One Step LH Ovulation Test (Cassette)

INTENDED USE

One Step LH Ovulation Test is a rapid chromatographic immunoassay for the qualitative detection of luteinizing hormone (LH) in urine to aid in the detection of ovulation. The test is designed for over-the-counter and in vitro diagnostic use.

SUMMARY AND EXPLAINATION

Ovulation is the release of an egg from the ovary. The egg passes into the fallopian tube where it is ready to be fertilized. In order for pregnancy to occur, the egg must be fertilized by sperm within 24 hours after its release. Immediately prior to ovulation, the body produces a large amount of luteinizing hormone (LH). This is known as the "LH surge" and usually takes place in the middle of the menstrual cycle. LH triggers the release of an egg from the ovary.

AI DE One Step LH Ovulation Test is a complete system to help you predict the time of ovulation and peak fertility. It is during this fertile time that pregnancy is most likely to occur. AI DE One Step LH Ovulation Test detects the LH surge in urine, signaling that ovulation is likely to occur in the next 24 – 36 hours.
Important: the LH surge and ovulation may not occur in all cycles.

PRINCIPLE OF TEST

The One Step LH Ovulation Test is a rapid chromatographic immunoassay for the qualitative detection of luteinizing hormone (LH) in urine to aid in the detection of the onset of ovulation. The test utilizes a combination of antibodies including mouse monoclonal anti-LH antibodies and goat polyclonal anti-mouse antibodies to selectively detect elevated levels of LH. The assay is conducted by adding urine specimen to the test device and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific colored antibody conjugates and form a darker or equal dark colored line at the test line region of the membrane compared to the control region. Absence of this colored line or the colored line lighter than the control line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

REAGENTS

Coated Antibodies: Control region: Goat anti-mouse (IgG) polyclonal antibody
Test region: Mouse monoclonal anti-LH antibody A
Labeled Antibodies: Colloidal gold conjugate of monoclonal anti-LH antibody B

MATERIALS PROVIDED

1) One Step LH Ovulation Test
2) Disposable pipette
3) Instructions for use

MATERIALS NEEDED BUT NOT PROVIDED

1) Clean glass or plastic container for specimen's collection
2) Timer

WARNINGS & PRECAUTION

1) For in vitro diagnostic use for OTC use only.
2) Check expiration date on package label before use. Do not use test kit beyond the expiry date.
3) Inspect pouch for damage before use. Do not use if pouch is visibly damaged before opening.
4) The test kit should not be reused.
5) The test kit is moisture sensitive and should be used immediately after taking out of the pouch. When handling, avoid touching the test membrane.
6) Urine specimens may be infectious; insure proper handling and dispose of all used reaction devices into a biohazard container.

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, count the first day of bleeding as day 1. Calculate what the usual length of your menstrual cycle has been over the last few months. Once you have worked out the length of your cycle refer to the chart to determine on which day of your menstrual cycle you should begin testing.

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

Example:

If your cycle is normally 28 days, the cycle chart above indicates you should begin testing on Day 11. The calendar below shows you how to work out when day 11 is.

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

SAMPLE CALENDAR

3 = the first day of menstrual bleeding (day 1)
13 = the day to begin ovulation testing (day 11)

NOTE:
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 until the LH surge has been detected.

SPECIMEN COLLECTION

A fresh urine specimen should be used, no special pre-treatment is necessary. Specimens should be collected in a clean glass or plastic container.

Once you have identified what day you should begin testing you should then begin to collect your urine on a daily basis.

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.

Urine samples may be stored for later testing within the same day. Urine can be stored at room temperature for up to 8 hours or in the refrigerator for up to 24 hours. Do not freeze. For the best result, test the urine sample on the same day of collection. If sample has been previously refrigerated, let it equilibrate to room temperature before testing (about 30 minutes). Do not shake the collection container. If sediment forms at the bottom of the collection container, allow the sediment to settle. Only test urine from the top of the container.

