

UK

Alvita Ovulation Test Kit

The Alvita Ovulation Test Kit is a qualitative test used to predict when there is a LH (Luteinizing Hormone) surge, and in turn, when you are likely to ovulate. (For in vitro self test use only. For external use only.)

HOW DOES IT WORK?

The LH (Luteinizing Hormone) which is in the urine of normal women will increase dramatically in the middle of the menstrual cycle. The LH increase triggers ovulation which is when the egg is released periodically from normal fertile women. (WHO experts state that LH testing is a reliable way to detect ovulation.) Ovulation will occur 24-48 hours after a positive test.

When a urine specimen is applied to the absorbent tip of the stick, capillary action carries the urine along the membrane. If a detectable level of LH is present in the urine that reaches the Test Zone region, it will form a coloured line. Absence of this coloured line suggests a negative result.

To serve as a control procedure, a coloured line will appear in the Control Zone region. If the test has been performed properly. The test stick detects ovulation with a high degree of certainty. It is a valuable tool in helping to achieve pregnancy since it determines the period when the woman is at her most fertile. Ovulation may be irregular because of circumstances, emotions and other factors in your life. You cannot presume that ovulation always occurs at the same time after menstruation. Therefore, you should test again in each menstrual cycle.

CONTROL ZONE

1. Seven pouches containing a test stick and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.

2. Leaflet with instructions for use.

WHAT ELSE DO YOU NEED?

1. A clean, dry, plastic or glass container to be used to collect urine as an alternative to urinating directly onto the absorbent tip.

2. Timer (watch or clock).

PRECAUTIONS

- 1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test stick cannot be used more than once.
3. Do not use test kit beyond expiration date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.

STORAGE AND STABILITY

- 1. Store at 4°C to 30°C in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. DO NOT FREEZE.
4. Preferably open the pouch only shortly before the test.

SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR THE TEST?

A urine specimen collected at any time during the day is appropriate for Ovulation Testing. We suggest that you limit your fluid intake for about two hours before you collect your urine because heavy intake of fluids prior to testing will dilute the hormone in your urine.

HOW TO COLLECT URINE?

Urine specimens may be collected in any clean, dry, plastic or glass container.

WHEN TO BEGIN TESTING

The length of the menstrual cycle is the duration from your first menstrual bleeding day to the day before the next bleeding begins. Determine the length of menstrual cycle before testing. Please refer to the chart below to determine when you should start testing. If your cycle is shorter than 21 days or longer than 38 days, consult a physician. If you do not know your cycle length, you may begin testing 11 days after your first period because 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.

Invalide. No visible line in the control zone. Repeat with a new test kit. If test still fails, please contact the distributor or the store where you bought the product, with the lot number.



Cycle Length

Table with 2 columns: Cycle Length (21-40 days) and Day (Day 5-24)

Cycle Chart

Table with 2 columns: Day (1-31) and Cycle Chart (dots representing ovulation)

Example: If your cycle is normally twenty-six days, the Cycle Chart indicates testing should begin on day 10. The following calendar shows how to determine day 10.

Sample calendar table showing days 1-7

3rd of the month = The first day of menstrual bleeding
12th of the month = The day to begin testing (Day 10)

HOW TO DO THE TEST

- 1. To begin testing, open the sealed pouch by tearing along the notch. Remove test stick from the pouch.
2. Hold the round end of the stick with one hand. Use the other hand to pull out the cap and expose the absorbent tip.
3. Point the absorbent tip downward and place it in the urine stream for at least 10 seconds to be thoroughly wet. Do not urinate above the arrow mark.
4. Alternatively, you can collect your urine into a clean container and dip half of the absorbent tip into the urine for at least 3 seconds.
5. Re-cap the device and wait for the colour bands to appear. Read the result in five minutes. Do not read results after more than 5 minutes.

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Control Line



LIMITATIONS

- 1. The test works only when the test procedures are precisely followed.
2. This test may not be used as a form of birth control.
3. Consult a doctor if irregular or unusually long cycles are experienced.
4. This is a qualitative screening assay. It is not designed to determine the quantitative concentration of LH.
5. The device is only suitable for human urine test.
6. Unclean specimen or interfering substances in the urine may cause false result.
7. Unclean test device may cause false result.

PERFORMANCE CHARACTERISTICS

ACCURACY

429 urine specimens were tested with the Alvita Ovulation Test Kit and a reference test in a clinical Reference Laboratory. The correlation between the Alvita Ovulation Test Kit and the reference test was 99.8%.

AGREEMENT OF THE POSITIVE WITH THE REFERENCE TEST

Table showing agreement of positive results with reference test: Alvita Test (+/-) vs Reference Test (+/-/Total)

AGREEMENT OF THE NEGATIVE WITH THE REFERENCE TEST

Total Agreement with the reference test: 99.8% (428/429)

SENSITIVITY AND SPECIFICITY

The Alvita Ovulation Test Kit will detect hLH in human urine at the level higher than 25 mIU/mL. The test has been calibrated by the W.H.O. Standard (2nd WHO International Standard (S) 80/552). No cross-reaction appears when hFSH (200 mIU/mL), hTSH (250 mIU/L), and hCG (500 mIU/mL) were added to the negative (0 mIU/mL LH) and positive (25 mIU/mL LH) specimens.

INTERFERING SUBSTANCE

The following potentially interfering substances were added to LH negative and positive specimens.

Table listing interfering substances: Acetaminophen, Acetylsalicylic acid, Ascorbic acid, Atropine, Caffeine, Gamtic acid, Glucose, Hemoglobin, Tetracycline, Ampicilline

QUESTIONS & ANSWERS

- 1. There is much difference between the control lines of two tests. Is this a concern?
2. Can test results be interpreted after more than five minutes?
3. How long should I continue to perform the test?
4. A pink background color and vertical streaking appeared in the result area during the testing period. Is this a concern?

QUESTIONS & ANSWERS

1. There is much difference between the control lines of two tests. Is this a concern?
No. Variations in the color of the Control line will not affect the test result. It is only effective to compare the colour of the Test line to that of the Control line of the same device on the day the test is performed.

2. Can test results be interpreted after more than five minutes?
No. Test results must be read at 5 minutes. Though a positive result should not change for several days, a negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading. It is always best to read the results at the 5 minute testing period and then discard the test to avoid confusion.

3. How long should I continue to perform the test?
At least 5 days or until the LH surge has been detected.

4. A pink background color and vertical streaking appeared in the result area during the testing period. Is this a concern?
No. Each urine sample will vary in its chemical makeup, as will the humidity of the air in testing chamber (room). Such variations in physical conditions can cause the vertical streaking and/or the pink-rose background color but will not affect the test results. As long as the Control line appears within five minutes, the test is working properly.



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