



Clearblue Advanced Digital Ovulation Test

Identifies a wider fertile window than any other ovulation test for more opportunities to get pregnant naturally



Clearblue Professional Series



About Clearblue

Clearblue® is the world's leading brand in home pregnancy and fertility testing. 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 products are also trusted and recommended by doctors, many of whom recognize that Clearblue is supported by over 25 years of expertise, quality, and innovation in consumer diagnostics.

Clearblue

Clearblue Advanced Digital Ovulation Test

Today's busy lifestyles mean women often wish to actively plan their families and expect pregnancy to happen quickly. Clearblue Advanced Digital Ovulation Test helps a woman become pregnant naturally and sooner by assisting her to appropriately time intercourse within her fertile window.

The only ovulation test to identify a wider fertile window

The Clearblue Advanced Digital Ovulation Test is the first and only ovulation test that accurately identifies more of a woman's fertile window by measuring luteinizing hormone (LH) and estrone-3-glucuronide (E3G)*, a principal urinary metabolite of estradiol. This means that the test can typically identify a woman's four best days to get pregnant, two more fertile days than any other ovulation test, for more opportunities to get pregnant naturally.¹

The Clearblue Advanced Digital Ovulation Test incorporates the latest fertility monitoring technology, which is more than 99% accurate at detecting the LH surge.² The device accurately adapts to a woman's personal menstrual cycle to identify a wider fertile window than any other ovulation test by tracking the changing levels in the urinary metabolites of these two hormones that control fertility, E3G* and LH.

*Estrone-3-glucuronide, E3G, is recognized by the World Health Organization as a principal metabolite of estradiol³ that can be used to identify the onset of the fertile phase. The urinary levels of E3G correspond to the serum levels of estradiol.⁴



How does the Clearblue Advanced Digital Ovulation Test work?

The Clearblue Advanced Digital Ovulation Test consists of disposable Test Sticks and a Test Holder (Figure One). The Test Sticks incorporate a rapid dual hormone assay to measure E3G and LH in urine. The Test Holder reads the Test Sticks to identify changes in these hormone levels which control fertility, in order to detect the user's fertile window.

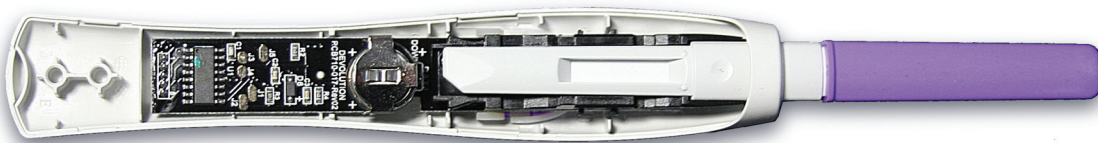


Figure One: Inside the Clearblue Advanced Digital Ovulation Test

Adaptive algorithm which measures the cycle's unique hormone profile

Each menstrual cycle has a unique hormone profile. The Test Stick Holder contains software with a sophisticated algorithm that adapts to a woman's individual hormone levels in order to accurately identify her fertile window. This is an obvious advantage over some other ovulation tests which measure LH to a constant uniform threshold, ignoring the fact that women have different baseline hormone levels, which can themselves vary between cycles.

Many women have a low level of LH present in their urine throughout their cycles. Therefore the Clearblue Advanced Digital Ovulation Test sets a personalized threshold level for each woman, by measuring changes in their hormone levels from baseline. 'Peak Fertility' is displayed when the LH surge is detected. 'High Fertility' is detected by a sustained rise in E3G level above baseline a few days prior to ovulation. Trend analysis is applied to the E3G measurements to identify the first day of sustained rise, on which the device will start to display 'High Fertility'.



The fertile window

Changes in hormonal levels control the fertile window

The menstrual cycle is controlled by the anterior pituitary gonadotrophins (follicle-stimulating hormone and LH) and the gonadal sex hormones (estrogen and progesterone).⁵ Changing plasma hormone levels throughout the menstrual cycle control ovum development and ovulation.⁶

