

Fertility Monitor

Proven to increase the chances of conception by 89%^{1,a}

Professional Series Fertility



About Clearblue[®]

Clearblue is the world's number one 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.

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Fertility

Clearblue Advanced Fertility Monitor

Proven to increase the chances of conception by 89%^{1,a}



Accuracy in the palm of your hand

The Clearblue Advanced Fertility Monitor has been shown to accurately predict ovulation, correlating closely with serum hormone measurements and vaginal ultrasound scans.^{2,c} It identifies changes in urine levels of two key hormones that control fertility, to accurately identify a woman's fertile window (the days leading up to and including the day of ovulation).³ With features such as an intuitive touchscreen display and the ability to show up to six cycles of fertility information, the Clearblue Advanced Fertility Monitor is an effective and easy-to-use aid for women trying to conceive.

Designed to detect the entire fertile window to increase the chances of achieving pregnancy

The chances of conception increase in the days leading up to ovulation. The duration of the fertile window is determined by the lifespan of the ovum and the viability of the sperm in the days preceding ovulation:

- It is generally accepted that sperm can survive for up to 5 days in sperm-supportive cervical mucus⁴
- Ova typically survive for 12–24 hours after ovulation^{5,6}

The fertile window can be identified by tracking two key hormones, estradiol and luteinising hormone (LH). Estradiol is the major physiological determinant of the onset of the fertile window, with levels beginning to rise in the early stage of a woman's cycle before triggering a sudden increase in LH, known as the LH surge.⁷ The LH surge is the best indicator of impending ovulation, which typically occurs 24–36 hours after the LH surge, and will not occur in its absence.⁸

The Clearblue Advanced Fertility Monitor has significant advantages over many other methods of predicting ovulation because it is designed to identify the entire fertile window.³ Conception is most likely to occur when intercourse takes place on the day of ovulation or the preceding day,⁹ but it is still possible throughout the entire fertile window (Figure One). In fact, it has been proposed that intercourse across the entire fertile period is more likely to lead to pregnancy than intercourse at peak fertility alone.⁹ Furthermore, the monitor has been proven to have a positive impact on factors that affect couples trying to conceive, such as stress and anxiety. This can improve the user's confidence that conception will happen.¹⁰



Figure One: Probability of conception with respect to day of ovulation⁴

The Clearblue Advanced Fertility Monitor algorithm is clinically proven to predict peak fertility

Figure Two shows the changes in urinary levels of estrone-3-glucuronide (E3G), a principal metabolite of estradiol, and LH throughout a woman's menstrual cycle. These data can be used to estimate peak fertility; however because cycle length varies by 7 days or more in over 46% of women aged 18-40, the length and onset of the fertile window can vary considerably.¹¹⁻¹⁴

The technology used in the Clearblue Advanced Fertility Monitor has been shown to accurately predict ovulation, when compared to serum hormone measurements and vaginal ultrasound scans.^{2,15,c} In 150 cycles, the measurement of urinary hormones by the monitor correlated very closely to serum levels, and ovulation was detected by ultrasound during the predicted 2-day peak fertility period in 91% of cycles.²

In a randomised controlled trial involving over 600 women trying to conceive, use of Clearblue Advanced Fertility Monitor technology significantly increased the chances of conception by 89%.^{1,a}



Simple and easy to use

The Clearblue Advanced Fertility Monitor test sticks are available in two pack sizes (10 or 20 test sticks) to accommodate the variability in women's cycle length.

To perform a test with the Clearblue Advanced Fertility Monitor, the user simply removes the test stick from its foil wrapper, takes off the cap and either holds the test stick pointing downwards in her urine stream for 3 seconds or dips the test stick for 15 seconds in a urine sample collected in a clean, dry container.

After performing the test, the test stick is inserted into the test slot on the front of the monitor. While the monitor is reading the result, a countdown screen will appear, and after 5 minutes the screen will display the result.

Innovative technology that improves the user experience

The Clearblue Advanced Fertility Monitor has a touchscreen display and other features that make it an effective and easy-to-use aid for women trying to conceive.

All information recorded and input into the Clearblue Advanced Fertility Monitor is displayed on a monthly summary screen and cycle summary chart, which can be stored for up to six cycles at a time.

Example of monthly summary screen and explanation of symbols:



The user can enter additional cycle information into the Clearblue Advanced Fertility Monitor, such as:

- Dates and level of menstrual bleeding
- Dates of intercourse

Furthermore, the monitor will prompt the user to test every day for either 10 or 20 days, depending on the cycle length and when the LH surge is detected.

