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Luteinizing Hormone (LH) tests

(Ovulation tests)

INTENDED USE

Luteinizing Hormone (LH) tests are single use, rapid immunoassay for in vitro qualitative determination of human luteinizing hormone (LH) in urine to predict when there is LH surge, and in turn, when you are likely to ovulate. It is intended for use by the lay users.

PRINCIPLE

Antibodies to LH are precoated onto membrane as capture reagent on the test zone. During the test, specimen is allowed to react with the colloidal gold particles, which have been labeled with antibodies to LH. If LH is present, a red colored line will develop on the membrane in proportion to the amount of LH present in the specimen.

When test line is similar to or darker than control line indicated that there is a LH surge. When test line is lighter than control line, showing LH level is not in the peaking. Only control line is colored, showing LH level is very low. To serve as a procedural control, red colored line in the control zone will always appear regardless of the presence of LH.

COMPONENTS

REAGENTS AND MATERIALS PROVIDED

Each kit contains:

1. Each pouch contains one strip with one desiccant bag
2. Instruction for use
3. Urine cup

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or stopwatch

WARNING AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Read directions for use carefully before performing this test. Pay attention to the position of the C and T line.
3. Do not use beyond the labeled expiration date.
4. Do not use if pouch has been perforated.
5. Do not reuse the test devices. Discard it in the dustbin after single use.
6. Urine that has been chemically treated, heated, diluted, or otherwise modified may give
inaccurate results.
7. Always interpret the results under good light conditions to avoid misreading of the results.
8. If desiccant bag is not present in the pouch, DO NOT USE the test.
9. Always add accurate volume of specimen by following the instruction.
10. The tests provide a presumptive diagnosis for the time of ovulation. The user should not make a decision on medication without consulting medical practitioner.

STORAGE

Luteinizing Hormone (LH) tests should be stored at room temperature (4-30°C, do not freeze) for 24 months from the date of manufacture. Keep the test strip in sealed pouch until use. Once you have taken the test strip out of the pouch, perform the test as early as possible (within 1 hour) to avoid test strip from becoming moist.

SAMPLE COLLECTION AND TEST PREPARATION

WHEN TO START TESTING

1. Determine your Menstrual Cycle Length. The Menstrual Cycle Length is the number of days from the first day of your period (menstrual bleeding) to last day before your next period starts.
2. Determine the Days to Count Ahead after the period to start testing. Find your Menstrual Cycle Length on the first row of the Table 1 below, and read the corresponding Days to Count Ahead in the second row. This is the number of days after the period to begin testing.
3. Determine the day to start testing. Starting from and including the first day of the last period, count ahead the number of days indicated in the previous step. This is the day on which testing should begin. As a basic guideline, it is recommended to test once a day for five days.

Table 1 Menstrual Cycle Length

21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
4	5	6	7	8	9	9	9	9	10	10	10	12	13	14	15	16	17	18	19

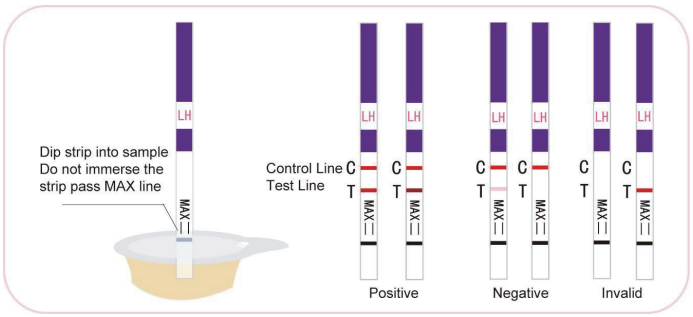
Note: If uncertain about the length of the subject' s menstrual cycle, use the shortest menstrual length (21 days) when reading the chart. In this case, it may be necessary to test for more than 5 days.

SAMPLE COLLECTION

1. Determine the time for urine collection. The best time to collect urine samples is between 10:00AM and 8:00PM. For best results, collect urine at about the same time each day. Do not collect the first urine after waking up.
2. Reduce liquid intake about 2 hours before collecting your urine as a diluted urine sample may cause false negative result.
3. Urine specimens exhibiting visible precipitates should be settled to obtain a clear specimen for testing.
4. Urine can be stored at room temperature for up to 8 hours, at 2-8°C for up to 72 hours or frozen at -20°C for maximum 3 months. Avoid specimen deterioration by multiple
freeze-thaw cycles.

