CE 0123

One Step LH Ovulation Test (Strip)
For Self-testing Use Only

INTENDED USE

One Step LH Ovulation Test is a self-performing immunochromatographic one step assay designed for in vitro qualitative determination of human Luteinizing hormone (hLH) in urine to predict time of ovulation.

SUMMARY AND EXPLANATION

Human luteinizing hormone (hLH) is a glycoprotein hormone secreted by anterior pituitary. LH together with other steroid hormones are known to play important roles in regulating the ovulation and ovarian functions during the menstrual cycle. In view of the characteristic variation of LH during the menstrual cycle, rapid and sensitive measurement of LH is an important tool in the diagnosis and management of infertility in females. 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 analysis of hLH has been used successfully to time oocyte retrieval for in vitro fertilization, and would similarly assist timing of artificial insemination.

PRINCIPLE

One Step LH Ovulation Test is a qualitative, double antibody sandwich immunoassay for the determination of human Luteinizing hormone (hLH) in urine. The membrane was pre-coated with anti-α hLH in the test line region and goat anti-mouse IgG polyclonal antibody in the control line region. During the test process, the patient urine is allowed to react with a colored conjugate (mouse anti-β hLH monoclonal antibody-colloid gold conjugate) which was pre-dried on the test strip. The mixture then moves upward on the membrane chromatographically by a capillary action. When hLH is present in the sample, a color band with a specific anti-β hLH -colored conjugate complex will be formed in the test line region of the membrane.On the other hand, goat anti-mouse IgG polyclonal antibody will react with mouse anti-β hLH monoclonal antibody-colloid gold conjugate,and light color band will always appear at the control region. This control band serves as a reference of the color intensity of approximately 25mIU/ml LH. When the intensity of test band is higher than that of control band, the test is positive, indicating that the LH surge is likely in process. On the contrary, Absence of this pink-colored band in the test line region or being lighter in color of the band in the test line region than that in the control line region indicate a negative result. The presence of this pink-colored band in the control region serves as: 1) verification that sufficient volume is added. 2) that proper flow is obtained, and 3) as a control for the reagents.

REAGENTS

One LH Ovulation test strip per foil pouch.
Ingredients: Test device comprised of colloidal gold coated with 1.5mg/ml goat antibody
mouse 1mg/ml mouse anti α LH antibody and 4mg/ml mouse anti β LH antibody.

MATERIALS PROVIDED
Each pouch contains:
1.One One Step LH Ovulation Test strip
2.Desiccant
Each box contains:
1.One One Step LH Ovulation Test foil pouch
2.Urine cup
3.Package insert
No other equipment or reagents are needed.

STORAGE AND STABILITY

Store test strip at 4– 30°C (room temperature). Avoid sunlight. The test is stable until the date imprinted on the pouch label.

ASSAY PROCEDURE

1.DETERMINATION OF TEST DATE
As we know, a peak of LH concentration will come before ovulation .The ovulation of ovaries has a close relationship with the peak of LH release in menstrual period. LH peak predicts ovulates in the coming 24-48 hours. Therefore, testing appearance of LH peak in the menstrual period could ensure the best time of fertilization .

So to determine when to start testing ,you must know firstly the length of your menstrual cycle .Your menstrual cycle length is the number of days ,which is from the first day of menstrual bleeding to the day before bleeding begins in your next menstrual period.

Here is a cycle chart form, you could refer to this form to determine on which day you should begin testing .

Note: if you are unsure your cycle length,you may begin doing this test for 11 days after your first period . According to the form ,you should begin taking the test at the 5th day of the menstrual period, one for each day and stop it until the LH surge has been detected. If your cycle is less than twenty-one days or greater than forty days, consult a physician.

CYCLE CHART OF MENSTRUAL PERIOD

Menstrual Cycle Length	Time of Starting test	Menstrual Cycle Length	Time of Starting tes
21days	The 5th day	31days	The15thday
22days	The 6th day	32days	The16thday
23days	The 7th day	33days	The17thday
24days	The 8th day	34days	The18thday
25days	The 9th day	35days	The19thday
26days	The 10th day	36days	The20thday
27days	The 11th day	37days	The21thday
28days	The 12th day	38days	The22thday
29days	The 13th day	39days	The23thday
30days	The 14th day	40days	The24thday

For example ,if your usual cycle is 28 days ,and your first day of last menstruation is the 7th day of the month showed in the formed as follows, then you should begin testing on the day of 18th.

