frida fertility Ovulation Test

Product Manual



INDICATIONS FOR USE

The Frida Fertility Ovulation Prediction Test is an immunochromatographic one-step in vitro assay. It will detect the presence of human Luteinizing Hormone in urine and is designed to be used to predict the time of ovulation in women. It is a fast, accurate, and convenient method to determine when the female body will ovulate, the most likely time for conception to occur. This device is intended for self testing.

HOW IT WORKS

When the Lutenizing Hormone [LH] in your body begins to rise, it signals to your brain that it's time to release an egg.

It's most likely to occur during a 24-hour period 1 to 3 days following the LH surge. The ovulation "window" only opens once a cycle, and for only about 24 hours.

Because the timing is different for everyone, tracking your LH levels helps detect your 24-48 hour peak fertility window.

Fertile Window Luteinizing Hormone (LH) LH Peak **Ovulation Window** Egg is likely to be released up to 36 hours after LH peak 2 3 Ŀ, 5 8 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28

HERE'S WHAT IT LOOKS LIKE

28 Day Cycle Scenario

Definitions:

- Fertile Window: 2 more fertile days at the start of the LH surge and the day of ovulation ^{1,2}
- LH peak: most likely day of a positive LH test

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- Ovulation Window: up to 36-hour timeframe after LH peak where ovulation is likely to occur
- Babymaking Window: because sperm can live up to 5 days in the body, it's recommended to start trying to conceive during the 5 days before ovulation (e.g. cycle day 10-14)^{1,2}

1. Faust, L. M.S., et al. Fertil. Steril. 2019, 112 (3), 450-457

2. Wilcox, A.J., et al. N Engl J Med 1995, 333(23), 1517-1521

WARNINGS / PRECAUTIONS

PRECAUTIONS

- Keep out of reach of children.
- For external use only.
- Store tests between 48°F 86°F [9°C 30°C]. Do not freeze.
- · Keep away from direct sunlight, moisture, and heat.

LIMITATIONS OF THE TEST

- For in-vitro diagnostic use only.
- · Single-use device. Do not reuse.
- · Do not open the test strip until ready to conduct the test.
- · Do not use if the foil pouch has been opened, ripped or punctured, or if the strips are damaged in any way.
- · Do not use the test after the expiration date located on the wrapper.
- Directions must be followed carefully for accurate results.
- Always compare the color of the test line to that of the control line of the same device on the day the test is performed. Do not compare lines from different devices.
- $\circ~$ Do not use the results of this test as an aid for contraception.
- · Consult a doctor if irregular or unusually long cycles are experienced.
- The ovulation test should not be used when pregnancy is suspected.
- Urine from pregnant women, women in menopause, or women who have recently received a hCG shot (injection) should not be used with this test, and will cause inaccurate results.

WHAT'S WHAT?



BEFORE GETTING STARTED

You'll need to determine the length of your period cycle. Use our chart below to find your ideal first test day to begin testing + tracking your LH.

Need help? We've got you covered.

- 1. Begin on the first day of your period = your first day of full bleeding.
- 2. Next, determine the length of your period cycle from first day of full bleeding in your menstrual cycle to the next first day of your next menstrual cycle.
- 3. Then, refer to the cycle chart below to determine on which day of the menstrual cycle to begin testing [aka CD or Cycle Day].

Cycle Chart

Cycle Length in Days	21 or less	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41 or more
Day of Cycle to Start Testing	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	See questions section

Sample Calendar

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

Example: if your cycle is normally 26 days, the cycle chart indicates testing should begin on day 10.

The first day of menstrual bleeding (day 1)

 \frown The day to begin testing (day 10)

HOW TO TEST

Tip: CONSISTENCY IS KEY - test at the same time every day, once or twice is up to you.

1 Once you know your first test day - Pick a time slot in the morning or afternoon that works best for you and set a daily phone reminder. You will want to test at the same time each day. (Refer to the "BEFORE GETTING STARTED" section to determine when that is for your period cycle.)



2 Collect a urine sample in a freshly rinsed + dry cup (we recommend our Pee-Cup).



3 Open the test strip right before use by tearing along the notch, and set aside.



- Make sure to always pick test up by the thumb grip, touching Pee-Pad will invalidate your results.
- Dip the Pee-Pad up to the "MAX" line for 10 seconds.



