

Clearblue™

CLEARBLUE DIGITAL OVULATION TEST WITH DUAL
HORMONE INDICATOR

Identifies a wider fertile window than any other ovulation test
for more opportunities to get pregnant naturally¹



Clearblue Professional Series

OVULATION



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 30 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 with Dual Hormone Indicator

Today's busy lifestyles mean women often wish to actively plan their families and expect pregnancy to happen quickly. The Clearblue Digital Ovulation Test with Dual Hormone Indicator helps a woman become pregnant faster naturally,[†] by assisting her to time intercourse appropriately within her fertile window.

The only ovulation test to identify a wider fertile window

The Clearblue Digital Ovulation Test with Dual Hormone Indicator is the first and only ovulation test that accurately identifies a wider fertile window. It tracks the changing levels in the urinary metabolites of the two fertility hormones, luteinising hormone (LH) and estrone-3-glucuronide (E3G),[‡] a principal urinary metabolite of estradiol. The Clearblue Digital Ovulation Test with Dual Hormone Indicator 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 typically identify four or more fertile days; this is more days than any other ovulation test, thus providing more opportunities to get pregnant naturally.¹



How does the Clearblue Digital Ovulation Test with Dual Hormone Indicator work?

The Clearblue Digital Ovulation Test with Dual Hormone Indicator consists of disposable Test Sticks and a Test Holder. The Test Holder reads the Test Sticks to identify changes in the hormone levels of E3G and LH.

[†] Using the Clearblue Digital Ovulation Test with Dual Hormone Indicator to identify a woman's most fertile days can help her get pregnant faster than not using any method.

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

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

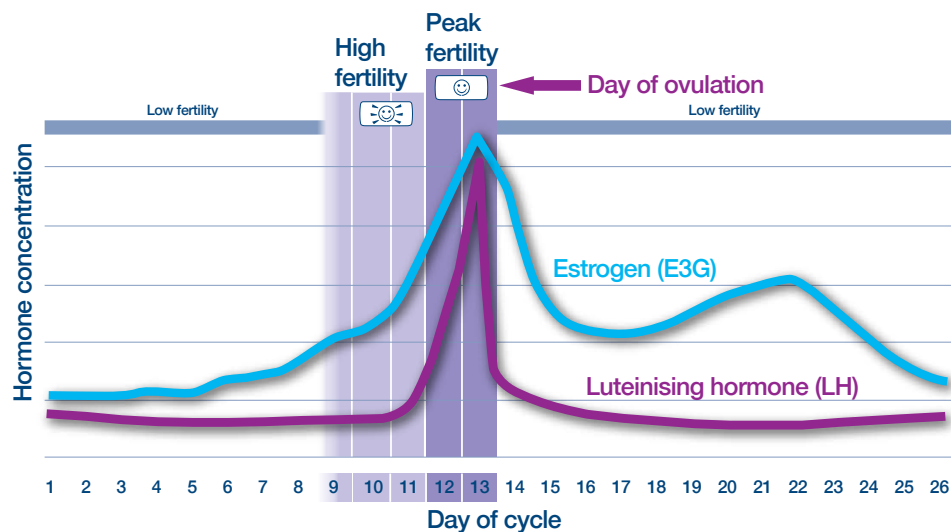


Figure One: The urinary level of reproductive hormones corresponds to their level in serum.

Estrone-3-glucuronide (E3G)

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 0–48 hours – see Figure One).⁷ A sustained increase in E3G in urine can be used to identify the onset of the fertile period when the chance of pregnancy is high.^{8–10}

Luteinising hormone (LH)

The level of LH suddenly surges immediately prior to ovulation, making LH an ideal ovulation marker.⁹ Ovulation typically occurs within 24–36 hours of the LH surge;^{6,7} 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.

The chance of conception increases in the days preceding ovulation

The duration of the fertile window is determined by both 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 while ova typically survive for 12–24 hours after ovulation.

