

Clearblue®

CONNECTED))) Ovulation Test System



Read this leaflet carefully before testing

1 How to use the Clearblue® Connected app



Search for the Clearblue® Connected app and download from your app store. The app is compatible with most iPhones® and Android™ phones equipped with Bluetooth 4.0/BLE.



To find out if your phone is compatible and the app is available in your country, check out: www.clearblue.com/connectivity

- Open the app on your phone and create your Clearblue® account.
- To finalize creating your account you'll need to click on the link sent to you by email.
- Find the wake-up stick in your pack. Use this to connect the holder to your phone, following the instructions on the app.

- ✓ Use the wake-up stick to connect the holder to your phone



✗ Do not use a test stick to connect the holder

- Once your holder is connected press the eject button to remove the wake-up stick.
- Keep the wake-up stick as you may need to activate Bluetooth® on your holder so you can sync results to your app.
- The Clearblue® Connected app will tell you when to test, display your synced results and let you record details about your period and when you had sex.
- It will also track and compare your cycles and can advise you when to test for pregnancy.

Questions and Answers about the app

I can't connect my holder to the app. What should I do?

Check that Bluetooth® on your phone is turned on. Insert the wake-up stick and wait for flashing symbols to appear on the holder display. If no symbols appear there is a problem with the holder. Please call the Clearblue® Helpline. You can still test using this holder but you'll be unable to sync results to the app.

Do I need my phone to test?

No. Test normally following the instructions from step 3. The holder will display a flashing asterisk to show data is available to sync. When Bluetooth® on your holder and phone is turned on and the app is open, the result will sync. To turn on Bluetooth® on your holder insert the wake up stick and wait for the Bluetooth® symbol to appear.

My result hasn't been synced to the app and it's no longer on the holder display. What should I do?

If your test stick is still inserted into the holder eject it and the result will re-appear on the display. While it is displayed, Bluetooth® will be activated and your result will sync to the app if your phone has Bluetooth® turned on and the app is open.

If you have ejected the test stick and the result is no longer displayed you need to insert the wake-up stick to activate Bluetooth®. Your result will then be synced to the app if your phone has Bluetooth® turned on and the app is open. Eject the wake-up stick once your result has been synced.

Where is my information stored?

Synced results and information you have entered on the app are stored on your phone. When you are connected to the internet all your information is also transferred to your personal account. This is a secure and confidential area so it's a good idea to keep your personal account updated in case you lose or change your phone. You can check when this was last done by going to Menu.

How does the app know the day my period is due?

The app will estimate when your period is due based on the information you have provided on your cycle length and last period.

Can I connect more than one holder?

No, you can only connect one holder to the app at a time. Please check that you have synced all your results **before** connecting a new holder. To connect a new holder go to Menu > My holder.

When you connect a new holder your old holder will automatically disconnect and you cannot reconnect it.

What happens if I travel outside my normal time zone?

If the time on your phone is changed to local time you may find the app requests you test twice in 24 hours or you may miss a test depending on the time difference.

What if I change my phone?

Download the Clearblue® Connected app to your new phone and sign in with your email and password to access your data. Your holder will continue to sync results to your new phone.

2 Important points you need to read before testing

1. Peak Fertility is displayed constantly for 48 hours after it first appears. The holder will not be able to read another test while this is displayed.
2. Every woman's cycles are unique and hormone patterns differ so the number of fertile days you see is personal to you. In a study of 87 women, this is what we saw:

Number of High Fertility days before Peak Fertility	% of women
0-4	66%
5-9	25%
10+	1%
No Peak Fertility after High Fertility	8%
TOTAL	100%

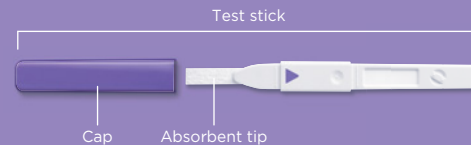
3 How to take a test

Determine when to start testing

- Use the table below to determine when to start testing.
- 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 your cycle length varies use the shortest cycle over the last 6 to determine when to start testing.

How long is 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
Start testing on the day shown under your cycle length.	5	6	6	6	7	7	7	8	9	10	11	12	13	14	15	16	17	18	19	20	20 days before you expect your next period

Test stick and holder:



4 Insert the test stick into the holder

- a) When you are ready to test, take a test stick out of the foil and take off the cap.



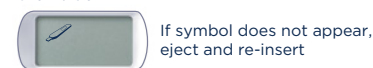
- b) Put the test stick into the holder making sure the arrows line up as shown.



- c) The first time you use the test the new cycle symbols will flash briefly.



- d) The 'test ready' symbol will then appear. Take the test straight away. If this symbol does not appear or the screen goes blank eject the test stick and put it back into the holder.



