One Step Ovulation Test Midstream (Urine)

For self-testing and In Vitro diagnostic use only

CE0197

INTENDED USE

The One Step Test is an immunochromatographic one step assay designed for in vitro qualitative determination of human luteinizing hormone (hLH) in urine to predict time of ovulation. LH surge usually comes before ovulation, which means release of an egg. An egg can only live for 24 hours or less after it is released, while sperm survives only a few days in your body. Consequently, the One Step Test can help you predict the two most fertile days following the detected LH surge. Having intercourse within these days will maximize your chances of becoming pregnant.

REAGENTS AND MATERIALS

Each **One Step Test** midstream is individually sealed in a foil pouch.

Materials Required But Not Provided: Timer, specimen container.

STORAGE AND STABILITY

The test kit is to be stored at room temperature (4°C to 30°C) in the sealed pouch for the duration of the shelf life.

PRECAUTION

Do not use the test kit beyond the expiry date.

WHEN TO START TESTING

First, determine the average length of your menstrual cycle. The length of menstrual cycle is the number of days from the first day of menstrual bleeding to the day before bleeding begins on the next period. Determine the usual length of the menstrual cycle over the last few months. Then refer to the Cycle Chart to determine on which day of the menstrual cycle to begin testing.

Cycle Chart

Usual cycle length	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
Days to begin testing	06	06	07	07	80	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23

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.

Example Calendar

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TEST PROCEDURE

- 1. Choose a convenient time of the day to perform the test. Try to test at about the same time each day for the entire cycle. For best results, test between 10:00 am and 8:00 pm. Remove the midstream test from the foil pouch.
- 2. Remove the Cap.
- 3. Hold the midstream test by the handle with the exposed tip pointing downward, directly into your urine stream for at least 10 seconds until it is thoroughly wet.
- 4. After removing the midstream test from your urine, immediately replace the cap over the tip, lay the midstream test on a flat surface with the Test and Control window facing upwards, and then begin timing.
- 5. Read the results at 5 minutes.
- 6. DO NOT INTERPRET RESULT AFTER 10 MINUTES.

INTERPRETATION OF RESULTS

^{()—}The first day of menstrual bleeding < >--The day to begin the ovulation testing (day 11).

<u>Positive for L.H. surge</u> - 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. You should ovulate within the next 24-36 hours. Sexual intercourse is advised at anytime after the first positive test.

<u>Negative for L.H. surge</u> - 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.

<u>Invalid result</u> - 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.



SURGE