DIRECTIONS FOR USE

Allow the test and the specimen to equilibrate to room temperature (15-30°C) prior to testing

1. Determine the day to begin testing.
2. Collect urine sample in a clean and dry container.
3. To begin testing, open the sealed pouch and remove the test cassette and Pipette. Do not remove the cassette until you are ready to begin testing.
4. Place the test Cassette laterally on a flat and clean surface. Draw 0.2ml (about 4 drops) sample into the pipette, and dispense it into the sample well on the cassette.
5. Wait for coloured bands to appear. Depending on the concentration of LH in the urine specimen, positive results may be observed in as short as 40 seconds. However, to confirm negative results, the complete reaction time of 10 minutes is required. Do not read results after 30 minutes.

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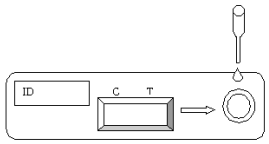
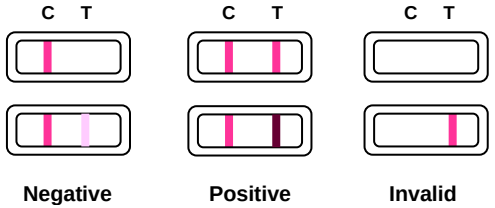


Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 30 minutes.

INTERPRETATION OF RESULTS

After each test, you must decide if you are having a L.H. surge. To determine your result, you must compare the colour intensity of the test band to the control band. The control band is used to compare the test band against and also confirms that you have completed the test correctly.

- **Positive for L.H. surge:** If two colour bands are visible and the test band is of almost 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. You should ovulate within the next 24-36 hours. Sexual intercourse is advised at any time after the first positive test.
- **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. You should continue with daily testing.
- **Invalid result:** If no control band appears within 5 minutes, the result is invalid and should be ignored. A visible control line is needed in all cases to confirm a proper test result. Repeat test with a new test kit.



STORAGE AND STABILITY

The test kit can be stored at temperatures between 2 to 30 ℃ in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat. The expiration dating was established under these storage conditions.

QUALITY CONTROL

A pink line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

LIMITATIONS

1. The test works only when the test procedures are precisely followed from the test insert.
2. Do not reuse the test kit. It is strictly for one time use.
3. This test is not be used as a form of birth control.
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 this one step ovulation test. In addition, the test will not work properly if the urine sample is from a person who is pregnant, menopausal, or taking birth control pills.

PERFORMANCE CHARACTERISTICS

Laboratory Studies have shown that the sensitivity of the AI DE One Step LH Ovulation Test is 20 mIU/mL in studies with spiked urine samples. The results are shown in Table 1.

Table 1: Cutoff Concentration Study of AI DE One Step LH Ovulation Test

LH mIU/mL	0	10	20	40	100
Negative	20	19	0	0	0
Positive	0	1	20	20	20

Laboratory Studies have shown that the AI DE One Step LH Ovulation Test has 99% accuracy in comparison studies with a predicate device. . The results are shown in Table 2.

Table 2: Comparison Studies with Predicate Device

		Predicate		Subtotal
		+	-	
AI DE LH (Cassette)	+	41	1	42
	-	0	78	78
Subtotal		41	79	120

Specificity has been determined from cross reaction with high physiological concentrations of FSH and TSH at 1000 mIU/mL. Under these circumstances, the AI DE One Step LH Ovulation Test did not show any cross reactivity with the expected test results. The results are shown in Table 3.

Table 3: Cross-reactivity study of One Step LH Ovulation Test

LH Conc. in Sample (mIU/mL)	Without Spiking	Spiked Urine Samples (mg/mL)	
		FSH 1000 mIU/ml	TSH 1000 μIU/ml
0	-	-	-
20	+	+	+
100	+	+	+

Interference testing was tested on the AI DE One Step LH Ovulation Test with the following compounds. None of these compounds at the concentration interfered with the assay. The results are shown in Table 4.

Table 4: Interference Studies

Acetaminophen	20 mg /mL
Acetylsalicylic Acid	20 mg/mL
Ascorbic Acid	20 mg/mL
Atropine	20 mg/mL
Caffeine	20 mg/mL
Gentesic Acid	20 mg/mL
Glucose	2 g/dL
Hemoglobin	1mg/dL

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GRAPHICAL SYMBOLS USED

	Storage temperature	LOT	Lot number
IVD	In vitro diagnostic device		Expiry date
	Read instruction before use		Manufacturer
	Do not reuse		

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