- Do not allow the urine level to exceed the "MAX" line indicated by the arrows. If it does, the test will not perform correctly.
- → You will see the liquid slowly travel up towards the test line during this step.

5 Lay test strip on a flat surface and wait 3 minutes to read your results.



- ① Do not read the results past the 5 minutes.
- → See page 8 for the Ovulation Tracking System section for logging your results.

READ YOUR RESULTS

Positive for the LH Surge

If the test line is of equal or greater intensity (equal or darker) than the control line, this is a positive result and a good indication that the LH surge is occurring.

Negative for the LH Surge

If the test line is of lesser intensity (lighter) than the control line or cannot be seen, this means that the LH surge is not in progress.

Note: Listed below are some of the reasons why a surge may not be detected.

- 1. Urine is collected at different time of each day.
- 2. The concentration of LH is too low to accurately detect.
- 3. Testing is performed too early or too late in the menstrual cycle.
- 4. Testing is stopped before the surge occurs, and should have been continued for a few more days.
- 5. A LH surge did not occur during this menstrual cycle.

Invalid Result

If no color appears on the control line within 5 minutes, the result is invalid. Try again with another test strip.

ANSWERS TO YOUR QUESTIONS

Should I restrict my diet before taking the test?

No, diet will not affect the test results.

Does alcohol, aspirin, or any other common drug affect the test?

If you have ingested (or suspect you have ingested) any alcohol, aspirin, or other drugs, seek professional advice from a physician to confirm the test results.

Should the test be used for contraception?

No, the test is not designed to prevent or help prevent conception and should not be used to do so.

Today's control line is a different shade of red than yesterday's. Is this a concern?

No. Variations in the control line will not affect the test result.

Can test results be interpreted after five minutes?

No. Test results must be read at 3 minutes. After 5 minutes the test becomes invalid. 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.

A pink background color and vertical streaking appeared in the test line during the testing period. Is this a concern?

No. As long as the control line appears within 5 minutes, the test is working properly.

My cycle length is outside the range shown in the table. When should I begin testing?

If your cycle is 21 days or less, start testing on day 5. If your cycle is longer than 40 days, start testing 17 days before your next period. However, you should always consult your doctor if your cycle is under 21 days, over 41 days or if you've been diagnosed with a condition like polycystic ovary syndrome [PCOS] to help you determine your ovulation cycle.

Do I need to use all the strips?

No. You can stop once you've detected your LH surge, and save the remaining tests to use next cycle, if needed.

Can I begin testing if I've recently stopped taking hormonal contraceptives?

Yes, but your natural hormone pattern might have been disrupted by the hormonal contraceptive so it may take some time to stabilize. You might want to wait 2-3 cycles before beginning.

I followed the directions but no color showed in the test line?

This may be because too much or too little urine was used or the test strip was not laid flat after being dipped in urine.

I've done all the tests as instructed, but I've still not been able to detect my surge. Why & what should I do?

This can be because testing was stopped before the surge occurred, and should have been continued for a few more days. Some women do not ovulate each cycle, or you might ovulate later than you expect. If you can't detect your surge during your first cycle, try testing twice a day in the next cycle. If you continue having trouble, consult your doctor to learn more.

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WHAT'S WHAT?



HOW TO TRACK

Picking + matching your results to our sticker sheet will help you accurately track your LH surge.

1 Tuck the test strip into the left-most pocket of the insert card. Feel free to mark the date on the card.



Note date/time of test & repeat the next day. 2 Now match a sticker with a similar shade of darkness and place it just below the strip. Even if the test strip fades, the sticker will remember.



WARNING: Do not use the stickers to interpret the results of your test. They are to be used to track your ovulation strip results only and not for any diagnosis or detection. If you have questions about your results, please consult your doctor.

3 Every time you take another test, add the strip next to the previous ones. There are three pockets, and each pocket can hold a week's worth of tests. This insert card fits inside the tracker case – and can be replaced with a new insert next month if you are still tracking ovulation then.



Now you just need to repeat this test every day and keep track of the color. It's best to test for 15 days to see the full range of your hormone levels. Yay, more peeing in the cup!



Invalid Test

After testing for a while, you'll notice a pattern. When the test line is darkest, that's your "spike." That's your magic window.

CONTACT

Carefully follow these instructions for best results. If you do not understand these instructions of use or have any questions, please contact us at frida.com/help.

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