The cycle summary chart screen displays data from the previous six cycles in a graph format. It displays a summary of cycle length and days of High and Peak Fertility, together with recordings of intercourse on High and Peak Fertility days. The recorded information can then be shared with healthcare professionals for review and analysis should the user fail to become pregnant.

Example of cycle summary chart:



Intuitive touchscreen display makes results easy to interpret

The Clearblue Advanced Fertility Monitor gives women comprehensive, personalised information that is unique to each cycle. It has a touchscreen display that guides women through their cycles and prompts the user when to perform tests. Test results are displayed onscreen as 'Low', 'High' or 'Peak'.



will result in pregnancy.



in LH that occurs 24–36 hours before ovulation, and indicates that the user is at the most fertile time in their cycle.

Enables both fertility monitoring and pregnancy testing

In addition to monitoring fertility hormones, the Clearblue Advanced Fertility Monitor can also test for pregnancy. Clearblue Advanced Fertility Monitor pregnancy test sticks contain an assay for human chorionic gonadotrophin (hCG), which is an established and accurate marker of pregnancy.¹⁷⁻¹⁹

The Clearblue Advanced Fertility Monitor is over 99% accurate at detecting pregnancy from the day of the expected period.²⁰ The monitor displays the test result in a clear digital format, displaying the words 'Pregnant' or 'Not Pregnant.'



Can be used up to 3 days before the period is due

The Clearblue Advanced Fertility Monitor pregnancy test is sensitive enough to be used up to 3 days before the period is due. The results of clinical testing of the Clearblue Advanced Fertility Monitor using early pregnancy urine samples are shown in Table One.

Table One: Results from clinical testing of the Clearblue Advanced Fertility Monitor with early pregnancy urine samples²¹

Days before the period is due	1	2	3
Pregnancy detection rate (%)	96	91	74

Highly accurate for all women, regardless of age^{22,d}

Although in clinical testing with early pregnancy samples the Clearblue Advanced Fertility Monitor is sensitive enough to be used up to 3 days before the period is due, the proportion of false-positive results associated with the device is extremely low. In a study of non-pregnant peri-menopausal and menopausal women, the Clearblue Advanced Fertility Monitor was over 99% accurate at detecting pregnancy for all women, regardless of age.^{22,d}

Advantages of the Clearblue Advanced Fertility Monitor over other methods for determining ovulation

The Clearblue Advanced Fertility Monitor has significant advantages over many other methods of aiding conception because it is designed to accurately identify the entire fertile window.³

In a study of 895 cycles from 101 women, the calendar method was found to identify appropriate fertile days in only 35% of the cycles tested.²³

- The basal body temperature (BBT) method is a commonly-used method to detect ovulation, but this has recognised limitations.²⁴⁻²⁸ This method identifies ovulation after the event, so the user is limited to using retrospective information to predict her next ovulation, which can be inaccurate due to cycle variability.^{12,25}
- 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.²⁹

The accuracy of predicting ovulation to within 1 day is reported to vary between 57-70% for the BBT method and 48-76% for the cervical mucus method.²⁹

Women are increasingly turning to fertility apps to help them predict their fertile window. However, many apps predict day of ovulation and fertile days using a calendar-based method, without accounting for between-cycle variability.¹² As it has been demonstrated that cycle length varies by 7 days or more in over 46% of women,¹¹ this is often a major limitation of fertility apps using cycle-based methods alone. Furthermore, few apps publish the algorithm used to determine fertile days.

In a simulation of 108 English language iOS apps, only 19% of free apps were found to be accurate. In this study, the simulation assumed ovulation 13–15 days before the start of the next cycle.³⁰ Another study found that out of 55 cycle tracking apps, the highest probability of predicting the day of ovulation by any app was 21% when the inputted cycle length was 28 days and ovulation occurred on day 16.¹²

Limitations

Clearblue Advanced Fertility Monitor fertility testing:

