

OVULATION TEST STRIP

INSTRUCTIONS FOR USE

Catalogue No. See Box Label

INDICAID $^{\text{TM}}$ Ovulation Test Strip is a qualitative test used to predict when there is a luteinizing hormone (LH) surge, and in turn, when you are likely to ovulate.

For in vitro diagnostic use.

It is intended for over-the-counter use.

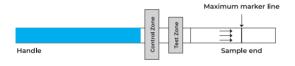
HOW DOES IT WORK

Luteinizing hormone (LH) 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. Per WHO, LH testing is a reliable way to detect ovulation. Ovulation will occur after 24-48 hours following a positive test.

When the strip is immersed into a urine specimen, capillary action carries the specimen to migrate along the membrane. When LH in the specimen reaches the Test Zone region of the membrane, it will form a colored band. Absence of this colored band suggests a negative result.

To serve as a procedure control, a colored band will appear at the Control Zone if the test has been performed properly.

The test strip detects ovulation with a high degree of certainty. It is a valuable tool in helping to achieve pregnancy since it determines the period that the egg and the sperm cells will meet in the best conditions. 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.



CONTENT OF THE TEST KIT

- INDICAID™ Ovulation Test Strips, each in one pouch with one desiccant. The desiccant is for storage purposes only and is not used in the test procedures.
- 2. Package Insert

WHAT ELSE DO YOU NEED

- 1. A clean, dry, plastic or glass container to collect the urine.
- 2. Timer (watch or clock)

PRECAUTIONS

- 1. This kit is for external use only. Do not swallow.
- 2. Discard after first use. The test strip 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 39°F-86°F (4°C-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?

Any urine specimen is appropriate for ovulation testing.

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 test. 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 your physician. 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 over a 5 days period, or until the LH surge has been detected.

	Cycle Length	Day of Cycle to Begin Testing	
Cycle Chart	21 days	Day 5	
	22 days	Day 6	
	23 days	Day 7	
	24 days	Day 8	
	25 days	Day 9	
	26 days	Day 10	
	27 days	Day 11	
	28 days	Day 12	
	29 days	Day 13	
	30 days	Day 14	
	31 days	Day 15	
	32 days	Day 16	
	33 days	Day 17	
	34 days	Day 18	
	35 days	Day 19	
	36 days	Day 20	
	37 days	Day 21	
	38 days	Day 22	
	39 days	Day 23	
	40 days	Day 24	

Example: If your cycle is normally 26 days, the Cycle Chart indicates testing should begin on day 10. The following calendar shows how to determine day 10.

Example Calendar

1	2	3+ Day 1	4	5	6	7
8	9	10	11	12# day 10	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

3+ = The first day of menstrual bleeding (Day 1)

12# = The day to begin testing (Day 10)

HOW TO DO THE TEST

- 1. The test strip and urine have to be at room temperature $59^{\circ}F-86^{\circ}F$ ($15^{\circ}C-30^{\circ}C$) for testing.
- 2. Remove the test strip from the sealed pouch.
- 3. Immerse the strip into the urine with the arrow pointing towards the urine. Take the strip out after 5 seconds and lay the strip flat on a clean, dry, non-absorbent surface (such as the mouth of the urine container).
 IMPORTANT: Do not allow the urine level to exceed the MAX Marker Line, otherwise the test will not perform correctly.
- 4. Read results in 5 minutes. Do not read results after more than 5 minutes.

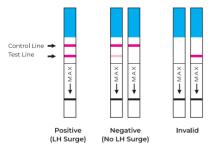


HOW TO READ THE RESULTS

Negative (No LH Surge): Only one colored band appears in the Control Zone, or the colored band appears in the Test Zone but is lighter than the control band. This means there is no LH surge.

LH Surge: If two color bands are visible, and the test band is equal to or darker than the control band, you will probably ovulate in the next 24-48 hours. If trying to get pregnant, the best time to have intercourse is after 24 but before 48 hours.

Invalid: No visible band at all. 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.



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.

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 band will not affect the test result. It is only effective to compare the color of the test band to that of the control band of the same device on the day the test is perform.

2. Can test results be interpreted after more than 5 minutes?

No. Test results must be read in 5 minutes. Although a positive result should not change for several days, a negative result may change to a false positive

within minutes after the test period ends, which would not be an accurate reading. It is always best to read the results in 5 minutes testing period and then discard the test after 5 minutes 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 band appears within five minutes, the test is working properly.

5. Do alcohol or common medications affect the test?

No, but you should consult your physician if you are taking any medication.

6. Once I see a positive result, when is the best time to have intercourse? Ovulation is likely to occur within 24-48 hours. This is your most fertile time. Sexual intercourse is advised within this time frame.

7. I am now using the basal body temperature method (BBT). Does this test replace BBT?

The rising in basal body temperature primarily indicates that ovulation has already occurred. This test indicates that ovulation is about to occur.

8. I have received a positive result and had intercourse during these fertile days. I have not become pregnant. What shall I do?

Many factors can affect your ability to become pregnant. Often you may need to use the test kit for 3-4 months. You and your partner should consult your physician if pregnancy is not achieved after 3-4 months.

9. Will the amount of liquid I drink affect the result?

We suggest that you limit your fluid intake for about two hours before you collect your urine. Heavy intake of fluids prior to testing will dilute the hormone in your urine.

ASSISTANCE

If you have any additional questions or concerns regarding this product, please call our Toll-Free Number +1 877-934-9344 (9 a.m. to 5 p.m. CDT M-F).

MEANING OF SYMBOLS ON PACKAGE



Keep away from sunlight



Store between (39°F-86°F) 4°C-30°C



Keep dry



Do not re-use



Consult instructions for use



Expiration date



Contains sufficient for <n> tests



In vitro diagnostic medical device



Batch number



Catalog number

Distributed by:

Phase Diagnostics, Inc. 10527 Garden Grove Blvd. Garden Grove, CA 92843 Tel: +1 877-934-9344 Website: www.indicaidhealth.com Made in China

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