

Instructions for Use

The Eveline Ovulation Test, plus monitoring app is designed to help facilitate pregnancy by identifying the most fertile days of each cycle.

READ ALL THE INFORMATION IN THIS LEAFLET CAREFULLY BEFORE PERFORMING THE TEST.

THE DIRECTIONS SHOULD BE FOLLOWED PRECISELY IN ORDER TO OBTAIN THE CORRECT RESULTS.

- For in-vitro diagnostic use only.
- Do not use after expiration date.
- Keep out of the reach of children.
- Not to be taken internally.
- The test device should remain sealed until use.
- Handle all specimens as potentially infectious.
- Not for contraceptive use or gender selection.
- Do not reuse the test. Discard in the dustbin after single use.

How the Eveline Ovulation Test works

The Eveline Ovulation Test works by detecting the surge in luteinizing hormone (LH) in urine, which triggers ovulation (the release of an egg from the ovary) in approximately 24-36 hours. The Eveline Ovulation Test can also be used in conjunction with a smartphone and the monitoring app, which will help predict the time of ovulation and display the daily fertility status to assist in conception.

Important: LH levels fluctuate daily and vary from woman to woman. The surge and ovulation may not occur in all cycles.

When to Start Testing

Determine the length of your menstrual cycle. Your menstrual cycle length is the number of days from the first day of your period (menstrual bleeding) to the day before your next period starts. Think back over the last few months to determine your usual cycle length. Circle your usual cycle length on the WHEN TO START CHART below. Select the number directly beneath the circled number.

Starting from the first day of your last period, count ahead the selected number of days on your calendar. This is the day you should begin testing.

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

Count ahead this number of days STARTING WITH THE FIRST DAY of your LAST period.

△ **Note: If you are unsure about your cycle length, you may wish to use your shortest cycle length when reading the chart. If you do this, you may need to test for more than 5 days.**

1 When you are ready to test

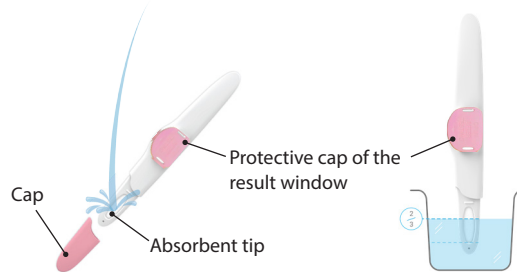
Remove the test from the foil wrapper and use this immediately.



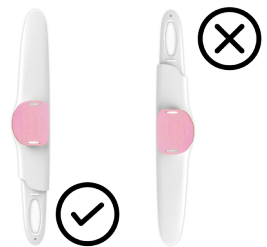
2 Perform the test

Remove the cap and you can...

- **Either** test directly in your urine stream.
- Place only the absorbent tip, pointing downwards in your urine stream for 10 seconds.
- Do not allow urine to splash into the result window
- **Or** test a sample of your urine collected in a clean, dry container
- Dip only the absorbent tip in your collected urine sample for 15 seconds



△ After testing, keep the absorbent tip pointing downwards or lay the test flat. Throughout testing do NOT hold the test with the absorbent tip pointing upwards.



3 Wait for result

Place the cap back on the test and lay the test stick flat on a horizontal surface with the result window facing upwards. Wait for red lines to appear. The test should be read in approximately 7 - 10 minutes.

△ **Note: Results after 10 minutes may not be accurate.**

4 Interpretation of results

Negative:

One colored band appears in the control region, no band is found in the test region, or the color of the test band is less intense than the color of the control band (which is used as reference). The result indicates the basal LH level of the tested specimen.

Positive:

Two colored bands appear, and the color of the test band is the same as or more intense than the color band. This result indicates an LH surge level of the tested specimen.

Invalid:

If no colored bands appear in the control region, the test result is invalid. Retest the specimen using a new test device.

You may also use the Eveline LH App to help you interpret the result. Download and install the **Eveline LH App** on your smartphone via App Store or Google Play to improve the tracking of fertile days. Compatible smartphone OS:

- iOS 9.0 or later

△ Android 5.0 or later

Note: Keep away from sources of electromagnetic radiation such as microwaves while using the APP.

The **Eveline LH App** provides the following major functions:

- ✓ **Analysis**
Interpretation of results
- ✓ **Calendar**
Record and review cycle information
- ✓ **Test Report**
Test result record and sharing
- ✓ **Reminder**
A reminder to perform the ovulation test

Follow the instructions on the App to register (log in) and confirm your settings to start monitoring your fertility status.



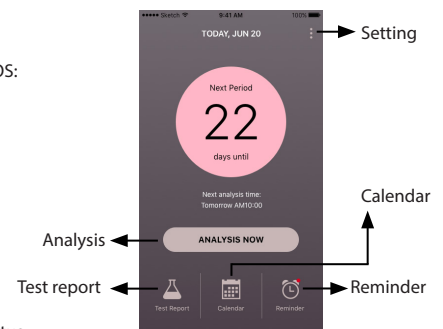
Indication of the result window after removing the protective cap




Positive

Negative

Invalid



How the Eveline LH App works

1. Tap the "Eveline LH" icon  to activate the App.
2. Tap the button "ANALYSIS NOW" to interpret the result.
3. Attach the test to the holder and the smartphone attachment clip to your smartphone (Fig. 1).
 Δ Note: remember to remove the protective cap before attaching the test to the holder.
4. Follow the instructions given by the animation to correctly position the holder (Fig. 2).
 Δ Note: make sure the test is read in 7-10 minutes after the urine has been absorbed.
 Δ Note: the App will only continue with the next step once the test and holder and clip have been correctly installed and positioned.
 Δ Note: if the App remains on the same page and doesn't continue to the next step, check whether the test is invalid and if so, replace with a new one and try again.
5. Once the holder is positioned, a red square will appear on the display. Adjust the holder to make the red square fit in the marked frame. While the square fits in, its color will turn green. (Fig.3)
6. When the frame turns green, do not move the holder and press the "NEXT" button to obtain the result (Fig.4).
7. The fertility status will be shown in around 7 seconds.