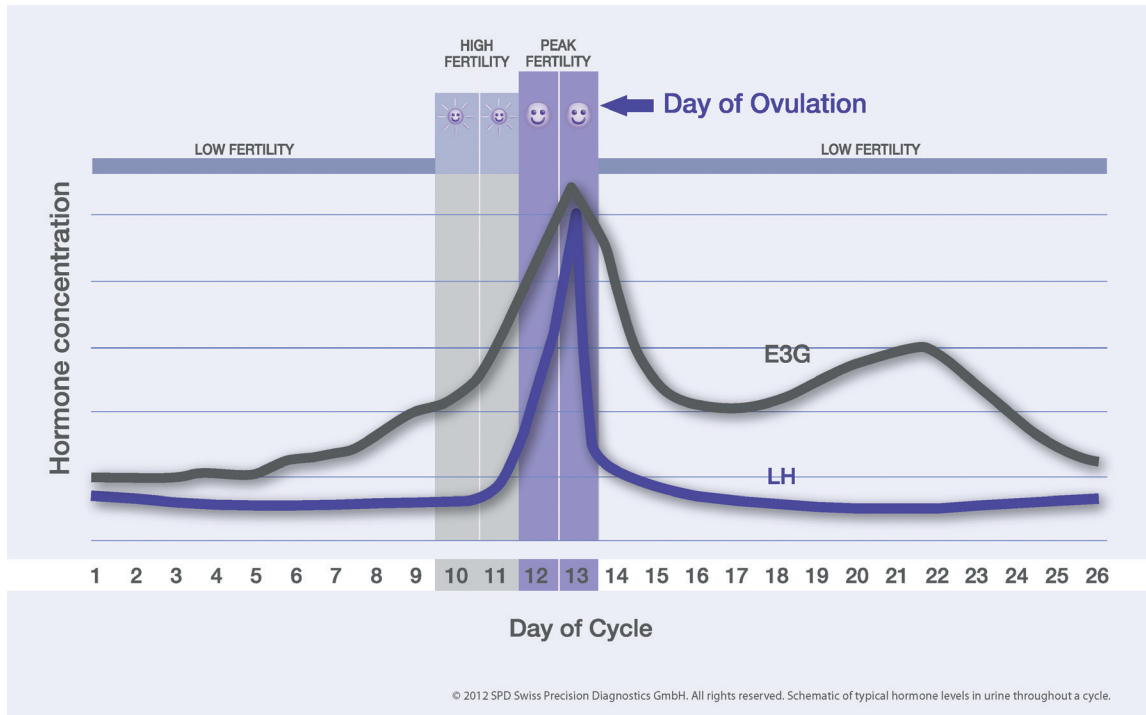


Figure Two: Schematic of typical hormone levels in urine throughout a cycle

The Clearblue Advanced Digital Ovulation Test is the only test that typically identifies four fertile days during the menstrual cycle by monitoring two key urinary fertility hormones:

- Estrone-3-glucuronide (E3G), a major urinary metabolite of estradiol and
- Luteinizing hormone (LH).

Estradiol

- Estradiol is responsible for the type and quantity of cervical mucus⁶
 - fertile mucus supports sperm survival and assists sperm motility
 - non-fertile mucus blocks the cervix, preventing sperm penetration
- It plays an important part in follicular development and oocyte maturation⁶
- It facilitates the surge in LH.⁶

The concentration of E3G in urine gradually increases from the start of the cycle, and usually reaches its peak around 24 hours prior to ovulation (range 0 to 48 hours – see Figure Two).⁷ A sustained increase in E3G in urine can be used to identify the onset of the fertile period during which there is the highest chance of pregnancy.⁸⁻¹⁰

Luteinizing hormone (LH)

The level of LH suddenly surges immediately prior to ovulation, making LH an ideal ovulation marker.⁹ Ovulation typically occurs within 24 to 36 hours of the LH surge,^{6,7} and this timing is crucial because once ovulation has occurred, the ovum has a lifespan of just 24 hours.^{11,12} Following the LH surge, it also becomes increasingly difficult for sperm to penetrate the cervical mucus.¹³ This is due to a fall in the level of estradiol and a rise in progesterone. The fertile window closes shortly after ovulation, thus intercourse after this point can no longer lead to conception in that cycle.

The chances of conception increase in the days preceding ovulation

The duration of the fertile window is determined by the viability of the sperm in the days preceding ovulation and the lifespan of the ovum; it is generally accepted that sperm can survive for up to 5 days in sperm-supportive cervical mucus and that ova typically survive for 12-24 hours after ovulation.

Several studies have examined the length of the fertile window, for example Wilcox and colleagues looked at the menstrual cycle in 221 women. They found that the fertile window was 6 days long, ranging from 5 days prior to the Estimated Day of Ovulation (EDO) to the EDO itself. Results showed that for every cycle in which conception occurred, there was intercourse at least once in this 6-day period. Conversely, where no intercourse occurred during this period, pregnancy did not result (Figure Three).¹⁴

