Clearblue®

Digital
Ovulation Test

Digital read for
greater accuracy[a]

Professional Series
Ovulation

[a] Provides easier and more accurate reading in consumers' hands than traditional line tests[1]

About Clearblue®

Clearblue® is the world's #1 selling brand in home pregnancy and fertility tests.[b] Consumers trust the Clearblue® brand because it delivers the accurate information they want. The Clearblue® product range is built on a strong foundation of peer-reviewed science and consumer understanding. Clearblue® is supported by over 30 years of expertise, quality, and innovation in consumer diagnostics.

If you are a healthcare professional and wish to contact a member of the Clearblue® support team about any product in the Clearblue® range, please send an email to **spdproductsupport@spdspark.com**

Clearblue® Digital Ovulation Test

Digital read for greater accuracy[a]

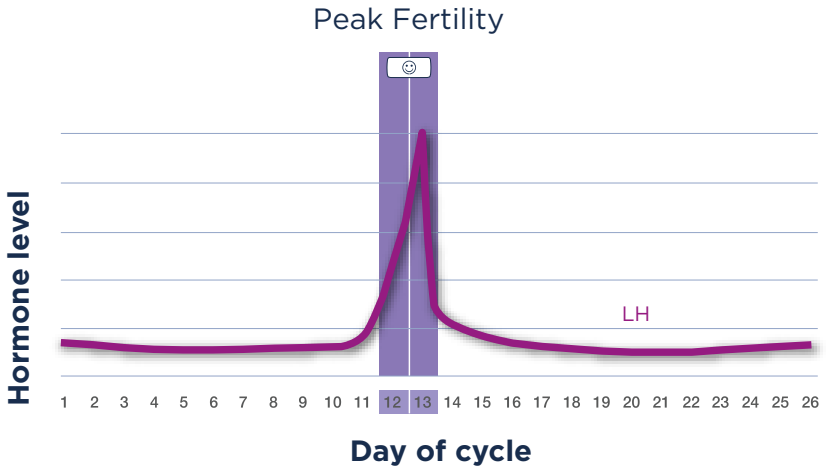
The Clearblue® Digital Ovulation Test is an easy-to-use home ovulation test that is over 99% accurate at detecting the luteinizing hormone (LH) surge,[2] and which provides easier and more accurate reading in consumers' hands than traditional line tests.[1]

Proven method of detecting Peak Fertility

There are only a few days per cycle when a woman is fertile and can conceive. Evidence shows that this fertile window usually spans 6 days, starting approximately 5 days prior to ovulation and ending on the day of ovulation itself.[3] The day of ovulation and the preceding day are the two most fertile days in a woman's cycle; these are known as her days of Peak Fertility.[4]

Predicting when ovulation occurs can be beneficial for women who are trying to conceive; however, even women actively trying to conceive can have an inaccurate perception of their day of ovulation.[5] Data show that women who are aware of their peak fertile days have an increased likelihood of conceiving when compared to women who are unaware of their ovulatory pattern.[6,7] The Clearblue® Digital Ovulation Test helps women to pinpoint the two most fertile days in their cycle by measuring levels of LH. LH levels rise rapidly 24–36 hours prior to ovulation (i.e. during the time of Peak Fertility – see Figure One).[8] Various studies show that this surge in LH is an accurate and reliable marker of impending ovulation.[9–13] Extensive laboratory studies have shown that the Clearblue® Digital Ovulation Test is over 99% accurate at detecting the pre-ovulatory LH surge.[2]

Figure One: An example of how the LH surge could appear during a menstrual cycle



Advantages over traditional methods for determining ovulation

Detection of the LH surge using the Clearblue® Digital Ovulation Test allows women to time intercourse to coincide with their most fertile time by alerting them to approaching ovulation. Thus, it provides women with a prospective method of identifying their period of Peak Fertility and has advantages over traditional methods of identifying ovulation.