Sun.	Mon.	Tus.	Wnds.	Thurs.	Fri.	Sar.
	1	2	3	4	5	6
(7)	8	9	10	11	12	13
14	15	16	17	<18>	19	20
21	22	23	24	25	26	27
28	29	30	31			

( ) First day of your last period
<>Begin testing with the ovulation test strip (urine)

2.SPECIMEN COLLECTION AND HANDLING
The One Step LH Ovulation test is formulated for use with fresh urine specimens. The test should be used right after the specimen collected. Urine cup should be used to collect specimens, and the urine does not require any special pre-treatment. 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. For best results, collect it between 10:00 am and 8:00 pm.

3.TEST PROCEDURE
1) Remove the test strip from the foil pouch
2) Immerse the strip into the urine with the arrow end pointing toward the urine. Do not cover the urine over the MAX (maximum) line. You may take the strip out after a minimum of 15 seconds in the urine and lay the strip flatly on a non-absorptive clean surface. (See picture below)
3).Read the result at 10 minutes .
DO NOT INTERPRET RESULT AFTER 10 MINUTES.
4) Discard the test device after single use in a dustbin

4. NTERPRETATION OF RESULTS
Negative:
Only one pink line appears in the control region (C).or both of the lines in the control region and the test region appear, but the test line (T) present is lighter than that of the control line (C) in color intensity .This indicates that no LH surge has been detected and you should continue daily testing .
Positive :
Two distinct pink lines appear, one is in the test region (T), and the other in the control region (C), the test line (T) is equal or darker than the control line (C)in color intensity .Then you will probably ovulate in the next 24-48 hours. And if you want to be pregnant ,the best time to have intercourse is after 24hours but before 48 hours.
Invalid:
If there is no pink-purple colored lines visible both in the test region(T) and control region(C), or there is pink-purple colored line in the test region(T), but no line in control region(C), the test is invalid. It is recommended that the test should be repeated in this case.

Positive **Negative** **Invalid**

QUALITY CONTROL

Built in Quality Control Features
After adding the sample, these colored bands migrate along the membrane at the leading edge of the dye conjugate and are "removed" from the test strip completely.

When the test is complete, you will see only a pink-purple colored band in the "C" area of the test strip or both of bands of the test line and the control line, with the colour of the test line is lighter than that of the control line on negative samples, and a pink-purple colored band in the "T" and "C" areas shows up, with the colour of the test line is equal to or darker than that of the control line on positive samples. The appearance of the CONTROL band indicates that the test strip is performing properly and serves as a procedural control.

PERFORMANCE CHARACTERISTICS

1.ANALYTICAL SENSITIVITY & DIAGNOSTIC SENSITIVITY
Use the three transfer lots to test the standard solution with concentration as 0mIU/ml, 10mIU/ml, 25mIU/ml, 50mIU/ml, 100mIU/ml, and each concentration have tests three times. Read results at 10 minutes.

according to the test results, One Step LH Ovulation Test had shown the positive results at the concentration 25mIU/ml, so the sensitivity of the test is 25mIU/ml.

2. ACCURACY
Random urine specimens were received and tested for ovulation using One Step LH Ovulation Test and Egens LH Test

Samples were random samples collected at various times throughout the day. Comparing test from One Step LH Ovulation Test with Egens LH Test

A total of 160 urine samples were collected in the hospital, with 90 positive. No discrepancies were observed. One Step LH Ovulation Test demonstrates 100% accuracy when compared with the Egens LH Test.

3. REPRODUCIBILITY
Use three lots devices to confirm the reproducibility of the device in three different places, and by three different people.
According to the test results, three lots One Step LH Ovulation Test devices had a good reproducibility.

4.VARIABILITY
Use three lots devices to confirm the variability of the device, to test the luteinizing hormone at the point time on the a.m. and p.m. in each day, each solution had test 5 times, and read results at 10 minutes.

