One Step LH Ovulation Urine Test (Midstream) CE 0123

For Self-Testing

In vitro Diagnostic Use

Can not be reused

Consult instructions for use

Batch number

Use before

Keep dry

Keep away from sunlight

Disposal of all waste material should be in accordance with local guidelines.

Manufacturer

Store at between 2-30°C

Date of Manufacture

INTRODUCTION

The One step LH Ovulation Test is an immuno-chromatographic in vitro assay for the qualitative and semi-quantitative determination of the human luteinizing hormone (LH) in urine to predict the time of ovulation in women.

Each pouch contains one immunochromatographic test. Each One step LH kit contains a test membrane with an anti-LH antibodies and conjugates, in a stabilizing matrix containing proteins and sodium azide.
Storage conditions
Store below 30°C; do not freeze.
Limitations:

- One step LH is for in vitro diagnostic use only. Elevated concentrations of chorionic gonadotropin (hCG) interfere with LH testing. Do not test samples from pregnant women and people with pathologic conditions causing higher hCG levels.
- Do not use One step LH as an aid in contraception

PEINCIPLE

Luteinizing hormone is always present in human urine. LH increases dramatically just before a woman's most fertile day of the month in a process commonly referred to as the "LH Surge." This LH increase triggers ovulation, the process during which an egg is released from a woman's ovary. Because the egg can only be fertilized between 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 11:00 am to 3:00 pm and between 5:00 pm to 10:00 pm. Early morning testing is not recommended as LH does not appear in the urine until later in the day. To ensure that you do not miss your surge, you may test twice a day, once in the earlier time frame and once in the later time frame. The detection limit for the LH Test Kit is 30 mIU/ml LH. Urine samples with LH concentrations of 30 mIU/ml or greater will induce a positive result.

TEST PROCEDURE AND INTERPRETATION OF RESULTS

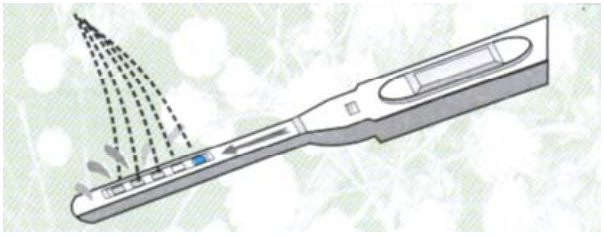
For each test, collect a fresh urine sample at about the same time each day. Do not use first morning urine. Use a clean, dry container. For optimal results, perform the test on a fresh sample. If necessary, the sample may be stored for up to seven hours at room temperature, or up to 24 hours in a refrigerator. Do not freeze the test sample.

NOTES
Do not open the test pouch until you are ready to perform the test.
If a sample or a test kit was refrigerated, allow it to warm up to room temperature before performing the test.

TEST PROCEDURE

1. Allow the sealed LH Midstream test pouch, patient's urine sample and control solution to reach room temperature (18-30°C).
2. Remove the LH Midstream test device from the sealed pouch.
3. Hold the round end of cover with one hand. Use the other hand to pull out the test device and expose the absorbent.(see picture 1)
4. Point the absorbent tip downward, place the absorbent tip in urine stream for at least 5 seconds 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.
5. Re-cap the device and wait for color bands to appear. Depending on the concentration of LH, positive result may be observed in as short as 40 seconds. However, to confirm negative results, the complete reaction time (5 minutes) is required. Do not read results after 5 minutes.

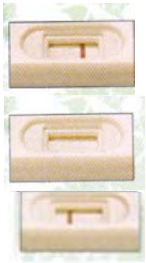
Picture 1



INTERPRETATION OF RESULTS

Positive for L.H. surge - If two colour bands are visible and the test band is of equal or greater colour intensity (darker) than the control band, this is a positive result and a good indication that the L.H. surge is occurring.
Negative for L.H. surge - If two bands are visible but the test band is of a less intense colour (paler) than the control band or cannot be seen, this means the L.H. level is at or near its normal level and that the surge is not in progress.
Invalid result - If no control band appears within 5 minutes, the result is invalid and should be ignored.

Positive
The test line is of equal or greater intensity than the control line. LH surge is detected.



Negative
The test line is of less or intensity than the control line, or the test line is not visible. LH level is not elevated (LH surge is not detected).

Invalid
The test is invalid if the control line is not visible at five minutes. The test failed, or the test procedure was not followed properly. Verify the test procedure and repeat the test with a new testing device.

WHEN TO BEGIN TESTING

First, you must 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 again. Please refer to the 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 a 5 day period or until the LH surge has been detected.

