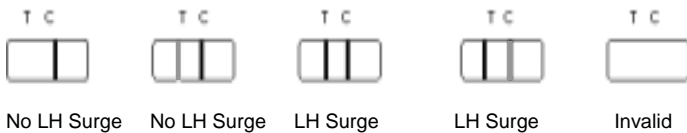


Negative - No LH Surge: Only one color band appears on the control (C) region or the test (T) band is much lighter than the control band. There is no LH surge.

Positive - LH Surge: If two color bands are visible and the test (T) band is equal to or darker than the control (C) band, ovulate will probably take place within the next 24-48 hours.

Invalid: No visible band at all. Repeat test with a new test kit. The control band will not appear if an insufficient volume of specimen is added to the test kit. Proper procedures may not have been followed in performing the test. Repeat with a new test kit. Please consult above instructions and follow precisely.

Function of the Control Band: The Control Band is used as a reference and built in quality control check. If the Test Band is darker or similar to the Control band, the test result is considered positive. If the Test Band is lighter than the Control Band, the test result is considered negative. The Control Band is also used for procedural control to check whether the test reagents are working properly and that a sufficient amount of urine sample has been applied to the absorbent wick.



STORAGE AND STABILITY

1. The test devices should be kept from prolonged exposure to direct sunlight, moisture, heat, and other related conditions.

2. The test kit can be stored at normal room temperature (2 to 30) in the sealed pouch up to the expiration date of 2 years, which is indicated on the package.

DISPOSAL

Urine samples and used test devices are potentially infectious so please keep them away for direct contact with objects. Proper handling, hands washing, and immediate disposal is recommended.

WARNING AND PRECAUTION

1. Keep away from children and prolonged exposure to extreme storage conditions.
2. This test is designed for single in vitro diagnostic use only.
3. Do not use test kit beyond expiry date printed on package.
4. Tests results may vary for different individuals.
5. Confirm all test results with a qualified specialist.