According to the test results, three lots devices had a good variability, and the device performance had shown the stable states.

According to the test results, three transfer lots device had a good variability, and the device performance had shown the stable states.

5.SPECIFICITY
1) Use the three transfer lots to demonstrate that if One Step LH Ovulation Test has no interference with commonly encountered substances in the urine. All the results were read at 10 minutes.

2) All the substances listed below are prepared in the laboratory of the R&D Department.

Acetaminophen	20mg/dl
Acetosalicylic Acid	20mg/dl
Albumin	200mg/dl
Ampicillin	20mg/dl
Ascorbic Acid	20mg/dl
Atropine	20mg/dl
Caffeine	20mg/dl
Creatinine	100mg/dl
Gentesic Acid	20mg/dl
Glucose	2g/dl
Hemoglobin	1mg/dl
Tetracycline	20mg/dl

Strip from each lot was tested with two urine samples containing above substances respectively, one sample has LH standard solution (25mIU/ml), the other without it. Observe the results to see if the substance in the urine will affect the test result. Testing the 12 substances one by one and record the results of the tests.

All samples were tested with One Step LH Ovulation Test. No interference was observed. The results demonstrate that One Step LH Ovulation Test has no interference with commonly encountered substances in the urine.

3)A male urine specimen was spiked with 200mIU/ml follicle stimulating hormone (FSH) 200μIU/ml thyroid stimulating hormone (TSH) tested using the One Step LH Ovulation Test. Then the urine samples were spiked with LH to give the final concentration of 25mIU/ml. Record the results.

All samples were tested with One Step LH Ovulation Test. No interference was observed. The results demonstrate that One Step LH Ovulation Test has no significant cross-reaction with 200mIU/ml hFSH and 200μIU/ml hTSH.

LIMITATION OF THE PROCEDURE

1.Alcohol may interfere the test result. It is not recommended using the test after drinking.
2.Drugs which contain HCG(such as pregnyl, profasi, novarel) or LH can affect the test result, and clomid can give a misleading positive result if you begin testing too early in your menstrual cycle. Aspirin, paracetamol, painkillers, antibiotics and any other common drug, that do not contain HCG or LH, should not affect the test result, but hormonal medications can interfere with the test results. If such medications are being taken or are suspected, seek professional advice from a physician, to confirm the test result.
3.Occasionally specimens containing less than 25mIU/ml for urine also yield positive results.
4.Women suffering from polycystic ovary syndrome may have elevated LH concentration (1). In this case, test result is false positive.
5.Pregnant women should not use this test. Since urine of pregnant women contains high concentration of HCG and reagents used in the test kits are cross-reactive with hCG, there will be false positive result.
6.As is true with any diagnostic procedure, the user should evaluate data obtained by the use of this kit in light of other clinical information and consult to the physicians for the final diagnosis of ovulation before any decision of medical relevance.
7.First morning urine is not recommended to be the test specimen, because LH concentration in the serum surges in the early morning, for most women, which, however does not show up in the first morning urine.

WARNING

FOR IN VITRO DIAGNOSIT USE ONLY
1.Read directions for use carefully before performing this test. Pay attention to the position of the C and T line.
2.Do not use beyond the labeled expiration date.
3.Do not reuse the test devices. Discard it in the dustbin after single use
4.Do not use if pouch is damaged or opened.
5.Do not touch the membrane on the strip
6.Once open the pouch, the test device should be used immediately. Prolonged exposure to ambient humidity will cause product deterioration
7.Treat urine samples and used devices as if they are potentially infectious. Avoid contact with skin
8.Examine if the urine cup exists before usage.
9.The ideal time to test is in the afternoon, not early morning, though testing may safely take please from 10am to early evening.
10.Consult a doctor if irregular or unusually long cycles are experienced.
11.The antibodies have 0.01% sodium azide.

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EC REP

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	Do not reuse
IVD	For in vitro diagnostic use only
4°C 30°C	Store at 4°C to 30°C
	Consult instruction for use
	Keep away from sunligh
LOT	Batch code
	Date of manufacture
	Manufacturer
EC REP	Authorized Representative
	Use by

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