SPECIMEN COLLECTION

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 - 8pm. Pick a regular time that suits you best.
3. Collect urine at about the same time each day.

Reduce liquid intake about 2 hours before collecting your urine as a diluted urine sample can prevent the test from detecting LH surge.

Your Cycle Length	Start To Test On
21 days	Day 6
22 days	Day 6
23 days	Day 7
24 days	Day 7
25 days	Day 8
26 days	Day 9
27 days	Day 10
28 days	Day 11
29 days	Day 12
30 days	Day 13
31 days	Day 14
32 days	Day 15
33 days	Day 16
34 days	Day 17
35 days	Day 18
36 days	Day 19
37 days	Day 20
38 days	Day 21
39 days	Day 22
40 days	Day 23

PERFORMANCE CHARACTERISTICS:

Empirical Evidence:

According to BS EN ISO14971:2007 method for Implementation of risk analysis can refer to the list of judgment of risk analysis report in following:

Urine samples: 187 randomly selected urine samples from specimen bank which is maintained in Dept. of Obstetrics and Gynecology at the Hospital.

Analysis of the Results

The sensitivity and specificity will be calculated as follows:

$$\text{Sensitivity}(\%) = 100 \times \frac{\text{No. of urine samples showing positive result}}{\text{No. of confirmed positive urine samples}}$$

$$\text{Sensitivity}(\%) = 100 \times \frac{\text{No. of urine samples showing negative result}}{\text{No. of confirmed negatitive urine samples}}$$

From 187 urine samples taken, both Sensitivity and Specificity figures are more than 99 %. Hence, the risk of false positives and false negatives is less than 1 %.

1. *SENSITIVITY*
One Step LH Ovulation Test will display positive results with specimens containing LH at the level close to or greater than 30mlU/ml.

2. ACCURACY
Comparison studies on the One Step LH Ovulation Test with a legally marketed device were performed in-house and in a clinical reference laboratory. Positive and negative results were compared and the correlation was >99 %.

3. SPECIFICITY

Cross Reactivity
The cross reactivity of LH test kits was evaluated with LH homologous hormones. Homologous hormones FSH and TSH were added to urine samples containing LH at concentration of 0, 30 or 100 mIU/mL. No cross reactivity was observed in the study (shown as Table 1).

Non-specific interference
One-step LH test was checked for possible interference from visibly hemolyzed, lipemic and icteric samples. Human hemoglobin, bilirubin or albumin was spiked into samples with different concentration of LH and tested using un-spiked sample as controls. No significant interference was observed in 20 sample testing results that were either positive or negative for LH. The results are shown as Table

Table 1 - Cross-reactivity study of One-step LH test kit

LH conc. in urine sample (mIU/mL)	Unspiked urine samples	Urine samples spiked with homologous hormones	
		FSH	TSH
		1000 mIU/mL	1000 mIU/mL
0	-	-	-
	-	-	-
	-	-	-
30	+	+	+
	+	+	+
	+	+	+
100	+	+	+
	+	+	+
	+	+	+

Table 2 - Non-specificity study of One-step LH test kits

Sample No	Unspiked samples	Urine samples spiked with (mg/mL)			
		Hemoglobin		Bilirubin	Albumin
		10	1	0.06	100
1	-	-	-	-	-
2	-	-	-	-	-
3	-	-	-	-	-
4	-	-	-	-	-
5	-	-	-	-	-
6	-	-	-	-	-

7	-	-	-	-	-
8	-	-	-	-	-
9	-	-	-	-	-
10	-	-	-	-	-
11	+	+	+	+	+
12	+	+	+	+	+
13	+	+	+	+	+
14	+	+	+	+	+
15	+	+	+	+	+
16	+	+	+	+	+
17	+	+	+	+	+
18	+	+	+	+	+
19	+	+	+	+	+
20	+	+	+	+	+

The data collected to date indicate that our One-Step LH test kits are stable for at least 24 months at 2-30°C.

QUALITY CONTROL

Appearance: All materials are visually inspected before their use in manufacturing.

Specificity: 10 test kits are randomly selected and tested with no LH Surge control panel. All test results must be negative.

Cut Off: 10 test kits are randomly selected and tested with a control panel that contains more than 30 mIU/mL LH. All test results must be positive.

Internal Control: A colored band must appear in the control region of the membrane with each tested kit, which indicates proper performance and reagent reactivity.

Reproducibility: Randomly selected test kits from different lots must give the same results when assaying the same sample.

STORAGE AND STABILITY

The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch for 24 months。 The test kit should be kept away from direct sunlight, moisture and heat

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