- The basal body temperature (BBT) method requires women to chart their daily temperature to detect a rise associated with ovulation. However, it is not ideal for timing intercourse because the rise in temperature cannot be detected until after ovulation has occurred.[14] Furthermore, most studies examining the BBT method have concluded that it can be unreliable due to inaccurate interpretation of temperature curves, either through patient error or confounding factors (alcohol intake, timing of temperature reading, or certain medications)[15,16]
- Monitoring of cervical mucus can provide prospective information that ovulation has occurred, but it requires a level of training, is less accurate than monitoring the LH surge, and may not be acceptable to all women[15]
- The calendar method relies on previous cycle length to predict when ovulation is likely to occur in the current cycle. It is an unreliable method for the purpose of timing intercourse to conceive because women's cycles are known to vary from cycle to cycle, and the day of ovulation itself is therefore variable.[17–19] Studies have shown that the calendar method correctly identifies women's fertile days in only a third of cycles[20]

The accuracy in predicting the LH surge to within 1 day is reported to vary between 57–70% for the BBT method and 48–76% for the cervical mucus evaluation method.[15]

Adapts to a woman's own LH surge threshold

The Clearblue® Digital Ovulation Test is a rapid 'sandwich' immunoassay which uses monoclonal antibodies to detect the LH molecule. An optical system, contained within the test holder, then measures the density of the lines formed by the binding of LH to the antibodies. If above a defined threshold, an 'LH surge' result will be displayed.

As many women have low levels of LH present in their urine throughout their cycles, the Clearblue® Digital Ovulation Test does not measure the LH surge to a constant uniform threshold. Instead, the Clearblue® Digital Ovulation Test sets a personalized threshold level for each woman by measuring their change in LH level from their personal baseline. This is an obvious advantage over tests that ignore the fact that different women have different baseline LH levels, and that levels can even vary between cycles.

Easy to use

The Clearblue® Digital Ovulation Test comprises an electronic test holder and a supply of foil-wrapped test sticks. The pack also contains an instruction leaflet; an abbreviated version of these instructions is provided below.

Prior to using the Clearblue® Digital Ovulation Test, the user must remove a test stick from its foil wrapper, take off the test stick cap and insert the test stick into the test holder. The test stick and test holder are marked with pink arrows. The user must align these when inserting the test stick into the test holder.

The test stick clicks into place when inserted and the 'test ready' symbol appears on the display.

When the 'test ready' symbol appears, the user simply holds the absorbent tip in her urine stream for 5–7 seconds. Alternatively, she can collect a sample of urine in a clean, dry container and immerse the tip in the collected specimen for 15 seconds. After 20–40 seconds, the 'test ready' symbol will flash to show that the test is working.


Test ready


Test in progress

After 3 minutes, the test holder automatically reads and interprets the test result and presents a ◯ for a 'no surge detected' result and a ☺ for an 'LH surge detected' result.


No surge detected


LH surge detected

The Clearblue® Digital Ovulation Test is available in two pack sizes (10 or 20 test sticks) to accommodate the variability in women's cycle length.[c] In addition, the test holder is reusable during the following cycle, should the user have test sticks left over from their current testing cycle.

When to start testing

Women should use the chart found in the package instruction leaflet to calculate when they should start testing with the Clearblue® Digital Ovulation Test, based on their cycle length (Table One). A woman who does not know her usual cycle length is advised to wait for at least one menstrual cycle, and note the length of this cycle, before using the Clearblue® Digital Ovulation Test. Women with variable cycle lengths should use their shortest cycle in the last 6 months to calculate when to start testing.

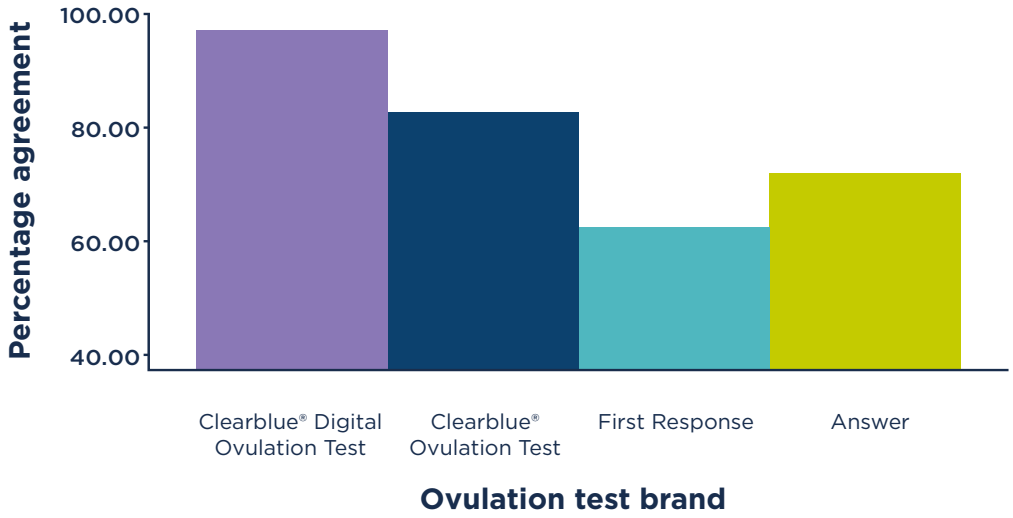
Table One: Table to indicate which day to start testing

