



CLEARBLUE DIGITAL OVULATION TEST

Digital Read, for Greater Accuracy*



* Provides easier and more accurate reading in consumers' hands than traditional line tests



About Clearblue

Clearblue® is the world's number one selling brand in home pregnancy and fertility tests.* 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 25 years of expertise, quality, and innovation in consumer diagnostics.

* Based on international sales in nearly 20 countries compiled using independent market research data.

Clearblue Digital Ovulation Test

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



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 before, and day of ovulation are the two most fertile days in a woman's cycle; these are 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 luteinising hormone (LH). LH levels rise rapidly 24–36 hours prior to ovulation (i.e. during the time of peak fertility – see Figure One)⁸ and various studies show that this 'LH surge' 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.¹

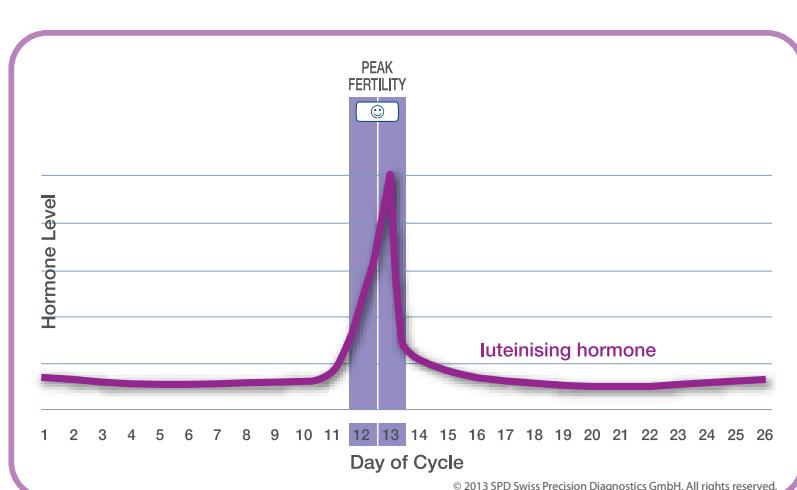


Figure One: An example of how the LH surge could appear during a menstrual cycle

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 LH surge, and may not be acceptable to all women¹⁵
- 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.^{17,18,19} 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 basal body temperature method and 48–76% for the cervical mucus evaluation method.¹⁵

Adapts to a woman's own LH surge threshold

The Clearblue 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, and if above a defined threshold, a positive '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 personalised threshold level for each woman, by measuring their change in LH level from their personal baseline. This is an obvious advantage over visual tests which 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 of 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 Sampler in her urine stream for 5–7 seconds. Alternatively, she can collect a sample of urine in a clean, dry container and immerse the sampler in the collected specimen for 15 seconds. After 20 to 40 seconds, the 'Test Ready' symbol will flash to show that the test is working.

After 3 minutes, the Test Holder automatically reads and interprets the test result and delivers a \bigcirc for a 'No LH surge' result and a \smiley for a positive 'LH surge' result.

The Clearblue Digital Ovulation Test is available in variable pack sizes to allow women to purchase a 1 or 2 month supply and to accommodate the variability in women's length of cycle.* In addition, the Test Holder is reusable the following month, should the user have Test Sticks left over from their current testing cycle.



*Not all pack sizes are available in all countries

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. 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.

Most accurate reading – easier to read than a ‘line test’

It has been shown that 1 in 4 women can misread a traditional line test.² However, the Clearblue Digital Ovulation Test has a clear, digital display that provides two simple results: a O for a ‘No LH surge’ result and a (smiley face) for a positive ‘LH surge’ 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 (see Figure Two).²

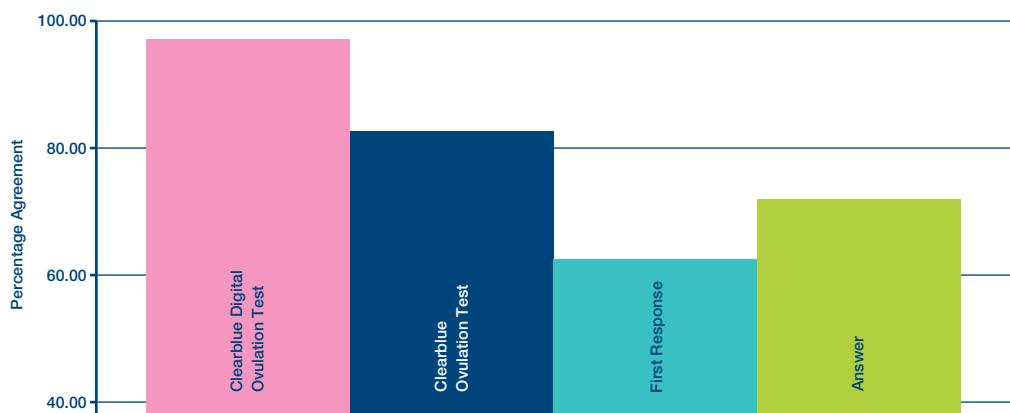


Figure Two: In a study of 72 women reading ovulation tests using urine samples from normal cycles, more women obtained the same result as a laboratory professional when reading the Clearblue Digital Ovulation Test than when reading three other leading visual Ovulation Test brands. The study was done on tests available in the UK and US markets.²