5 Take the test



- a) **Either...** put just the absorbent tip pointing downwards into your urine stream for 3 seconds. Take care not to get the holder wet.



- Or...** collect a sample of your urine in a clean, dry container and put just the absorbent tip into the sample for 15 seconds.



- b) Replace the cap and wipe off any excess urine. Keep the absorbent tip pointing down or lying flat.

3. If you started testing on the right day and you see more than 9 High Fertility days you may wish to stop testing as it's unlikely that you will see Peak Fertility this cycle. See Q4.
4. Only test once a day until you see High Fertility. For reliable results you must use the first urine after your longest sleep. When you see High Fertility you can test more often. Drink normally and it's important not to urinate for 4 hours before testing again.
5. If you remove the battery from the holder you will not be able to use it again.

- If you don't know how long your cycle is, we recommend you wait at least one cycle and note the length of it so you know when to start testing. If you don't want to wait you can use the default cycle length of 28 days. You can select this on the app.
- It's important to start testing on the day shown in the table, for example if your cycle lasts 27 days start testing on day 7.
- Always test using the **first urine** after your longest sleep.

6 Wait for your result



Within 1 minute the test ready symbol will flash to show the test is working. After 5 minutes the display will show your result. Do not eject the test stick yet.

7 Read your result

		Your most fertile time	
Your result			
What it means	Low Fertility: small chance of getting pregnant Having sex today is just for fun as it's unlikely that you will get pregnant. Test again tomorrow.	High Fertility: increased chance of getting pregnant Have sex to increase your chances of getting pregnant. A rise in estrogen has been detected. High Fertility will be displayed until your LH surge is detected (Peak Fertility).	Peak Fertility: highest chance of getting pregnant Have sex to maximize your chances of getting pregnant. Your LH surge has been detected - today and tomorrow are your most fertile days. Once the first day of Peak Fertility is displayed don't try to test again this cycle.
How long it will be displayed			
Low and High Fertility results are displayed for 8 minutes. If you miss seeing your result, eject the test stick and it will re-appear for another 2 minutes.			Peak fertility is displayed constantly for 48 hours.

If no result is displayed see 'Holder symbols - error and other symbols'.

8 Check Bluetooth® on your phone is turned on.

While your result is displayed on the holder it will be synced automatically with the app providing Bluetooth® is turned on, your phone is close to the holder and the app is open. As soon as the result is synced the Bluetooth® and asterisk symbol will no longer be displayed on the holder. If your result is no longer displayed and has not synced see 'Q&As about the app'.

9 When you've finished with the test

Press the eject button to remove your test stick as soon as possible after you have seen the result on your holder. Throw away the test stick in your normal household waste.

10 Doing your next test

Follow the instructions from step 4 using a new test stick.

Further information

- This test works differently to other ovulation tests which detect one hormone. This test detects **2 key fertility hormones** – estrogen and luteinizing hormone (LH). It's important for the test to establish 'baseline' levels of these hormones so start testing as advised and keep testing with the same holder until you see Peak Fertility.
- If there's no significant rise above the baseline level of hormones Low Fertility is displayed. You may see a number of Low Fertility days before you see High or Peak Fertility.
- Estrogen rises in the days before the LH surge and prepares your body for ovulation. When an estrogen rise is detected High Fertility is displayed each day until Peak Fertility is detected.
- High Fertility is indicated as a flashing smiley face.
- If an estrogen rise isn't detected, or the estrogen rise and LH surge are close together, you may not see High Fertility.
- An LH surge happens about 24-36 hours before an egg is released from an ovary – 'ovulation'. When your LH surge is detected Peak Fertility is displayed and is generally displayed **after** Low and High Fertility.
- Peak Fertility is displayed as a static smiley face (**it does not flash**) and stays on the display constantly for 48 hours. If your LH surge is detected on the first day of testing Peak Fertility will be displayed.
- You may not see Low, High and Peak Fertility days every cycle. This is not unusual. Refer to Questions and Answers for more information.
- Have sex on High and Peak Fertility days to maximize your chances of getting pregnant.**

Holder symbols – how you connect



Bluetooth® symbol
Bluetooth® on your holder is turned on.



Bluetooth® symbol and asterisk
When both these symbols are shown, data on the holder is ready to sync providing Bluetooth® on your phone is turned on.



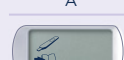
Flashing asterisk
The asterisk will flash slowly to show you have data on the holder to sync. When Bluetooth® is turned on this will happen automatically providing Bluetooth on your phone is turned on and the app is open. You can turn on Bluetooth® by inserting the wake-up stick, or it will automatically turn on when you have taken your next test. Remember to eject the wake-up stick once the data has been synced. When completed the asterisk will no longer be displayed.

