

Before applying urine to the test stick it **must** be inserted into the test holder. Please read this leaflet carefully before doing a test.

### How Clearblue Digital Ovulation Test works with you

Clearblue Digital works by detecting the increase (surge) in a hormone called luteinising 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**.

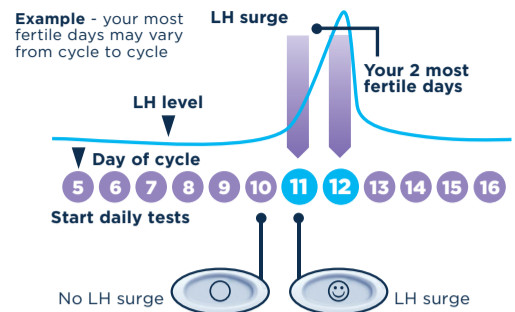
Your 2 most fertile days begin from the time that Clearblue Digital detects your LH surge. Make love at any time during the following 48 hours to maximise your chance of becoming pregnant.

### 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. The day your period starts (first day of full bleeding) is Day 1. Your cycle length is the total number of days from Day 1 up to and including the day before your next period starts. If you do not know your usual cycle length or your cycle length varies, refer to Q1 overleaf.

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's important to drink normally and not to urinate for 4 hours 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	Refer to Q2 overleaf



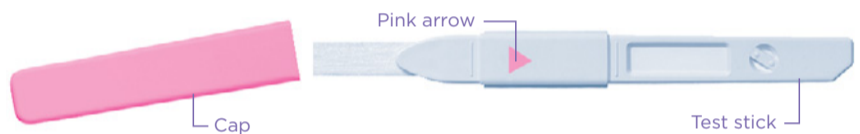
### 1 When you are ready to test...

- Remove the test stick from the foil wrapper. Use the test stick straight away.
- Before applying urine to the test stick it **must** be inserted into the test holder. Follow the steps below.



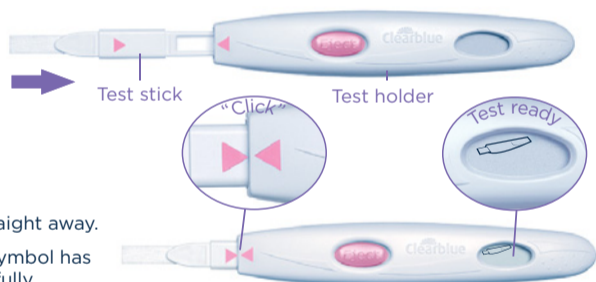
### 2 Remove the cap

- Find the pink arrow on the test stick.



### 3 Assemble the test

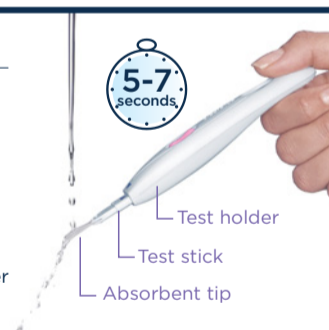
- Find the pink arrow on the test holder.
- Line up both pink arrows.
- Insert the test stick into the test holder until it clicks into place and the test ready symbol appears.
- Do not use until** the test ready symbol appears.
- When the test ready symbol appears, do the test straight away.
- If the 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 Q17 overleaf.



### 4 Do 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.



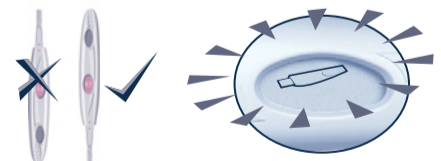
**OR** 15 seconds.

- 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 Q5 overleaf.



### 6 Read 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.



- 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 read your result from any lines that you see on the test stick.
- Your result will remain on the display for 8 minutes.

- 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 maximise your chance of becoming pregnant. There is no need to carry on testing during this cycle.

- 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 Q14 overleaf.

#### Error B

- Refer to Q15 overleaf.

#### Error C

- Refer to Q16 overleaf.

## Further information

### Disposing of your digital test

- 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 read your results. The test stick is not reusable.
- Once you have finished using the test holder, 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 scheme. **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 scheme for electrical equipment. Do not dispose of electrical equipment in fire.

### Using the test holder again

- Whilst 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 whilst 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's important not to urinate 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. Once you have determined your cycle length you can use the instructions overleaf 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 Q9).

### 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. It's important not to urinate 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 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 Q15 and 'Using the test holder again'.

### 6 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.

### 7 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 Q15.

### 8 How accurate is Clearblue Digital?

Clearblue Digital 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 is 40mIU/ml.

### 9 I've not detected my LH Surge. Why is this?

Your LH surge may be too low to be detected, or you may not have ovulated this cycle. This is not unusual but we recommend you see your doctor if you do not detect your LH surge for 3 consecutive cycles. If you miss a test you may not see your LH surge so remember to test as advised.

### 10 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 the menopause or have polycystic ovarian syndrome you may get a misleading result. This may also be true if you are taking fertility drugs containing luteinising hormone or human Chorionic Gonadotrophin. Please check with your doctor.
- If you have a medically diagnosed fertility problem you should ask your doctor if Clearblue Digital is suitable for you.
- Clomiphene citrate 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.
- If you do get unexpected results you should discuss them with your doctor.

### 11 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 stabilise. You may wish to wait until you have had two natural menstrual cycles, and note the length of these cycles, before using Clearblue Digital.

### 12 I think I have become pregnant, what should I do?

Try using our range of Clearblue Pregnancy Tests, which are over 99% accurate at detecting pregnancy from the day of the expected period. 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.

### 13 I've used Clearblue Digital for several months and haven't become pregnant. Why is this?

It can take normal healthy couples many months to achieve a pregnancy. We recommend you see your doctor if you are under 35 years and haven't become pregnant after trying for 12 months. If you are over 35 years you should see your doctor after trying for 6 months, and if you are over 40 years see your doctor straight away.

## Error messages

### 14 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 Q15.

### 15 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'.

### 16 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.

### 17 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.

This IVD digital device meets the emissions and immunity requirements of EN 61326-2-6:2006. The EMC countermeasures employed within the electronic instrument will provide reasonable protection against electromagnetic interference effects likely to be encountered in the home environment.

The following preventive warnings apply to EN 61326-2-6:2006 compliant equipment.

- Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc) may cause damaging static discharges that may cause erroneous results.
- Do not use this instrument in close proximity to sources of strong electromagnetic radiation (e.g. mobile phones), as these may interfere with the proper operation.

## www.clearblue.com

For product enquiries, please contact Customer Support at the address below.

Marketing Authorisation Holder SPD Swiss Precision Diagnostics GmbH (SPD), Route de St Georges 47, 1213 Petit-Lancy, Geneva, Switzerland.

Manufacturing Site: Alere (Shanghai) Diagnostics Co. Ltd. Shanghai, China. Clearblue is a trademark of SPD. © 2019 SPD. All rights reserved.

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

For self-testing at home.

For *in vitro* diagnostic use only.

Not for internal use. Do not reuse test sticks.

Test sticks for single use.

Keep out of reach of children.

Store between 2° - 30°C.

Bring to room temperature for 30 minutes if refrigerated.

Do not use if the foil wrapper containing the test stick is damaged.

Do not use a test stick after the 'use by' date.

Only use test sticks for Clearblue Digital Ovulation Test with the holder.

Not for contraceptive use.

IVD	In vitro diagnostic medical device	LOT	Batch code	Manufacturer
TEMP	Temperature limit 2°C - 30°C	USE BY	Use-by date	