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
Note the day your period starts as day 1. 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

Accurate reading – Easier to read than a line test[a]

It has been shown that one in four women can misread a traditional line test.[1] However, the Clearblue® Digital Ovulation Test has a clear digital display that provides two simple results: a ◯ for a 'no surge detected' result and a ☺ for an 'LH surge detected' result. Indeed, a study which compared four leading ovulation test brands found that the Clearblue® Digital Ovulation Test was the test that women read most accurately (Figure Two).

Figure Two: In a study of 72 women reading the results of ovulation tests performed using urine samples from normal cycles, more women obtained the same result as a laboratory professional when reading the Clearblue® Digital Ovulation Test than when reading test results from three other leading visual ovulation test brands. The study was performed with tests available in the UK and US markets[1]



Stress and digital ovulation tests

A recent study involving over 200 women demonstrated that the use of digital ovulation tests neither increases nor decreases the levels of stress in users, and importantly may shorten the time to conception. In the study, 77% more women became pregnant compared with women advised to have regular intercourse. The study also found that the use of digital ovulation tests provided additional benefits, including an increased understanding of the menstrual cycle, reassurance and confidence in focusing intercourse around the correct time in the cycle.[21]

Can apps be used to accurately predict ovulation?

Many women turn to apps to help them identify their fertile days. However, many apps estimate day of ovulation and fertile days using cycle length information alone, without accounting for cycle length variability.[22] Furthermore, few apps publish the algorithm used to determine fertile days.

Examination of 108 English language iOS apps found only 19% of free apps are accurate. In this study, simulation assumed ovulation 13–15 days before the start of the next cycle.[23] A further study of 33 Android and iOS apps using a simulated 28-day cycle found only 9% accurately predicted the fertile window.[24]

Limitations

- Users should always read the manufacturer's instructions for any medication they are taking before conducting a test
- Certain medical conditions and medications can adversely affect the performance of the test, e.g. pregnancy, a recent pregnancy, the menopause, or polycystic ovary syndrome may produce misleading results. Fertility drugs containing LH or human chorionic gonadotropin can also interfere with testing. Should any of these conditions apply, women are advised to consult their healthcare professional
- Clomiphene citrate does not affect the test, but may affect cycle length and, therefore, when to start testing. If the cycle length is longer than expected, the user may need to start a new pack and use the new test holder and test sticks to continue testing
- If a woman has recently stopped using hormonal contraception, this will not affect the results. However, the natural hormone pattern is disrupted by hormonal contraception, which can cause temporary irregularities in the menstrual cycle. Women in this position should wait until they have had two natural menstrual cycles, and should note the length of these cycles, before using the Clearblue® Digital Ovulation Test
- The Clearblue® Digital Ovulation Test should not be used as a method of contraception

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Clearblue® Digital Ovulation Test is:

Accurate – over 99% accurate at detecting the LH surge in urine[2]

Unmistakably clear – digital results for greater accuracy in consumers' hands[1,a]

Simple to use – convenient and easy to interpret

Reliable – uses innovation based on established technology

[a] Provides easier and more accurate reading in consumers' hands than traditional line tests.[1]
[b] Based on international sales compiled using independent market research data (data on file).
[c] Not all pack sizes are available in all countries.

Clearblue®

For more information about the Clearblue® Digital Ovulation Test, please visit our websites:

www.Clearblue.com
www.swissprecisiondiagnostics.com

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