

INTENDED USE

The luteinizing hormone (LH) Ovulation Test is a rapid and convenient immunochromatographic *in vitro* assay. It is used for detecting LH in urine and predicting the time of LH surge and ovulation. The test provides a visual, qualitative result, and all positive specimens are advised to be confirmed with other qualified assays.

SUMMARY AND PRINCIPLE OF THE ASSAY

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. Early morning testing is not recommended as it does not show up in the urine until later in the day. If you want to make sure that you catch your surge, you may test twice a day, once in the earlier time frame and the other in the later time frame. The detection limit for the LH Ovulation Test Device is 30 mIU/ml LH. Urine samples equal to or greater than 30 mIU/ml will be tested positive.

When to begin testing: The test can be done at any time of the day, preferably after 10am and before 8pm. If testing twice a day, testing at least 8 hours apart will help catch shorter LH surges. Test should be done at approximately the same time each day. Reduce liquid intake for 2 hours before testing.

To find out when to begin testing, determine the length of normal period cycle. The length of 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 the 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.

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

How to recognize the LH surge: After reading the results of each test, LH surge can be decided. If the test result is positive, you are probably experiencing your LH surge. If your test result is negative, you are probably not having your LH surge. A LH surge can last from one to three days depending on your cycle and other biological factors. A pink test band lighter than the control band shows that there is only a very low level of LH in your urine.

When to stop testing: Stop testing once the LH surge is detected unless specified by your doctor.

PACKAGE CONTENTS

- Pouch Contents: Midstream Cassette, Desiccant
- Test instruction

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.
- Do not use after the expiration date shown on the pouch.
- Dispose all specimens and used devices in a proper biohazard container
- Keep out of children's reach.

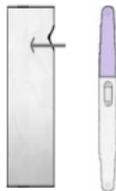
SPECIMEN COLLECTION AND PREPARATION

- Urine specimen may be collected at any time in a clean, dry container either plastic or glass without preservatives.
- If specimen cannot be assayed immediately, they can be stored at 2-8°C for up to 72 hours prior to testing frozen at -20° C for longer period of time.
- Specimens should be equilibrated to room temperature before testing if they were refrigerated or frozen.
- Urine specimen exhibiting visible precipitates should be filtered, centrifuged, or allow settling so that clear aliquots can be obtained for testing.

TEST PROCEDURES

1

Remove the testing device from the sealed pouch by tearing at the notch. Hold the device by the colored cap.



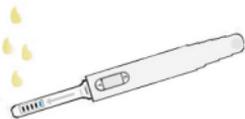
2

Uncap the device.



3

Point the absorbent tip downward. Place the absorbent tip in urine stream for at least 5 seconds for it to be thoroughly wet. Otherwise, you can collect your urine into a clean cup and dip half of the absorbent pad into the urine for at least 5 seconds.



4

Re-cap the device.



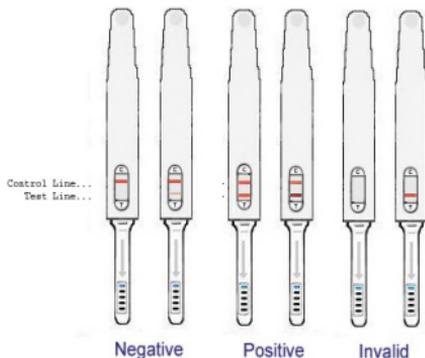
5

Read the result in 10 minutes. Ensure that the background of the test area is white before interpreting the results.



**DO NOT INTERPRET
RESULTS AFTER 30
MINUTES**

RESULT INTERPRETATIONS



Negative

One pink colored band appears at the control region, or the test band is lighter than the control band.

Positive

Distinct pink colored bands appear at the control and test line regions, and the test band is equal to or darker than the control band.

Invalid

No visible band at the control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30°C up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.