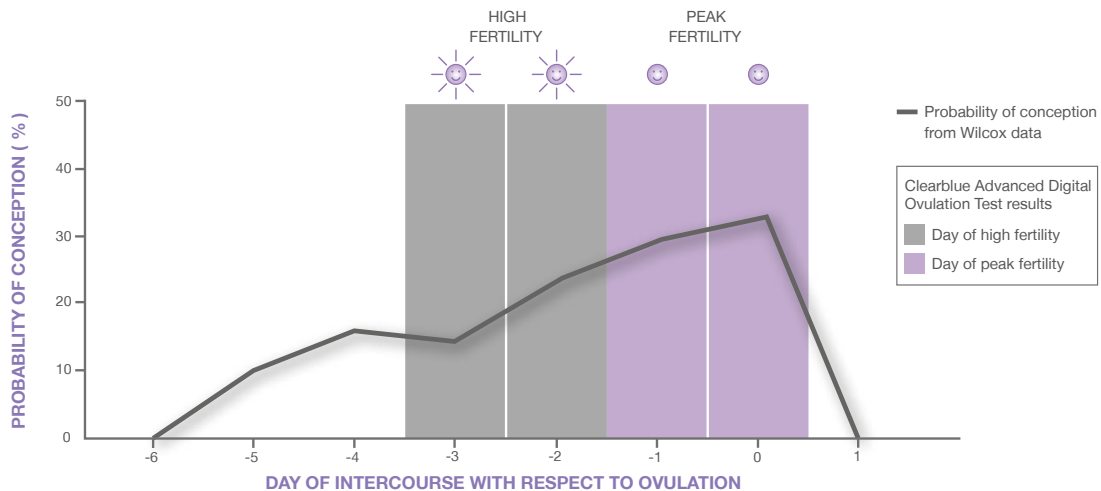


Figure Three: Probability of conception with respect to day of ovulation (data from 129 ovulatory cycles in which a single act of intercourse led to pregnancy were used to calculate the probability of conception, and data from the statistical model applied to 625 ovulatory cycles). Adapted from Wilcox *et al* (1995).¹⁴

There are a myriad of reasons for failing to conceive quickly, but one factor that is easily corrected is mistiming of intercourse and it is important that couples planning for pregnancy are aware of the timing of the fertile window, to help them to plan intercourse on days with the maximum probability of pregnancy.^{15,16} Conception is most likely to occur when intercourse takes place on the day before, or day of ovulation,¹⁵ but is possible throughout the fertile window. Conception has been proposed to occur more quickly with fertility-focused intercourse¹⁵⁻¹⁷ and intercourse across the fertile period is more likely to lead to pregnancy, than intercourse at peak fertility alone.¹⁸ Compared with other ovulation tests, the Clearblue Advanced Digital Ovulation Test typically identifies two additional days of high fertility during each cycle, thereby maximizing the chances of conception.¹

The importance of timing intercourse

There are two main reasons why couples may incorrectly time intercourse.¹⁹ Firstly, couples may be unaware of the most appropriate time in their cycle to try to conceive.

Secondly, the assumption that the fertile window usually occurs between days 10-17 of the menstrual cycle is often not correct.^{15,20,21} This is because although women with a normal menstrual cycle have a mean cycle length of 27-28 days, the range both within and between individuals is considerably wider. In a population of 101 women, considered to have normal menstrual cycles, the range in cycle length was recorded as 13-51 days.²² In another study of over 130 women, 46% were found to have a individual cycle range of 7 days or more.²³ Most of this variability is attributable to the follicular phase of the cycle.^{22,24}

A study amongst women trying to conceive examined how accurately they predict their day of ovulation and found that only 12.7% correctly estimated their ovulation day. In the same study only 55% of women provided an estimate of their day of ovulation that fell within their fertile window.²⁵ This study demonstrates the importance of a prospective method of identifying the fertile days, rather than relying on menstrual cycle characteristics.

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.²⁶ The study also found 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.



How to use the test

A woman needs to test every day from her calculated start date using her first urine sample after the longest sleep of the day. Women should use the table below (Figure Four), found in their in-pack instruction leaflet, to calculate when they should start testing. If a woman does not know her cycle length she should wait at least one menstrual cycle and note the length. Testing can be performed in-stream or on a collected sample.

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 of 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

Figure Four. Table to indicate which day to start testing

The Clearblue Advanced Digital Ovulation Test is available in a pack containing a 1 or 2 month supply of tests—a Holder and 10 Test Sticks or a Holder and 20 Test Sticks. However, if a woman has not detected both High and Peak Fertility using the Test Sticks in her first pack, she can continue using the same Holder and Test Sticks from a new pack.

What the results mean

After 5 minutes, the Test Holder automatically reads and interprets the Test result and delivers a digital indication of the woman's fertility status:



Clear circle – Low Fertility

It is unlikely, but not impossible, that intercourse at this time will result in pregnancy. The woman should test again the following day. This result is displayed for 8 minutes.