Holder symbols – error and other symbols

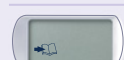
A symbol will be displayed within 10 minutes if an error has occurred.



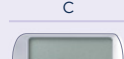
The test stick has been ejected too soon. Re-insert it quickly.



An error has occurred during testing. Test again using a new test stick. If you have collected urine, use this to test again as soon as the display is blank. Otherwise test as soon as you can but drink normally and don't urinate for 4 hours before testing again.



You cannot use this holder again, but you can use any unused test sticks. Test again using another holder from a new pack, following the instructions carefully.



When you insert a test stick, if the display remains blank, you may not have inserted it correctly. Eject the test stick and start again from step 4. If the test stick is inserted correctly and the display is still blank, the holder is no longer working and you will need to buy a new pack. If the display is blank after testing it may be that the holder has gotten very wet and it is no longer working.



This appears when you insert a test stick for first time. It will also appear if you are testing after you have seen Peak Fertility, or if you have not taken a test for 3 or more days in a row. If you miss 3 or more tests and have not seen Peak Fertility it's better to wait for your next cycle before testing again.

Questions and Answers

- What happens if I don't use the first urine after my longest sleep?**
You may get unexpected High Fertility results. Test as soon as you can but drink normally.
- How accurate is Clearblue® Connected Ovulation Test System?**
A laboratory study has shown the test to be over 99% accurate in detecting the LH surge (Peak Fertility).*
- I've not seen any High Fertility days. Why is this?**
It may be that the estrogen level is not high enough to be detected, or your hormone changes occur close together, or you started testing too late. You may still see Peak Fertility and you can rely on these results.
- I've not seen any Peak Fertility days. 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 see Peak Fertility for 3 consecutive cycles.
If you miss a test around your LH surge you may not see Peak Fertility so remember to test as advised, and use the same holder throughout your cycle.
- Can any medication or medical conditions affect the result?**
Always read the manufacturer's instructions for any medication that you are taking before testing. Certain medical conditions and medications can give misleading results, for example if you are pregnant, or have recently been pregnant, have reached menopause, have impaired liver or kidney function, have polycystic ovarian syndrome, are taking fertility drugs containing luteinizing hormone or human Chorionic Gonadotrophin, or are taking antibiotics containing tetracyclines.
Some fertility treatments such as clomiphene citrate may give misleading High Fertility results. Peak Fertility results should be unaffected.
If you do get unexpected results you should discuss them with your doctor.
If you have recently been pregnant you should wait until you have had 2 cycles before testing.
If you have recently stopped using hormonal contraception your cycles may be irregular so you may wish to wait until you have had 2 cycles before testing.
Please check with your doctor if you are taking any medication or have any medical condition before planning a pregnancy. If you have a medically diagnosed fertility problem you should ask your doctor if Clearblue® Connected Ovulation Test System is suitable for you.
- How do I recycle the battery and dispose of the holder?**
If you remove the battery from the holder you will not be able to use it again.
When you have finished using the holder and synced all your results, separate the upper and lower halves starting at the end nearest the display. Remove the battery from under the central metal cover, and dispose of them according to the appropriate recycling protocol. **Caution:** Do not take apart, recharge, or dispose of the battery 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.
- Are test sticks available separately?**
No. If you have used all the test sticks in the pack you will need to buy a new pack containing a holder and test sticks. Use the same holder throughout your cycle with new test sticks.
If you have any test sticks left at the end of testing, you can use these and the holder for your next cycle if needed.
- I've used Clearblue® Connected Ovulation Test System 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.



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 **[LOT]** 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 you try to conceive.

*The sensitivity of the LH detection in Clearblue® Connected Ovulation Test System is 40mIU/ml measured against the Third International Standard for urinary LH and FSH for Bioassay (71/264).

Made in PRC. Packaged in USA.

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Pat. – see www.swissprecisiondiagnostics.com/patents

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For self-testing at home. For *in vitro* diagnostic use only. Not for contraceptive use. Not for internal use. Do not reuse test sticks. Keep out of reach of children. Store between 36° – 86°F. 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® Connected with the holder.

Results must be read on the display or the app and not by any lines you might see on the test stick.

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Limits of the test

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

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 EMC countermeasures employed within the electronic instrument will provide reasonable protection against electromagnetic interference effects likely to be encountered in the home environment. Do not use this instrument in close proximity to sources of strong electromagnetic radiation as these may interfere with the proper operation.

Changes or modifications not expressly approved by the grantee will void the authority to operate this equipment.

This device should not be used in locations where cellular telephone and other electronic devices are prohibited, e.g. aircraft.

This device contains a 2.4GHz ISM band transceiver, maximum output power +10dBm.

Bluetooth® SMART wireless technology.