Several studies have examined the length of the fertile window. For example, Wilcox *et al* analysed the menstrual cycle in 221 women and found 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 Two).¹⁴

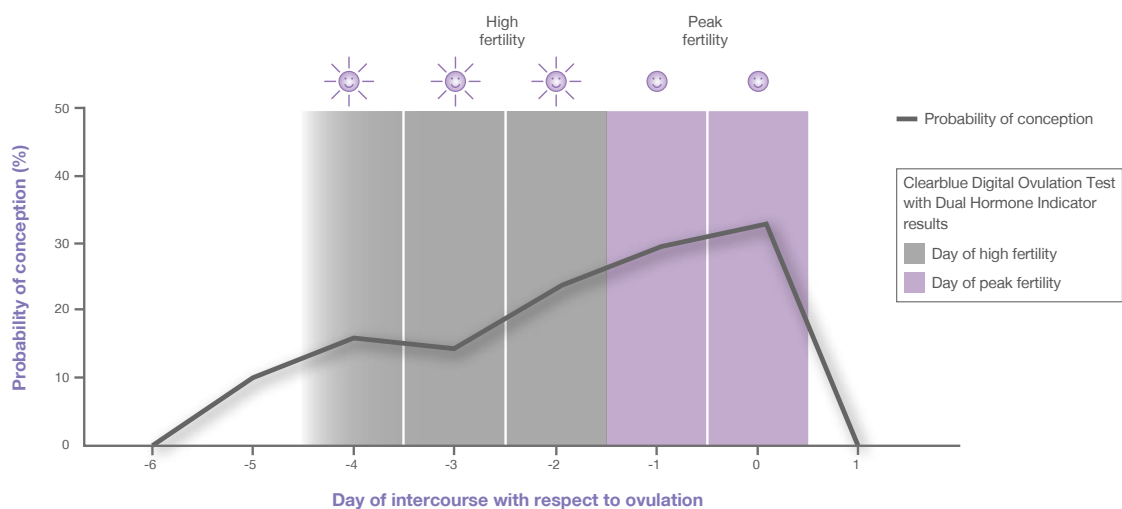


Figure Two: Probability of conception with respect to day of ovulation. Data from 129 ovulatory cycles in which a single act of intercourse led to pregnancy were used to calculate the probability of conception, and data from the statistical model applied to the 625 ovulatory cycles examined in this study.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

Adaptive algorithm which measures the cycle's unique hormone profile

- Each menstrual cycle is unique, therefore it is important for a test to be able to adapt to this individuality
- The Clearblue Digital Ovulation Test with Dual Hormone Indicator has an adaptive algorithm
- Trend analysis is applied to the E3G measurements to identify the first day of the sustained rise in E3G above baseline - on which the device begins to display 'High Fertility'
- As many women have low levels of LH in their urine, the device sets a personalised threshold level for each woman by measuring changes in hormone levels from baseline
- 'Peak Fertility' is displayed when the LH surge is detected.

The importance of timing intercourse

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 intercourse,¹⁵⁻¹⁷ while intercourse across the fertile period is more likely to lead to pregnancy than intercourse at peak fertility alone.¹⁸

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 an 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.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 study has 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 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.

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 Three), 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 Three: Table to indicate which day to start testing.

The Clearblue Digital Ovulation Test with Dual Hormone Indicator is available in a pack containing a 1 or 2 month supply of tests – a Test Holder and 10 Test Sticks, or a Test Holder and 20 Test Sticks. However, if a woman has not detected days of both high and peak fertility using the Test Sticks in her first pack, she can continue using the same Test Holder and Test Sticks from a new pack.

Once she has started testing, she should only test once a day until ‘High Fertility’ is displayed. When ‘High Fertility’ is displayed, she may test more than once a day if desired, but it is important that she does not urinate for 4 hours before testing.

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:

Low fertility	High fertility	Peak 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 will be displayed for 8 minutes.	A rise in E3G has been detected. Intercourse today could lead to pregnancy, but the woman must also test again the following day. This result will be displayed for 8 minutes.	The LH surge has been detected. This is the woman’s most fertile time and she should have intercourse today. ‘Peak Fertility’ will be displayed constantly for 48 hours and the woman should not attempt to test again during this cycle.

