

Ovulation Test

How Clearblue® DIGITAL Ovulation Test works with you

Clearblue® DIGITAL Ovulation Test works by detecting the increase (surge) in a hormone called Luteinizing Hormone (LH) in your urine. The LH surge occurs approximately 24-36 hours prior to the release of an egg from your ovaries – a process known as **ovulation**. You are at your most fertile on the day your LH surge is detected **and the day after**.

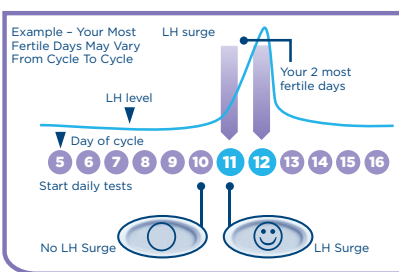
Your 2 most fertile days begin from the time that Clearblue® DIGITAL Ovulation Test detects your LH surge. Make love at any time in the next 48 hours to maximize your chance of becoming pregnant.

WHEN TO START TESTING

The day the LH surge occurs varies from woman to woman and from one cycle to another. To have the best chance of detecting your LH surge, you need to know your usual cycle length. To work out your cycle length, count the day your period starts (first day of full menstrual flow) as Day 1, and continue counting through to the day **before** your next period starts. The number of days is your cycle length. *If you do not know your usual cycle length or your cycle length varies, refer to **Question 1** in Q&A.*

Use the table below to work out the day you should start testing. You can test any time of the day, but it should be at about the same time each day (many women find it most convenient first thing in the morning). It is important that you have not urinated for at least 4 hours before testing, and you should avoid excessive fluid intake before testing.

Length of your cycle (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
Count the first day of your period as Day 1, start testing on the day shown under your cycle length.	5	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	See Question 2 in Q & A.



1 WHEN YOU ARE READY TO TEST...

- Remove the Test Stick from the foil wrapper. Use the Test Stick right away.
- Before applying urine to the Test Stick it **must be inserted** into the Test Holder. Follow the steps below.



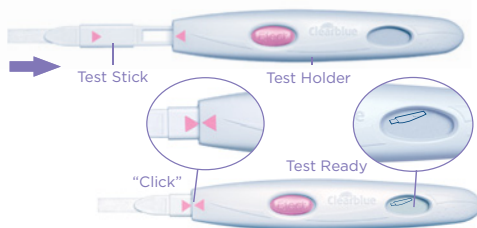
2 REMOVE THE CAP

- Remove the cap and find the pink arrow on the Test Stick.



3 ASSEMBLE THE TEST

- Find the pink arrow on the Test Holder.
- Line up both pink arrows.
- Insert the Test Stick into the Test Holder until it clicks into place and the test ready symbol appears.
- Do not use until** the test ready symbol appears.
- When the test ready symbol appears, do the test right away.
- If the test ready symbol does not appear, OR if the symbol has disappeared, eject the Test Stick and re-insert it carefully.
- If the symbol still does not appear refer to **Question 19** in Q&A.*



4 PERFORM THE TEST

With the test ready symbol showing on the display...

- Either** test directly in your urine stream.
- Place just the Absorbent Tip, **pointing downward** in your urine stream for **5-7 seconds**.
- Take care not to get the Test Holder wet.



OR

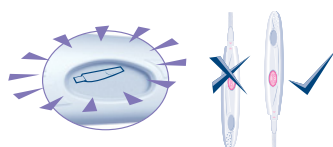


- Or** test a sample of your urine collected in a clean, dry container.
- Dip just the Absorbent Tip in your collected urine sample for **15 seconds**.



5 WAIT

- Keep the Absorbent Tip pointing downwards or lay the test flat. Throughout testing never hold the test with the Absorbent Tip pointing upwards.
- The test ready symbol will start flashing after 20-40 seconds to show the test is working.
- DO NOT EJECT THE TEST STICK.**
- Replace the Cap then wipe off any excess urine.
- If the test ready symbol does not start flashing, refer to **Question 6** in Q & A.*



6 SEE YOUR RESULT

- Within **3 minutes** the display will show your result.



- If your result is you have not detected your LH surge. Test again tomorrow at the same time using a new Test Stick.



- If your result is you have detected your LH surge and have reached your most fertile time. Make love at any time during the next 48 hours to maximize your chances of becoming pregnant. There is no need to continue testing during this cycle.

- Once you have read your result you **MUST** press the eject button and remove the Test Stick.
- The result of your test can only be read on the Test Holder display.
- You cannot determine your result from any lines that you see on the Test Stick.
- Your result will remain on the display for 8 minutes.
- If your Test Stick is still inserted and the display is now blank, eject the Test Stick and your result will re-appear for 2 minutes.
- Do not re-insert a used Test Stick.