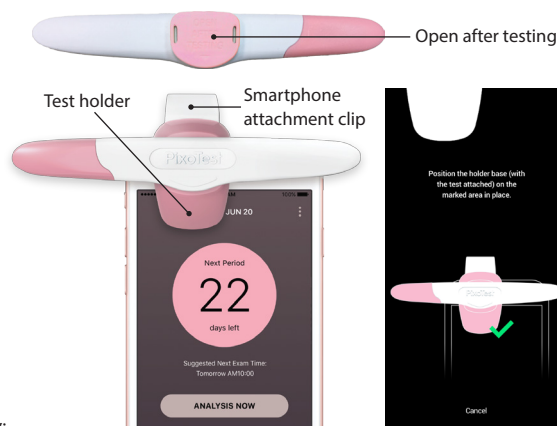


Fig. 1

Fig. 2

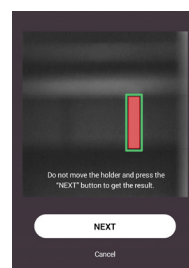


Fig. 3

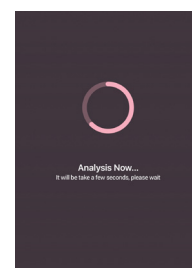


Fig. 4

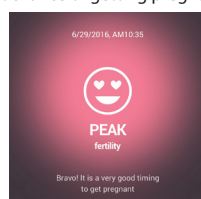
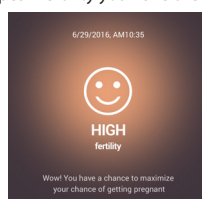
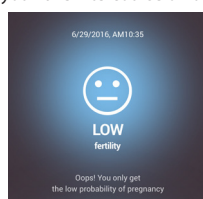
Fertility Status

The PixoText LH App will display your fertility status using three icons for three different levels of fertility: Low, High and Peak.

Low Fertility: Displayed at times during the cycle when your fertility hormones are low.

High Fertility: Displayed at times during the cycle when your LH level is increasing. If you have intercourse on days of high fertility you can maximize your chance of getting pregnant.

Peak Fertility: Displayed at times during the cycle when your LH level surges. If you have intercourse on days of peak fertility you have the greatest chance of getting pregnant.



Questions & Answers

Q: Do I need to use all of the tests?

A: No. You can stop testing when you detect an LH surge and save the remaining tests to use during your next cycle if necessary.

Q: How accurate is the Eveline Ovulation Test?

A: This test has been proven more than 99% accurate in detecting the LH surge in laboratory studies. The sensitivity of the Eveline Ovulation Test is 25mIU/ml

Q: I've done all the tests as instructed, but have not yet detected my surge. What should I do?

A: The number of tests in a Eveline Ovulation Test pack is sufficient for most women with regular cycles to detect their LH surge. Some women do not ovulate each cycle and will therefore not see an LH surge in these cycles. If you are concerned about your results please contact your physician.

Q: Do any medical conditions or drugs affect the test?

A: Certain medical conditions may adversely affect the reliability of the test for predicting ovulation. These include pregnancy, postpartum, post-abortion, polycystic ovary syndrome (PCOS), ovarian cysts, the onset of menopause, and untreated hypothyroidism. This may also be the case if you take fertility drugs containing Luteinising Hormone or human Chorionic Gonadotrophin. If you are undergoing therapy with Clomiphene Citrate, please ask your physician about the best time to begin testing. Women with medically diagnosed fertility problems should consult their physicians before using this product.

Q: Will oral contraceptives affect the results?

A: After using oral contraceptives, your cycle may be irregular and may take some time to stabilize again. You may wish to wait until you have had two normal periods before starting to use this product. Follow your physician's advice on when to try to become pregnant.

Q: As the test tells me when I'm fertile, can I use the Eveline Ovulation Test as a contraceptive?

A: No. As sperm can survive for several days, you could still get pregnant if you have intercourse before detecting the LH surge.

Q: I have been using the Eveline Ovulation Test for several cycles and am still not yet pregnant. Why not?

A: Conception is a complex biological process and there are many influencing factors. It can take many months to get pregnant. If you have not conceived after 6 consecutive cycles or you have other concerns, please consult your physician.

Specifications

Dimension:	Attachment Clip and Holder: 50.2(L) x 28.4(W) x 32.6(H) mm Test Cassette: 116.5(L) x 18.2(W) x 8(H) mm
Sensitivity:	≥ 25 mIU/ml
Specificity:	hFSH: 500mIU/ml; hTSH: 500μIU/ml
Operating Temperature Range:	10 - 30°C (50 - 86°F)
Test Strip Storage Temperature Range:	4 - 30°C (39 - 86°F)
Test Strip Shelf Life:	24 months

Symbols

	Consult instructions for use		Use by date
	Manufacturer		Do not reuse
	Authorized representative in the European Community		In-vitro diagnostic medical device
	Batch code		Temperature limitation
	Catalog number		Caution



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