

INTENDED USE

Sensit LH Ovulation Rapid test Kit is an in-vitro immunochromatographic assay designed for qualitative determination of human luteinizing hormone (hLH) in urine to predict the time of ovulation. The test provides a visual, qualitative result, and all positive specimens are advised to be confirmed with other qualified assays.

SUMMARY & TEST DESCRIPTION

Luteinizing Hormone is a hormone released by the pituitary gland, a small gland at the base of the brain. The hormone stimulates the ovaries to produce and release eggs each month during the menstrual cycle. The level of LH in the blood and urine is highest before ovulation. This increase in hormone level is sometimes called a "surge". If fertility drugs are given to stimulate ovulation, an LH ovulation test can help determine the best time for sexual intercourse. The LH ovulation test may also be used to determine when eggs are mature enough to be surgically removed from the ovary as part of the in vitro fertilization process.

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 LH 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 Test Kit is 30 mIU/ml LH. Urine samples equal to or greater than 30 mIU/ml will induce a positive test.

Sensit LH Ovulation Rapid Test Kit detects LH in urine in a qualitative format with sensitivity of 20mIU/mL (International Standard Value) and specificity is 99%. First, determine the length of your menstrual cycle. This is the number of days from the first day of your menstrual bleeding to the day before your next bleeding begins. Please refer below chart to determine when you should start testing. If your cycle is shorter than 21 days or longer than 40 days, consult your doctor. If you do not know your cycle length, you may begin the test 11 days after your first period since the average cycle length is 28 days. Perform 1 test each day over 5 day period, or until the LH surge has been detected.

Length of Normal cycle	Start to test on
21	6
22	6
23	7
24	7
25	8
26	9
27	10
28	11
29	12
30	13
31	14
32	15
33	16
34	17
35	18
36	19
37	20
38	21
39	22
40	23

PRECAUTIONS AND WARNING

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1. Use within 10 minutes after opening pouch.
2. Do not reuse test kit.
3. Do not touch result window.
4. Use only for in-vitro diagnostic purpose.
5. Do not use test kit beyond expiry date.
6. The test kit should be kept away from direct sunlight, moisture and heat.

REAGENTS & MATERIALS PROVIDED

1. Each Kit contains 30 test devices, each sealed in a foil pouch containing following items:
 - a. One test card
 - b. Dropper
 - c. Desiccant
2. Instruction Leaflet

MATERIAL REQUIRED BUT NOT SUPPLIED

Specimen collection containers.

STORAGE & STABILITY

Store the test kit between 4-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

SPECIMEN COLLECTION

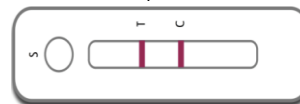
1. Urine specimen may be collected at any time in a clean, dry container either plastic or glass without preservatives.
 2. If specimen cannot be assayed immediately, it can be stored at 2-8°C for up to 48 hours prior to testing frozen at -20° C for longer period of time.
 3. Specimens should be equilibrated to room temperature before testing if they were refrigerated or frozen.
 4. Urine specimen exhibiting visible precipitates should be filtered, centrifuged, and settled so that clear aliquots can be obtained for testing.
- Choose a convenient time of the day to collect urine. Try to collect urine at about the same time each day for the entire cycle.*

TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 5 drops of the specimen to the sample hole (marked S) on the test card.
3. Wait for 5-10 minutes and interpret results. The result is considered invalid after 20 minutes. All results where control band does not appear are considered invalid.

INTERPRETATION OF TEST RESULT

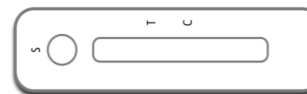
Positive: Color bands at position C and T.



Negative: Color band at position C.



Invalid: Color band at C does not appear



References

1. Lymphatic France, J.T. In Recent Advances in Obstetrics and Gynaecology Number 14, J. Bonner, ed., Churchill. Livingstone. New York, NY. 1982. Pp 215-239.
2. Moghissi KS, Syner FN, Evans TN: A composite picture of the menstrual cycle. Am J Obstet Gynecol 114:405, 1972.
3. Speroff, L., Glass, R.H., Kase N.G. Clinical Gynecologic Endocrinology and infertility, 3rd ed., Williams and Wilkins, Baltimore, MD, 1983.

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UBD/QA/IFU/S010-01

Rev. No: 1.00/13-02-2025