Error Symbols Error A

- You have ejected the Test Stick too soon. Re-insert the Test Stick into the Test Holder immediately. Refer to **Question 16** in Q&A.



Error B

- Refer to **Question 17** in Q&A.



Error C

- Refer to **Question 18** in Q&A.



FURTHER INFORMATION

Disposing of your Digital Test Stick

- Once your result has been displayed, dispose of the Test Stick with your normal household waste. To do this, press the eject button on the Test Holder. The Test Stick will automatically be released. When you eject the Test Stick you may notice one or two blue lines on the Test Stick. **These must be ignored**; only refer to the display on the Test Holder to determine your results. The Test Stick is not reusable.
- Once you have used all the Test Sticks in the pack you can dispose of the Test Holder in your normal household waste. Remove all batteries by separating the upper and lower halves starting at the end nearest the display. Remove all batteries from under the central metal cover. Dispose of the batteries according to the appropriate recycling protocol. **Caution:** Do not disassemble, recharge, or dispose of the batteries in fire. Do not swallow. Keep away from children. Dispose of the rest of the Holder according to the appropriate recycling protocol for electrical equipment. Do not dispose of electrical equipment in fire.

Using the Test Holder Again

- While doing a test the Test Holder may have been splashed with some urine. Ensure that you wipe it clean. A further test is not possible while your result or any error symbols are on the display. These will be displayed for 8 minutes (or 2 minutes if your display was blank and you have just ejected the Test Stick). It is important that you have not urinated for at least 4 hours before doing a test. If you have collected urine you can use the Test Holder again as soon as the display is blank. When you are ready to use the Test Holder again, repeat the instructions from step 1 using a new Test Stick.

QUESTIONS & ANSWERS

1 I do not know my usual cycle length or my cycle length varies. How do I know when to start testing?

If you don't know your usual cycle length you are advised to wait for at least one menstrual cycle, and note the length of this cycle, before using Clearblue® DIGITAL Ovulation Test. Once you have determined your cycle length you can use the instructions to work out when to start testing.

If your cycle length varies by more than 3 days then choose the shortest cycle you have had over the last 6 months to work out when to start testing. It is possible you may need to start a new pack and use the new Test Holder and Test Sticks to detect your LH surge.

Alternatively, if you wish to start testing without knowing your cycle length, we recommend you start testing on day 10. (However, in this case it is possible you may miss your LH surge because you have started testing too late or you may need to start a new pack to continue testing.) (Refer to question 10).

2 My cycle length is outside of the range shown in the table. How will I know when to start 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 you expect your next period.

3 What time of the day should I carry out the test?

You may test any time of day, but you should test at approximately the same time each day. You should not have urinated for at least 4 hours before testing.

4 Do I need to use all the tests?

No. You can stop testing when you detect your LH surge, and save the remaining Test Sticks and Test Holder to use next cycle if necessary.

5 Can I use the Test Holder with any other Test Sticks?

You can only use Clearblue® DIGITAL Ovulation Test Sticks with this Test Holder.

6 I have done a test, but the test ready symbol has not started flashing. What does this mean?

The test has not been done correctly. An error symbol will appear on the display within 10 minutes of testing. You should re-test with a new Test Stick. For information on re-testing refer to question 17 and 'Using the Test Holder again'.

7 What if the Test Holder gets wet?

If the Test Holder gets wet you should wipe it clean. Some splashing will not damage the Test Holder, but if it becomes very wet it may be damaged. If so, the display will either remain blank or an error symbol will be displayed.

8 I have done a test, but no result has appeared on the display. What does this mean?

Your result should appear on the display within 3 minutes of doing a test. If no result appears an error symbol will appear on the display within 10 minutes. Refer to question 17.

9 How accurate is Clearblue® DIGITAL Ovulation Test?

The Clearblue® DIGITAL Ovulation Test has been shown in extensive laboratory trials to be over 99% accurate in detecting the LH surge prior to ovulation. The sensitivity of the Clearblue® DIGITAL Ovulation Test is 40mIU/ml.

10 I've not yet detected my surge. What should I do?

If your cycle length varies by more than 3 days then it is possible that you may need to use more tests to detect your LH surge. Some women do not ovulate each cycle and therefore will not see an LH surge in such cycles. If you are concerned about your results please see your doctor.

11 Can any medication or medical conditions affect the result?

Always read the manufacturer's instructions for any medication that you are taking before conducting a test.

