One Step Ovulation Test CE 0123

One Step LH Urine Ovulation Test (Strip)

INTRODUCTION:

Ovulation is the release of an egg from the ovary. The egg then passes into the fallopian tube where it is ready to be fertilized. A baby is conceived when the male sperm successfully fertilizes the female egg. When a woman is about to ovulate, her body releases a large amount of a hormone called L.H. (Luteinising Hormone). L.H. is always present in your urine but the levels increase (surge) in the middle of your cycle, causing you to release an egg from the ovary.

INTENDED USE:

The One Step Ovulation Test is an immunochromatographic 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. The test detects the sharp increase in LH concentration in urine, the so called "LH surge" which precedes ovulation. Conception is most likely to occur within 36 hours following the LH surge.

CONTENTS:

Each pouch contains one immunochromatographic test. Each test contains a membrane with anti-LH antibodies and conjugates, in a stabilizing matrix containing proteins and sodium azide.

STORAGE AND STABILITY:

Store below 30°C; do not freeze.

LIMITATIONS:

- **The One Step Ovulation Test** is for in vitro diagnostic use only.
- Elevated concentrations of Human Chorionic Gonadtropin (HCG) interfere with LH testing. Do not test samples from pregnant women and people with pathologic conditions causing higher HCG levels.
- **The One Step Ovulation Test** is not designed to prevent conception. As sperm can survive for 72 hours you might still become pregnant if you had intercourse before you detected your L.H. surge.

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.

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

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.

Manufactured by: AI DE Diagnostic Co. Ltd., 141 Zhu Zhou Road, Quingdao High-Tech Industrial Park, 266101 Shandong, P.R. China
EC REP EC REP: SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (Europe), Eiffestrasse 80, 20537, Hamburg, Germany
Distributed in the UK by Home Health UK Ltd Tel: 01923 711 511, Website: www.homehealth-uk.com, Email info@homehealth-uk.com

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SPECIMEN COLLECTION:

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

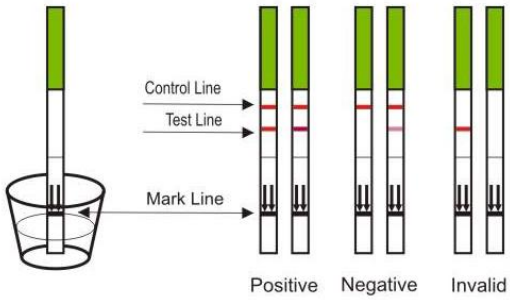
1. Do not use first morning urine samples as LH is synthesized in your body early in the morning. It will not show up in your urine until later in the day.
2. The best time to collect your urine is between 10am - 8pm. Pick a regular time that suits you best.
3. Collect urine at about the same time each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

BEFORE YOU BEGIN:

1. Read the instructions thoroughly before you begin.
2. Do not open the foil pouch until you are ready to begin the test.
3. Make sure you have a watch, clock or timer ready.
4. Allow urine samples and test kit to reach room temperature before testing (approx 20 mins).

TEST PROCEDURE:

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 strip. Do not remove the strip until you are ready to begin testing.
4. With the arrows pointing downwards towards the urine, place the test strip vertically (straight) into the urine sample, for at least 10 seconds. **DO NOT** allow the urine to go above the MARK level line.
5. Remove the strip from the urine and place on a clean, dry surface.
6. Wait for coloured bands to appear. Depending on the concentration of LH in the urine specimen, positive results may be observed within 1 minute. However, to confirm negative results, the complete reaction time of 10 minutes is required. Results obtained after 30 minutes may be considered invalid.



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 anytime 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.

If you do get unexpected results you should discuss them with your doctor.

Interpretation of the symbols:

	Storage temperature	LOT	Lot number
IVD	In vitro diagnostic device		Expiry date
	Read instructions before use		Manufacturer
REF	Catalogue Number		Do not reuse
Σ	Number of tests in pouch		

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