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 bleeding) as Day 1, and continue counting through to the day your period finishes.

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 | 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 you hear a "Click" sound.
- 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 downwards in your urine stream for 5-7 seconds.
  - Take care not to get the Test Holder wet.

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.
- 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** • 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 C** • Normal

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

Yes, you can use Clearblue® DIGITAL Ovulation Test Sticks with this Test Holder.

I have done a test, but the test result symbol has not started flashing. Why not?

The test has not been done correctly. An error symbol will appear on the display within 10 minutes if the test was not done according to the instructions. Please refer to 'Using the Test Holder again'.

What if the Test Holder gets wet?

If the Test Holder gets wet you should wipe it clean. Do not use a fan to dry the Test Holder, but if it becomes very wet it may be damaged. Store it in a cool, dry place. If the Test Stick is blank or an error symbol will be displayed.

I have done a test, but no result has appeared on the display within 10 minutes. 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.

How accurate is Clearblue® DIGITAL Ovulation Test?

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 greater than 99%.

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 may need to use an ovulation test for more than 1 cycle. If you are concerned about your results please see your doctor.

Can medication or medical conditions affect the result?

Always read the manufacturer's instructions for use carefully.

 Certain medical conditions and medications can adversely affect the performance of the test. If you are taking any of the following medications, or 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 lutetizing hormone or human Chorionic Gonadotrophin (such as Pregnyl® and Profasi®). Please check with your doctor or gynaecologist to confirm. Clomiphene citrate (e.g. Clomid®)*** does not affect the test, but may affect the length of your cycle. If you are taking this medication while testing you may need to start a new pack and use the New Test Holder and Test Sticks to continue testing.

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 need to use a longer period of natural menstrual cycles, and note the length of these, before using Clearblue® DIGITAL Ovulation Test.

Since it tells me when I am fertile, can I use Clearblue® DIGITAL Ovulation Test to prevent pregnancy and contraception?

No, it is not intended for this purpose. 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 made love before you detected your LH surge.

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 based on the results of one test.

If you are pregnant you should see your doctor for advice and may need to attend for further steps. The earlier you see your doctor, the better it is for your baby.

I've used Clearblue® DIGITAL Ovulation Test for several months and haven't become pregnant. Can you explain this?

This is normal. It can take many months to become pregnant. There is no guarantee that you will become pregnant even if you've been able to make love at your most fertile time. If after several months you have not conceived, you should consult your doctor.

ERROR MESSAGES

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

If the symbol 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 Stick was not laid flat, after urine was applied.

• Too much or too little urine was applied.

• The symbol was applied in error.

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'.

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 the Test Holder will need to be replaced.

LIMITS OF THE TEST

Can medical conditions and medications may or may not affect the reliability of this test for predicting ovulation. These can include pregnancy, post-partum menstrual symptoms, breast feeding, birth control pills, some medications and conditions such as polycystic ovarian syndrome (PCOS). Women with medical conditions are encouraged to ask their physicians if the product is suitable for them.

Home ovulation test.

For in vitro diagnostic use. Store at 36°-38°F (2°-3°C). Do not freeze. Keep out of children's reach. Do not use if the foil wrapper containing the Test Stick is damaged.

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

Do not reuse the Test Sticks.

These instructions are for SPD model number 50512.

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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. A LIFT from both the outer and inner packaging. Cals 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.

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

For questions and answers, see www.swissprecisiondiagnostics.com/patents