- The Clearblue Advanced Fertility Monitor is suitable for women whose natural cycle normally
 lasts 21-42 days. If her cycles are always shorter than 23 days or always longer than 37 days,
 it may not detect her LH surge. The majority of women will need 10 test sticks in each cycle.
 However, women with irregular or long cycles may have to use 20 test sticks each cycle in order
 to detect their most fertile time
- There are no products available that can guarantee success in achieving pregnancy. The Clearblue Advanced Fertility Monitor has been designed to assist in conception. It must NOT be used for contraception
- Certain medications and medical conditions (notably gestational trophoblastic diseases such as hydatidiform mole, choriocarcinoma and cervical intraepithelial neoplasia) can adversely affect the performance of the Clearblue Advanced Fertility Monitor.³¹ Women who have menopausal symptoms (e.g. night sweats, hot flushes), polycystic ovary syndrome, impaired liver or kidney function, are pregnant or have recently been pregnant (even if not carried to full term) may also get misleading results
- Similarly, misleading results may be obtained by women using antibiotics containing tetracyclines, hormonal treatments (e.g. hormonal contraception, hormone replacement therapy), fertility treatments containing hCG or LH or any treatment that may affect their cycle. Therefore, women are advised to consult their doctors if they are taking any medication and to wait until they have at least two natural menstrual cycles in a row (each lasting 23–37 days) before trying to get pregnant
- Clomiphene citrate may elevate estrogen levels, which may result in 'High Fertility' being displayed early in the cycle and more High Fertility days being displayed; in some cases, the monitor may not show 'Peak Fertility' even when ovulation occurs. Therefore, it is recommended that women taking clomiphene citrate consult their doctor for advice before using the Clearblue Advanced Fertility Monitor
- Recent pregnancy, breastfeeding, miscarriage or termination can also give misleading results. It is possible for hCG to be found in the body for up to 3 weeks after birth,³² miscarriage or termination.³³ Therefore, women are advised to wait until they have had at least two natural menstrual cycles in a row (each lasting 23-37 days) before using the Clearblue Advanced Fertility Monitor
- Women who have medically diagnosed fertility problems should consult their healthcare professional to ensure that the Clearblue Advanced Fertility Monitor is suitable for them

Clearblue Advanced Fertility Monitor pregnancy testing:

- Fertility drugs containing hCG can affect the ability of the Clearblue Advanced Fertility Monitor to perform an accurate pregnancy test. These are usually given by injection, and testing too soon (within 14 days) after administration can give a false 'Pregnant' result
- Other fertility therapies, painkillers and hormonal contraceptives (e.g. contraceptive pills) should not affect the result. However, if the woman has recently stopped taking hormonal contraception or is using fertility therapies her periods may be irregular, leading her to test too soon
- Recent pregnancy (including ectopic pregnancy and pregnancy not carried to full term), ovarian cysts, menopause and some rare medical conditions can give misleading results
- If a positive 'Pregnant' result is obtained and the woman later obtains a 'Not Pregnant' result, or her period starts, it may be due to natural loss during the early stage of pregnancy. This is not uncommon, as around one in four pregnancies end in early pregnancy loss^{34,35}
- Women should discuss any unexpected pregnancy test results with a healthcare professional

References

- Robinson J, et al. Increased pregnancy rate with use of Clearblue Easy Fertility Monitor. Fertil Steril. (2007) 87: 329-334^a
- Behre HM, et al. Prediction of ovulation by urinary hormone measurements with the home use Clearblue Fertility Monitor: comparison with transvaginal ultrasound scans and serum hormone measurements. Hum Reprod. (2000) 12: 2478–2482
- Stanford JB, et al. Timing Intercourse to Achieve Pregnancy: Current Evidence. Obstet Gynecol. (2002) 100: 1333–1341
- 4. Wilcox AJ, et al. Timing of sexual intercourse in relation to ovulation. N Engl J Med. (1995) 333: 1517-1521
- 5. Royston JP, *et al.* Basal body temperature, ovulation and the risk of conception, with special reference to the lifetimes of sperm and egg. Biometrics. (1982) 38: 397–406
- 6. Lynch CD, *et al.* Estimation of the day-specific probabilities of conception: current state of the knowledge and the relevance for epidemiological research. Paediatr Perinat Epidemiol. (2006) 20 (Suppl 1): 3–12
- 7. Burger HG. Estradiol: the physiological basis of the fertile period. Int J Gynaecol Obstet. (1989) 1: 5-9
- 8. Kerin JF, et al. Morphological and functional relations of Graafian follicle growth to ovulation in women using ultrasonic, laparoscopic and biochemical measurements. Br J Obstet Gynaecol. (1981) 88: 81-90
- 9. Wilcox AJ, *et al*. The timing of the "fertile window" in the menstrual cycle: day specific estimates from a prospective study. BMJ. (2000) 321: 1259–1262
- 10. Severy LJ, *et al.* Acceptability of a home monitor used to aid in conception: psychosocial factors and couple dynamics. Contraception. (2006) 73: 65–71
- Creinin MD, et al. How regular is regular? An analysis of menstrual cycle regularity. Contraception. (2004) 70: 289-292
- 12. Johnson SL, *et al.* Can apps and calendar methods predict ovulation with accuracy? Curr Med Res Opin. (2018) 34: 1587-1594
- Park SJ, et al. Characteristics of the urinary luteinizing hormone surge in young ovulatory women. Fertil Steril. (2007) 88: 684-690
- 14. Weller L, *et al.* Menstrual variability and the measurement of menstrual synchrony Psychoneuroendocrinology. (1997) 22: 115–128
- 15. 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^c
- Martinez AR, et al. Prediction and detection of the fertile period: the markers. Int J Fertil. (1995) 40: 139–155
- 17. Gnoth C, *et al.* Strips of Hope: Accuracy of Home Pregnancy Tests and New Developments. Geburtshilfe Frauenheilkd. (2014) 74: 661–669
- Johnson SL, 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
- 19. McChesney R, *et al.* Intact HCG, free HCG β subunit and HCG β core fragment: longitudinal patterns in urine during early pregnancy. Hum Reprod. (2005) 20: 928–935
- 20. SPD data on file: When compared to a laboratory reference method, the Clearblue Advanced Fertility Monitor has been shown to be 99% accurate at detecting pregnancy. A total of 350 urine samples were tested, using three different batches of the device. Reference method used: Perkin Elmer AutoDELFIA hCG.
- 21. SPD data on file: The Clearblue Advanced Fertility Monitor gave the following results: 96% of women received a 'Pregnant' result 1 day early, 91% of women 2 days early, and 74% of women 3 days early
- 22. SPD data on file: In a study testing urine samples in non-pregnant women of pre, peri and post-menopausal age the Clearblue Advanced Fertility Monitor was over 99% accurate at detecting pregnancy for all women, regardless of age