Stress and Digital Ovulation Tests

A recent study 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 this study involving over 200 women, those using digital ovulation tests took on average 10% less time to become pregnant, and 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 focussing intercourse around the correct time in the cycle.²¹

Additional points

- 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 luteinising hormone or human chorionic gonadotrophin can also interfere with testing. Should any of these 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. A 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 results. However the natural hormone pattern is disrupted by hormonal contraception and her cycles may be temporarily irregular. Women in this position may therefore wish to wait until they have had two natural menstrual cycles, and should note the length of these cycles before using Clearblue Digital Ovulation Test
- Clearblue Digital Ovulation Test should not be used as a method of contraception.

References

1. Data on file: Clearblue Digital Ovulation Test has been shown to be over 99% accurate when compared to a reference method in laboratory studies using urine samples from 123 cycles.
2. Johnson SR., et al. Comparison of a digital ovulation test with three popular line ovulation tests to investigate user accuracy and certainty. *Expert Opin Med Diagn* (2011) 5: 467–473.
3. Wilcox AJ., et al. Timing of sexual intercourse in relation to ovulation. Effects on the probability of conception, survival of the pregnancy, and sex of the baby. *N Engl J Med* (1995) 333: 1517–1521.
4. Ferreira-Poblete A. The probability of conception on different days of the cycle with respect to ovulation: an overview. *Adv Contracept* (1997) 13: 83–95.
5. Zinaman M., et al. Accuracy of perception of ovulation day in women trying to conceive. *Curr Med Res Opin* (2012) 28: 1–6.
6. Hilgers TW., et al. Cumulative pregnancy rates in patients with apparently normal fertility and fertility-focused intercourse. *J Reprod Med* (1992) 37: 864–866.
7. Stanford JB, Dunson DB. Effects of sexual intercourse patterns in time to pregnancy studies. *Am J Epidemiol* (2007) 165: 1088–1095.
8. World Health Organization. Temporal relationships between indices of the fertile period. *Fertil Steril* (1983) 39: 647–655.
9. Corson SL. Self-prediction of ovulation using a urinary luteinizing hormone test. *J Reprod Med* (1986) 31(8 Suppl): 760–763.
10. Guida M., et al. Efficacy of methods for determining ovulation in a natural family planning program. *Fertil Steril* (1999) 72: 900–904.
11. Behre HM., et al. Prediction of ovulation by urinary hormone measurements with the home use ClearPlan Fertility Monitor: comparison with transvaginal ultrasound scans and serum hormone measurements. *Hum Reprod* (2000) 15: 2478–2482.
12. Tanabe K., et al. Prediction of the potentially fertile period by urinary hormone measurements using a new home-use monitor: comparison with laboratory hormone analyses. *Hum Reprod* (2001) 16: 1619–1624.
13. Guermandi E., et al. Reliability of ovulation tests in infertile women. *Obstet Gynecol* (2001) 97: 92–96.
14. Royston JP. Basal body temperature, ovulation and the risk of conception, with special reference to the lifetimes of sperm and egg. *Biometrics* (1982) 38: 397–406.
15. Brezina PR., et al. At home testing: optimizing management for the infertility physician. *Fertil Steril* (2011) 95: 1867–1878.
16. Barron ML, Fehring RJ. Basal body temperature assessment: Is it useful to couples seeking pregnancy? *Am J Mat Child Nurs* (2005) 30: 290–296.
17. Johnson S., et al. Levels of urinary human chorionic gonadotrophin (hCG) following conception and variability of menstrual cycle length in a cohort of women attempting to conceive. *Curr Med Res Opin* (2009) 25: 741–748.
18. Lenton E., et al. Normal variation in the length of the follicular phase of the menstrual cycle: effect of chronological age. *Br J Obstet Gynaecol* (1984) 91: 681–684.
19. Small C., et al. Validity of self-reported menstrual cycle length. *Ann Epidemiol* (2007) 17: 163–170.
20. Ellis JE., et al. Superiority of Clearblue home ovulation tests in detecting the peak fertile days of the menstrual cycle compared to a simple calendar method. *Hum Reprod* (2011) 26: i76(O–191).
21. Tiplady S, et al. Home ovulation tests and stress in women trying to conceive: a randomized controlled trial. *Hum Reprod* (2013) 28: 138–151.

The Clearblue Digital Ovulation Test is:

- Accurate** – over 99% accurate in detecting the LH surge in urine¹
- Reliable** – uses innovation based on established technology
- Unmistakably clear** – digital results for greater accuracy in consumers' hands²
- Adaptive** – the only ovulation test brand that can adapt to a woman's individual hormone levels every time she tests
- Simple to use** – convenient and easy to interpret
- Trustworthy** – from Clearblue, the world's number one selling brand in home pregnancy and fertility tests*

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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

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

www.clearblue.com
www.swissprecisiondiagnostics.com



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