

CLEAR OVUM

One Step Fertility (LH) Rapid Test Device

INTENDED USE

The Clear Ovum Rapid Test is a rapid lateral flow chromatographic immunoassay for the qualitative detection of luteinizing Hormone (LH) level in urine to aid in the early detection of Ovulation.

KIT COMPONENTS

Test Cassette packed in individual foil pouches with desiccant and disposable specimen dropper

STORAGE AND STABILITY

The kit can be stored 4-30°C till the expiration date printed on the sealed pouch. DO NOT FREEZE.

PRECAUTIONS

- For professional in vitro use only.
- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Do not use test if pouch is damaged.
- The test should be discarded according to local regulations

SPECIMEN COLLECTION & PRESERVATION

- Determine the optimal time for urine collection. For best results, collect urine at about the same time each day. Some women have found that their best specimen is after 12 noon. Do not collect the first urine specimen after waking up.
- Reduce liquid intake approximately 2 hours prior to urine collection
- Record the date, cycle day and time of urine collection. See the TESTRESULTCHART at the end of this package.
- Urine specimen may be stored at 2-8°C for up to 24 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

DIRECTION FOR USE

Allow the test device, urine sample and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- Determine the day to begin testing. See the above section : (WHEN TO START TESTING)
- Remove the test device from sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 2-3 drops of urine (approx. 60- 90µl) to the specimen well (S) of the test device. Start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
- Wait for the colored line(s) to appear. Read result at 10minutes. Do not read the results after 10 minutes.

QUALITY CONTROL

A Procedural control is included in the test. A colored line appearing in the Control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

It is recommended that external positive and negative controls be tested with each new kit, lot or shipment of product, with each change in operator within the test kit, weekly as a check on continued storage conditions, and as otherwise required by your laboratories internal quality system procedures

A positive result indicates that the urine specimen contains the level of LH that would indicate the beginning of ovulation. Ovulation should begin in 24-36 hours.

Not every women ovulates mid-cycle, therefore a positive result may not appear during the selected days of testing. If you see no positive result, continue testing with the LH kit for several more days. If negative results persist, test again during the next menstrual cycle.

LIMITATIONS

- The test works only when the procedures are precisely followed.
- For OTC and professional in vitro diagnostic use.
- The test results should 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 the CLEAR OVUM Ovulation test kit. In addition the test will not work properly for subject's who are pregnant, in menopause or are taking birth control pills.
- Keep out of the reach of children.

PERFORMANCE CHARACTERISTICS

Laboratory studies show that the sensitivity of LH CLEAR OVUM one step rapid test is 25 mIU/ml and the accuracy is 99.0%.

INTERFERENCE

The CLEAR OVUM LH one step ovulation test device has been tested with commonly known drugs and hormones including FSH (1000 µIU/ml), and TSH (1000 µIU/ml). At the levels tested, none of these substances interfered with the expected test results.

REFERENCE

Elkind-Hirsch, K; Gibbons, WE and Besch, PK, Obstetrics and Gynecology, 67(3):450-453, 1986

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WHAT IS OVULATION & HOW IT IS USEFUL

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. In order to conceive, the egg must be fertilized by sperm within 24 hours after its release. About 24-36 hours before the mature egg release an LH Levels trigger which is called "LH SURGE". Approximately 12 to 36 hours after the LH SURGE, the enlarged follicle ruptures to release the mature egg. Following Ovulation, LH returns to its normal level in 48 hours. The rapid change of LH level in short period of time during the menstrual cycle makes LH an excellent predictor for Ovulation. CLEAR OVUM Kit detects this LH SURGE.

The CLEAR OVUM Rapid test kit detects the "LH SURGE" in urine, telling her that ovulation is likely to occur in the next 1-2 days. The identification of these 1-2 days are very important for perfect planning of Conception.

Note:- The "LH SURGE" and Ovulation may not occur in all cycles.

WHEN TO START TESTING

First determine the menstrual cycle length. The menstrual cycle length is the number of days from the first day of the subject's period (menstrual bleeding) to the last day before the next period starts.

MENSTRUAL CYCLE LENGTH TABLE




MENSTRUAL CYCLE LENGTH IN (DAYS)	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38
DAY TO START TESTING	6	6	7	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21

DAYS ON WHICH TESTING STARTS

Finally determine the day to start testing. Starting from and including the first day of the last period, count ahead the number of days indicated in the previous step. This is the day on which testing should begin. As a basic guide line, it is recommended to test once a day for five days.

If uncertain about the length of subject's menstrual cycle, use the shortest menstrual cycle length (21 days) when reading the chart. In this case, it may be necessary to test for more than 5 days.

EXAMPLE: The above chart shows the day on which LH testing Should be started for different female according to their menstrual cycle length. For example if your menstrual cycle length is 33 days and your first day of menstrual cycle (the day on which bleeding starts) is on Friday 5th date of calendar month then according to above menstrual cycle length Table, Starting from and including 5, count ahead 16 days to arrive at the 20. Urine collection should be done around 12 noon and testing should start on the 20th and proceed for next 4 days till 24th. See the Example specimen calendar below).

SUN	MON	TUE	WED	THU	FRI	SAT
	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 the last period				
		Begin testing with the CLEAROVUMONESTEPRAPIDTEST				
		Proceed testing with CLEAROVUMONESTEPRAPIDTEST				

RESULT & ITS INTERPRETATION

POSITIVE	Two lines are visible and the color intensity of the line in the test line region (T) is the same as or darker than the line in the control line region (C). This indicates probable ovulation in 24-36 hours.
NEGATIVE	Two lines are visible, but the line in test line region (T) is lighter than the line in the control line region (C), or there is no visible line in the test line region (T). This indicates that no LH surge has been detected.
INVALID	If there is no line in the control line region (C) at 5 minutes, the result is invalid. The test should be repeated. The test is not reusable. The most likely reasons for an invalid result are that not enough urine specimens were used, or the test was performed the wrong way. Review the directions for use and repeat with a new test. If the problem persists, discontinue using the test kit and contact your distributor.

In 33 days Menstrual cycle the LH Level remains normal (below 25 mIU/ml) from day 1 to 15 and LH Level before 24-36 hours of ovulation surges and if user do not conceive in this ovulation time LH level again comes to normal in next 48 hours.

If user conceive in this ovulation time the hCG Level will go high and shall be detected (only after 2-3 days of your expected period date) with the help of Pregnancy kit.

