LH Ovulation Rapid Test

For detection of LH in HumanUrine Specimens.

Introduction

Human luteinizing hormone (hLH) is a glycoprotein hormone secreted by the anterior pituitary. In view of the characteristic variation of hLH during the menstrual cycle, and sensitive measurement of hLH is an important tool in the diagnosis and management of infertility in females. Approximately 12 – 24 hours after the hLH surge, the wall of the enlarged follicle ruptures at ovulation and the mature ovum is extruded. Detection of the hLH surge can aid in predicting the time of ovulation. The onset of the hLH surge precedes ovulation by approximately 30 hours.

The LH ovulation test is an in-vitro immunochromatographic one step assay designed for qualitative determination of hLH in urine to predict time of ovulation.

The LH ovulation test contains a membrane strip, which is precoated with mouse monoclonal anti-hLH capture antibody on test band region. The mouse monoclonal anti-beta hLH -colloid gold conjugate and urine sample moves along the membrane chromatographically to the test region (T) and forms a visible line as the antibody-antigen-antibody gold particle complex forms. The LH ovulation test device has a letter of T and C as "Test Line" and "Control Line" on the surface of the case. Both the Test Line and Control Line in result window are not visible before applying any samples. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. Also, this control band serves as a reference of the color intensity of approximately 35 mIU/ml hLH. When the intensity of the test band is equal or higher than that of control band, the test is positive, indicating the hLH surge is

Kit Precautions and Storage Instructions

1) For best results, adhere to instructions provided
2) All specimens should be handled as potentially infectious
3) The test device should be stored at room temperature
4) The test device is sensitive to humidity as well as heat
5) Do not use beyond expiration date
6) Do not use test kit if pouch is damaged or seal is broken
7) Use test device immediately after removing from the pouch
8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
9) Store kit at room temperature (2 -30 ^{o}C). Do not expose the kit to temperature over 30 ^{o}C.
10) The stability of the test under above conditions is 24 months from the date of manufacturing.

Warnings

1) For in vitro diagnostic use only. DO NOT RE-USE test device
2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
3) Do not eat or smoke while handling specimens
4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
5) Avoid splashing or aerosol formation
6) Clean up spills thoroughly using an appropriate disinfectant
7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
8) Do not mix with other specimens.

When to Begin Testing

You may do this test at any time of the day, but you should test at approximately the same time each day. Reduce your liquid intake for 2 hours before testing. To decide when to begin testing, determine the length of your normal menstrual cycle. The length of your cycle is from the beginning of one period to the beginning of the next (count the first day of bleeding or spotting as day 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 to work out the day you should begin testing. The day you begin testing is listed opposite the number of days in your normal cycle.

LENGTH OF NORMAL CYCLE (DAYS)	START TESTING THIS MANY DAYS AFTER YOUR LAST PERIOD BEGAN
21	After 6 Days
22	After 6 Days
23	After 7 Days
24	After 7 Days
25	After 8 Days
26	After 9 Days
27	After 10 Days
28	After 11 Days
29	After 12 Days
30	After 13 Days
31	After 14 Days
32	After 15 Days
33	After 16 Days
34	After 17 Days
35	After 18 Days
36	After 19 Days
37	After 20 Days
38	After 21 Days
39	After 22 Days
40	After 23 Days

For example, if your period normally begins every 28 days, you should begin testing 11 days after the first day of your last period.

M	T	W	T	F	S	S
	1	2 (Day 1)	3	4	5	6
7	8	9	10	11	12(Begin Testing)	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

Specimen Collection, Storage and Precautions

1) Do not use first morning urine samples as LH is synthesized in your body early in the morning. It will not show up in your urine until later in the day.
2) The best time to collect your urine is between 10am and 8pm.
3) Collect urine at about the same time each day.
4) Reduce liquid intake about 2 hour before collecting your urine as a dilute sample can prevent the test from detecting the LH surge.

Test Procedure

Allow the sealed LH cassette test pouch, urine sample, and control solution to reach room temperature (18-30°C).

1) Remove the LH Cassette device from the sealed pouch.
2) Draw the urine sample to the urine dropper provided.
3) Hold the urine dropper upright about 1/2 inch above the sample well of the device. Add 5 drops of urine to this well.
4) Lay the test device on a flat surface with the result window facing up. Wait for colored bands to appear. Depending on the concentration of LH in the test specimen, positive results may be observed in as little as 40 seconds. However, to confirm negative results, the complete reaction time of 10 minutes is required.
5) Do not read results after more than 30 minutes.

Interpretation of Test Results

No LH Surge: Only one color band appears on the control (C) region or the test (T) band appears but is lighter than the control band. This means there is no LH surge.

LH Surge: Two color bands are visible, and the test (T) band is equal to or darker than the control (C) band. This means that one will probably ovulate in the next 24-48 hours. If trying to get pregnant, the best time to have intercourse is after 24 but before 48 hours.

Invalid: No visible band at all or no colored band appears on the control (C) region. Repeat with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Limitations of the Test

1) The LH ovulation test is not reusable. The test works only if the instructions are followed precisely. Although LH ovulation test is highly accurate in detecting ovulation, a low incidence of false results (positive when no ovulation exists or negative when ovulation is present) can occur.

2) The LH ovulation test should not be used for contraception.

3) Some prescription drugs, such as menotropins may affect the test result. Certain rare medical conditions or the onset of menopause can cause elevated levels of LH. Some women do not ovulate every cycle and they will not see any increase in the level of LH during these non-ovulating cycles.

Internal Quality Control

The LH ovulation rapid test device has a “Test line” and a “Control line” on the surface of the cassette. Both the Test Line and Control Line in the result window are not visible before applying any samples. The Control Line is used for procedural control. The Control line should always appear if the test procedure is performed properly and the test reagents of the control line are working.

Expected value

The LH ovulation test has been designed to produce a definitive color band at test region when tested with 35 mIU/ml or higher (100, 200 mIU/ml) of hLH.

Evaluation Data

150 urine specimens from 30 menstrual cycles were analyzed by LH ovulation test procedure in parallel with a commercial available rapid kit. The surge dates of all of these cycles were identified and agreed by both LH ovulation test and the competitor rapid kit.

Suggested Readings

1) Speroff, L., Glass, R.H., Kase N.G. Clinical Gynecologic Endocrinology and infertility, 3rd ed., Williams and Wilkins, Baltimore, MD, 1983.
2) France, J.T. In Recent Advances in Obstetrics an Gynaecology Number 14, J. Bonner, ed., Churchill Livingstone, New York, NY, 1982. pp 215- 239.
3) Edwards, R.G., Steptoe, P.C., Purdy, J.M., Br.J Obstet Gynaecol 87, 737-756 (1980)

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