Every woman’s cycles are unique and hormone profiles differ, therefore the number of fertile days seen with the Clearblue Digital Ovulation Test with Dual Hormone Indicator is personal to each woman. In a study of 87 women, the following was observed:²⁷

Number of days of high fertility before peak fertility	Percentage of women
0–4	66
5–9	25
10+	1
No days of peak fertility detected after days of high fertility	8
Total	100

Advantages of the Clearblue Digital Ovulation Test with Dual Hormone Indicator

Identification of additional fertile days provides 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 Digital Ovulation Test with Dual Hormone Indicator typically identifies more days than other ovulation tests; these days are prior to ovulation – to help women get pregnant sooner.† The Clearblue Digital Ovulation Test with Dual Hormone Indicator is suitable for women with all cycle lengths.

Measures intact (bioactive) LH

Levels of urinary intact LH have been shown to peak approximately 0.5 days prior to ovulation; however, total LH levels have been shown to peak approximately 1 day later, and could peak after ovulation has occurred.⁷ The Clearblue Digital Ovulation Test with Dual Hormone Indicator measures the intact form of LH to ensure accurate prediction of ovulation.

Digital format for unmistakably clear results

Women have been shown to read ovulation tests with a digital display more accurately than non-digital tests (tests with results in the form of colored lines). In one study, exploring how volunteers interpreted the results of a digital ovulation test versus three non-digital tests, over 97% of volunteers correctly read the result of the digital ovulation test compared with 84%, 73% and 64% for the non-digital ovulation tests.‡ Ninety seven percent of the volunteers also preferred the digital ovulation test.²⁸

More accurate than other commonly used methods

The Clearblue Digital Ovulation Test with Dual Hormone Indicator is over 99% accurate in predicting the LH surge. In comparison, the accuracy in predicting the LH surge to within 1 day is reported to vary between 57–70% for the basal body temperature (BBT) method, and 48–76% for the cervical mucus evaluation method.²⁹

- **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^{22,24,30}

† Using the Clearblue Digital Ovulation Test with Dual Hormone Indicator to identify a woman's most fertile days can help her get pregnant faster than not using any method.

‡ Although the study was conducted using the Clearblue Digital Ovulation Test rather than the Clearblue Digital Ovulation Test with Dual Hormone Indicator, it highlights that women find ovulation tests with a digital display easier to read than visual tests.

- **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)^{29,31}
- **Observation of cervical secretions** – monitoring of cervical mucus can provide prospective information, but it requires a level of training, is less accurate than monitoring the LH surge, and may not be acceptable to all women.²⁹



Limitations of use

- There are no products available that can guarantee success in achieving pregnancy. The Clearblue Digital Ovulation Test with Dual Hormone Indicator has been designed to assist in conception. It is NOT intended to be used for contraception
- Certain medical conditions and medications can adversely affect the performance of the Clearblue Digital Ovulation Test with Dual Hormone Indicator. 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 or hormone replacement therapy), fertility treatments containing human chorionic gonadotrophin (hCG) or luteinising 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 Digital Ovulation Test with Dual Hormone Indicator
- Women who are undergoing fertility treatments e.g. clomifene citrate or letrozole may receive misleading High Fertility results with the Clearblue Digital Ovulation Test with Dual Hormone Indicator. 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 Digital Ovulation Test with Dual Hormone Indicator, and to speak to their doctor if they need further advice.



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The Clearblue Digital Ovulation Test with Dual Hormone Indicator is:

- Unique** - the first and only ovulation test that typically identifies four or more fertile days¹
- Accurate** - the only ovulation test to accurately track two key fertility hormones
- Adaptive** - the only digital ovulation test brand 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 number one selling brand[†] in home pregnancy and fertility tests

[†] Based on international sales in nearly 20 countries compiled using independent market research data.

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