Flashing Smiley Face – High Fertility

Intercourse today could lead to pregnancy, but the woman must also test again the following day. The result will be displayed for 8 minutes.



Smiley Face – Peak Fertility

This is the woman's most fertile time and the result will be displayed for 2 days. She should have intercourse during these 2 days to maximize her chance of conception. She should stop testing after the first day that Peak Fertility is displayed. If she continues to test after the Peak Fertility symbol is displayed, the Test Holder display will show three error symbols simultaneously which indicates that she should wait until her next cycle before starting to test again.

Advantages of the Clearblue Advanced Digital Ovulation Test

Identification of additional fertile days providing couples with more flexibility to plan intercourse around their busy lifestyles

Most home ovulation tests only provide 1-2 days' advance warning of ovulation, through identification of the LH surge, which limits the opportunity to have multiple acts of intercourse before ovulation. The Clearblue Advanced Digital Ovulation Test typically identifies four fertile days – two more than other ovulation tests, and importantly, the additional days identified are prior to ovulation – to help women get pregnant sooner.¹ The Clearblue Advanced Digital Ovulation Test is suitable for women with all cycle lengths.

Digital format for unmistakably clear results

In a recent study, exploring how volunteers interpreted the results of a digital ovulation test versus three non-digital tests (tests with results in the form of colored lines), over 97% of volunteers correctly read the result of Clearblue Advanced Digital Ovulation Test.²⁷ It was also the test that women read with most certainty and the test that most users preferred.

More accurate than other commonly-used methods

The accuracy in predicting 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.²⁸

- **Calendar Method** – calendar calculations are unreliable 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^{22,24,29}
- **Basal Body Temperature (BBT)** – the BBT method is not ideal for timing intercourse because the rise in temperature cannot be detected until after ovulation has occurred.¹¹ 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)^{28,30}
- **Observation of Cervical Secretions** – Monitoring of cervical mucus can provide prospective information, but it requires a level of training, is less accurate than monitoring LH surge, and may not be acceptable to all women.²⁸

Additional points

- Certain medical conditions and medications can adversely affect the performance of the Clearblue Advanced Digital Ovulation Test. Women who have menopausal symptoms, polycystic ovarian syndrome, impaired liver or kidney function, are pregnant or have recently been pregnant (even if not carried to full term), may get misleading results. Similarly, misleading results may be obtained by women taking antibiotics containing tetracyclines, hormonal treatments (e.g. hormonal contraception, hormone replacement therapy), fertility treatments containing human chorionic gonadotrophin (hCG) or luteinizing hormone, or any treatment that might affect their cycle. Women affected by these medical conditions or medications are advised to wait until they have had at least two natural menstrual cycles in a row (each lasting 21-42 days), before using the Clearblue Advanced Digital Ovulation Test
- Women who are undergoing fertility treatments e.g. clomiphene citrate or letrozole may receive misleading High Fertility results with the Clearblue Advanced Digital Ovulation Test. Peak Fertility results should be unaffected
- Women are advised to read the manufacturer's instructions for any medication they are taking before using the Clearblue Advanced Digital Ovulation Test, and to speak to their doctor if they need further advice
- There are no products available that can guarantee success in achieving pregnancy. The Clearblue Advanced Digital Ovulation Test has been designed to assist in conception. It is NOT intended to be used for contraception.

About SPD Swiss Precision Diagnostics GmbH

SPD Swiss Precision Diagnostics GmbH (SPD) is a world leader in the research, design, production and supply of advanced consumer diagnostic products. Our brands, such as Clearblue®, Fact Plus®, and Accu-Clear®, are familiar in many countries, and are trusted for their accuracy and simplicity by women keen to know more about their own reproductive health. SPD brands are acclaimed for their pioneering innovation: Clearblue was the first brand to introduce a one-step pregnancy test, a one-minute test, a urine sample indicator and digitally-displayed results.

At SPD, we are committed to helping people make informed decisions about their health and well-being, through a continuing flow of new and inventive developments. Our research centre is at the leading edge of innovation, and is fully engaged in the development of reliable diagnostic products for better health and personal self-care.

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

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The Clearblue Advanced Digital Ovulation Test is:

- Unique** – the first and only Ovulation Test that typically identifies four fertile days, two more than any other ovulation test
- Accurate** – the only ovulation test to accurately track two key fertility hormones
- Adaptive** – the only digital ovulation test that can adapt to a woman's individual hormone levels every time she tests
- Unmistakably clear** – digital results displayed as a smiley face ☺
- Simple to use** – convenient and easy to interpret
- Reliable** – uses innovation based on established technology
- Trustworthy** – from Clearblue, the world's leading brand in home pregnancy and fertility testing



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

www.clearblueeasy.com

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