EXAMINATION PROCEDURE

Allow the test, urine specimen and/or controls to reach room temperature prior to testing.
1. Determine the day to begin testing. (See the above section: "WHEN TO START TESTING").
2. Before opening, allow the test strip to reach room temperature. Use it immediately after opening.
3. See the illustration below, immerse the test strip vertically in the urine specimen for at least 3-5 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip.
4. Place the test strip on a clean, dry, non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

1. ***Positive:*** Two lines are visible, but the line in test zone (T) is the same as or darker than the one in the control zone (C). This indicates probable ovulation in 24-48 hours.
2. ***Negative:***Two lines are visible, but the line in the test zone (T) is lighter than the one in the control zone (C), or there is no line in the test zone (T). This indicates that no LH surge has been detected.
3. ***Invalid:*** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test.

Built-In Control

Luteinizing Hormone (LH) tests have a built in procedural control that demonstrates assay validity. A red line appearing adjacent to the control zone (C) indicates that the test runs correctly.

LIMITATION

1. The test is intended for qualitative detection of LH.
2. Women are suffering from polycystic ovary syndrome may have elevated LH concentration.
3. The test will not work properly for subjects who are pregnant, in menopause, or taking birth control pills.
4. The test results should not be affected by pain relievers, antibiotics and other common drugs. Medication containing HCG or LH may affect the test and should not be taken while using the ovulation tests.

PERFORMANCE CHARACTERISTICS

Analytic Sensitivity: No less than 20mIU/mL.
Analytic Specificity: The test results show negative for the 200mlU/mL hFSH and 250μlU/mL
hTSH samples.
Interference Testing
The following substances were shown not to interfere with the Luteinizing Hormone (LH) tests at or below the following concentrations. The negative result is 100%.

Table 2 Interference substances

Acetaminoph	20mg/dL	Albumin	2000mg/dL	Estriol (E-3)	25ng/mL
Acetylsalicyli	20mg/dL	Caffeine	20mg/mL	Gentisic Acid	20mg/dL
Ascorbic Acid	20mg/dL	Cortisol	200ng/mL	Glucose	2000mg/dL
Ampicillin	20mg/dL	DHEAS	500ng/mL	Tetracycline	20mg/dL
Atropine	20mg/dL	Estradiol	25ng/mL	Uric Acid	10mg/dL

Precision

Intra-assay: 10 strips of the same lot number were used in LH standard solution with same concentrations. The reaction results should be consistent and the color should be uniform.
Inter-assay: Three lots of Luteinizing Hormone (LH) tests strip were used in LH standard solution with same concentrations prepared at 20mIU/mL. The reaction results should be consistent and the color should be uniform.

Clinical Study

Clinical evaluation was conducted comparing the results obtained using the test strip to another commercially available urine LH test. This clinical study selected 120 cases in ovulation women (positive group) and 120 cases of women did not enter the period of ovulation (negative group) test, continuous monitoring for 10 days, at the same time with the company agents and has listed the qualification test, results in the following table.

Table 3 Results of Performance

Method		Luteinizing Hormone (LH) tests		Total Results
Other LH Rapid Test	Results	Positive	Negative	
	Positive	120(A)	0(B)	120
	Negative	0(C)	120(D)	120

Sensitivity=A/(A+B)*100%=100.00% (95%CI: 99.30~100.00%)
Specificity=D/(C+D)*100%=100.00% (95%CI: 99.30~100.00%)

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INDEX OF SYMBOLS

	Do not re-use
REF	Catalogue number
IVD	For In Vitro Diagnostic medical device
	Use by date
	Date of manufacture
4°C 30°C	Temperature limitation
	Consult instructions for use
EC REP	Authorized Representative in the European Community
LOT	Batch code
Σ n	Contains sufficient for < n > tests
CE 0123	CE Mark
	Manufacturer

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