Certain medical conditions and medications can adversely affect the performance of the test; for example if you are actually pregnant, have recently been pregnant, have reached menopause or have polycystic ovarian syndrome you may get a misleading result. This may also be true if you are taking fertility drugs containing Luteinizing Hormone or human Chorionic Gonadotropin (such as Pregnyl® and Profasi®)*. Please check with your doctor. Clomiphene citrate (e.g., Clomid***) does not affect the tests, but may affect the length of your cycle and, therefore, when you should be testing. You may need to start a new pack and use the new Test Holder and Test Sticks to continue testing.

12 I've recently stopped using hormonal contraception (e.g. the contraceptive pill). Will this affect the results?

No, it will not affect your results. However your natural hormone pattern is disrupted by hormonal contraception and if you have recently stopped using it your cycles can be irregular and may take some time to stabilize. You may wish to wait until you have had two natural menstrual cycles, and note the length of these cycles, before using Clearblue® DIGITAL Ovulation Test.

13 Since it tells me when I am fertile, can I use Clearblue® DIGITAL Ovulation Test as a contraceptive?

No. Clearblue® DIGITAL Ovulation Test detects the LH surge, which occurs only 24-36 hours before ovulation. As sperm can survive for several days, you might still become pregnant if you have made love before you detected your LH surge.

14 I think I have become pregnant, what should I do?

You can find out if you are pregnant up to 5 days sooner than your missed period using a Clearblue® Pregnancy Test. In laboratory testing Clearblue® Pregnancy tests are more than 99% accurate*** in detecting whether or not you are pregnant when used from the day your period is due. If you are pregnant you should see your doctor who can advise what steps to take next. The earlier you see your doctor, the better it is for your own health.

15 I've used Clearblue® DIGITAL Ovulation Test for several months and haven't become pregnant. Can I be sure of getting pregnant?

It can take many months to become pregnant. There are many reasons why you may not become pregnant even if you've been able to make love at your most fertile time. If after several months you've had no success, you should consult your doctor.

ERROR MESSAGES

16 A flashing symbol (Error A) has appeared on the display. What does this mean?



The Test Stick has been ejected too soon. If it is not re-inserted quickly enough then a further error symbol will appear on the display. Refer to Question 17.

17 This symbol (Error B) has appeared on the display. What does it mean?



An error has occurred during testing. It may be that

- Urine has been applied to the absorbent tip before the Test Stick was inserted into the Test Holder.
- The absorbent tip was not kept pointing downward, or the test was not laid flat, after urine was applied.
- Too much or too little urine was applied.
- The Test Stick was ejected too soon.

This symbol will be displayed for 8 minutes. You should test again using a new Test Stick taking care to follow the instructions. Refer to 'Using the Test Holder again'.

18 This symbol (Error C) has appeared on the display. What does this mean?



The test has not performed as expected. This may be because the instructions for use were not followed. If you have unused Test Sticks in the pack, do not use them with this Holder. You will need to perform another test from a new pack. Please follow the instructions for use carefully.

19 The display has remained blank. What does this mean?



The test has not performed as expected. This may be because the instructions for use were not followed. If you have not applied urine to the Test Stick eject it and start again. If the Holder remains blank it will need to be replaced.

LIMITS OF THE TEST

Certain medical conditions and medications may or may not affect the reliability of this test for predicting ovulation. These can include pregnancy, post-partum, menopausal symptoms, breast feeding, birth control pills, some fertility medications and polycystic ovarian syndrome (PCOS). Women with medically diagnosed fertility problems should ask their physicians if the product is suitable for them.

*Pregnyl® is a registered trademark of Organon USA, Inc.
*Profasi® is a registered trademark of Ares Trading S.A.
**Clomid® is a registered trademark of Merrell Pharmaceuticals, Inc.
***99% accurate at detecting typical pregnancy hormone levels. However, some pregnant women may not have detectable amounts of the pregnancy hormone in their urine on the first day of the missed period or may have miscalculated the first day of their period.

Home ovulation test.

For *in vitro* diagnostic use.

Store at 36°-86°F (2°-30°C). Do not freeze.

Keep out of the reach of children.

Do not use if the foil wrapper containing the Test Stick is damaged.

Do not use a Test Stick that has passed its expiry date.

Do not reuse the Test Sticks.

These instructions are for SPD model number 505121.

www.clearblue.com

Clearblue® Helpline

Monday-Friday 8:30 a.m. - 5:00 p.m. Eastern Time.

Toll-free. **1-800-321-3279**

Please have the lot numbers **LO01** from both the outer and inner packaging. Calls are recorded for training and quality control.

As prenatal care is very important for a baby's health, we recommend that you consult your doctor before trying to get pregnant.

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Contact the dealer or an experienced radio/TV technician for help.

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The US Surgeon General advises pregnant women to abstain from alcohol consumption as this may lead to harmful effects on the baby such as Fetal Alcohol Syndrome Disorders (FASD). More information is available at www.surgeongeneral.gov