- 23. 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(Suppl 1): i75-i77
- 24. Lenton E. Problems in using basal body temperature recordings in an infertility clinic. Br Med J. (1977) 1: 803–805
- 25. Matthews C. Optimal features of basal body temperature recordings associated with conceptional cycles. Int J Fertil. (1980) 25: 318–320
- 26. Wetzels L. Basal body temperature as a method of ovulation detection: comparison with ultrasonographical findings. Gynecol Obstet Invest. (1982) 13: 235–240
- 27. Yong E. Simple office methods to predict ovulation: the clinical usefulness of a new urine luteinizing hormone kit compared to basal body temperature, cervical mucus and ultrasound. Aust N Z J Obstet Gynaecol. (1989) 29: 155–160
- 28. Moghissi K. Accuracy of basal body temperature of ovulation detection. Fertil Steril. (1976) 27: 1415-1421
- 29. Brezina PR, *et al*. At home testing: optimizing management for the infertility physician. Fertil Steril. (2011) 95: 1867-1878
- 30. Moglia ML *et al.* Evaluation of Smartphone Menstrual Cycle Tracking Applications Using an Adapted APPLICATIONS Scoring System. Obstet Gynecol. (2016) 127: 1153–1160
- 31. Stenman UH, *et al.* The classification, functions and clinical use of different isoforms of HCG. Hum Reprod Update. (2006) 12: 769–784
- 32. Korhonen J, *et al.* Disappearance of human chorionic gonadotropin and its alpha- and beta- subunits after term pregnancy. Clin Chem. (1997) 43: 2155–2163
- 33. Steier JA, *et al.* Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion, and removed ectopic pregnancy. Obstet Gynecol. (1984) 64: 391–394
- 34. Chard T. Frequency of implantation and early pregnancy loss in natural cycles. Clin Obstet Gynaecol. (1991) 5: 179–189
- 35. Macklon NS, *et al.* Conception to ongoing pregnancy: the 'black box' of early pregnancy loss. Hum Reprod Update. (2002) 8: 333–343



Clearblue Advanced Fertility Monitor is:

Proven – shown to increase the chances of conception by 89%^{1,a}

Unique – provides a daily fertility status by measuring two urinary hormones, LH and E3G, and tests for pregnancy

Effective - designed to detect the entire fertile window³ to help women conceive more quickly^e

Accurate – 99% accurate at detecting the LH surge in urine and over 99% accurate at detecting pregnancy ^{16,18,f}

Personalised - monitors individual hormone levels and adapts based on the last six cycles of data⁹

Interactive – dates of intercourse and levels of menstrual bleeding can be input and stored on the monitor for future reference

- ^a In the first two cycles of use.
- ^b Based on international sales in nearly 20 countries compiled using independent market research data.
- ^c Clearblue Ovulation assay showed 97% agreement with ultrasound-observed ovulation.
- ^d From the day period is due.
- ^e Vs not using a method to identify fertile days.
- ^f Over 99% accurate at detecting typical pregnancy hormone levels from the day the period is due.
- Note hormone levels may vary.
- ^g Completed cycle data if available.

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