

Clearblue

CLEARBLUE DIGITAL PREGNANCY TEST
WITH SMART COUNTDOWN

The Only Test that Counts Down to the Result



Clearblue Professional Series

PREGNANCY



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 Pregnancy Test with Smart Countdown

The Clearblue DIGITAL Pregnancy Test with Smart Countdown is an easy to use pregnancy test that is over 99% accurate from the day the period is due,¹ and it has a unique progression indicator (Smart Countdown), which appears after sampling and counts down to the result. It gives a digital result in words – 'Pregnant' or 'Not Pregnant', and is the only pregnancy test with a Smart Countdown to reassure a woman every step of the way until her result is displayed.

The Clearblue DIGITAL Pregnancy Test with Smart Countdown has the following innovative features:

- Smart Countdown – a unique progression indicator to reassure the user that the test is working, and provide a countdown to the result
- 50% wider absorbent sampler than a standard Clearblue DIGITAL Pregnancy Test, for easy sampling
- Integrated Floodguard™ to help prevent user error during testing.



Reassuringly easy to use

To perform a test with the Clearblue DIGITAL Pregnancy Test with Smart Countdown, the user simply removes the one-piece test stick from its individual foil wrapper, takes off the cap and places the absorbent sampler in their urine stream for 5 seconds.

Alternatively the user can place the absorbent sampler into a collected sample of their urine for 20 seconds.



50% wider absorbent sampler* for easy sampling

The Clearblue DIGITAL Pregnancy Test with Smart Countdown has a wide, 18 mm absorbent sampler. This helps the user to easily and confidently obtain an adequate sample directly from their urine stream, with minimal splashing or mess.



*50% wider absorbent sampler than the Clearblue DIGITAL Pregnancy Test

Integrated Floodguard™ feature helps prevent user error

The Clearblue DIGITAL Pregnancy Test with Smart Countdown has an integrated Floodguard™ feature which helps prevent user error. Occasionally with regular home pregnancy tests, when users fail to follow instructions correctly, excess urine can enter the device resulting in a test error. The innovative and unique Floodguard™ feature from Clearblue helps to prevent this primary cause of user error by absorbing any excess urine, thus ensuring the accuracy of the test in users' hands.

The only pregnancy test that counts down to the result



The Clearblue DIGITAL Pregnancy Test with Smart Countdown is the only pregnancy test that counts down to the result. It has a unique progression indicator, displayed in a four segment format on a liquid crystal display (LCD). The Smart Countdown reassures the user that the test is working and gives an indication of when they can expect their result to appear on screen. Results are displayed within 3 minutes, although in some cases a result may be displayed in as little as 1 minute, in which case the Smart Countdown feature will count down more quickly.

Displays a clear result in words



The Clearblue DIGITAL Pregnancy Test with Smart Countdown has a LCD display that shows a 'Pregnant' or 'Not Pregnant' result in words. This eliminates any uncertainty the user may have about their result.

It has been shown that one in four women can misread traditional line pregnancy test results.² The Clearblue DIGITAL Pregnancy Test with Smart Countdown contains an optical reader and software which converts the test signal into a clear digital result in words and eliminates this human error that can occur when reading traditional line tests. The display shows a 'Pregnant' or 'Not Pregnant' result within 3 minutes.

A 'Pregnant' result will be shown on the display for up to 6 months, enabling users to keep the test to show to their Healthcare Professional or their friends and family, if they wish. A 'Not Pregnant' result will be shown for approximately 24 hours.

In a study of 120 female volunteers comparing home pregnancy tests, 100% of volunteers said they were 'certain' or 'very certain' about the result of the Clearblue DIGITAL test compared with traditional line tests.²

Reassuring accuracy in a home-based test

Uses the universally accepted pregnancy marker hCG, enabling a quick and accurate pregnancy assessment

The Clearblue DIGITAL Pregnancy Test with Smart Countdown detects the presence of urinary levels of human chorionic gonadotrophin (hCG), a clinically accurate marker of pregnancy. The test is over 99% accurate in detecting typical pregnancy hCG levels when used from the day the period is due,¹ although hormone levels can vary between women.

The hormone hCG is produced in the earliest stages of pregnancy, where it plays a role in the survival of the corpus luteum.³ Initially hCG is produced by the embryo and therefore acts as a marker for its presence.⁴ Levels of hCG rise rapidly and predictably in the earliest days of pregnancy⁵ and it usually first appears in urine 9–10 days after conception.⁶ The levels of hCG in early pregnancy have also been found to be highly similar between women,⁵ making it an ideal urinary marker for quickly and accurately assessing whether a woman is pregnant or not.

Highly sensitive: can be used up to 4 days before the period is due⁷

Published literature show that, in pregnant women, the level of hCG reaches at least 50 mIU/mL on the day the period is due.^{8,9} Most women who test a few days before their period is due will have sufficient urinary hCG to provide a positive result.

Figure One shows a typical rise in urinary hCG from the first detection of pregnancy.⁵ Day 0 indicates the day the period is due (15 days following the urinary LH surge). As the rise in hCG can vary between women, not all women who test before their period is due will get a 'Pregnant' result.

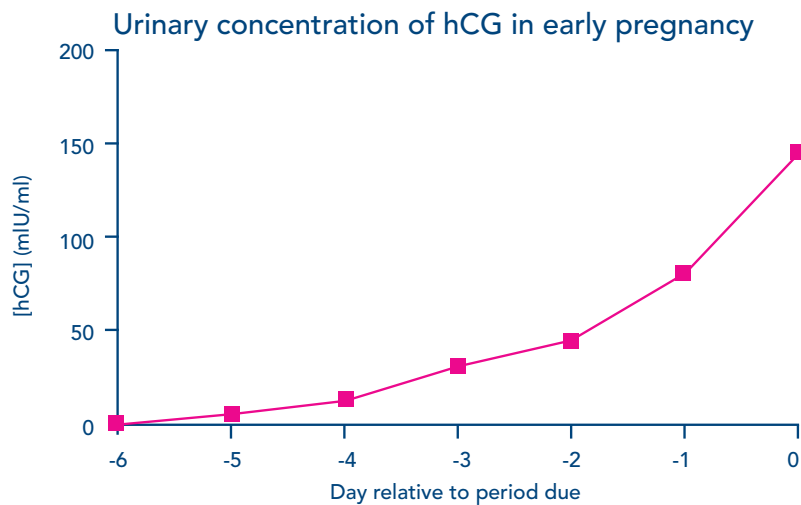


Figure One: Mean levels of hCG on days relative to the day the period is due (n=96 women).⁵

The Clearblue DIGITAL Pregnancy Test with Smart Countdown is sensitive enough to be used up to 4 days before the day the period is due.⁷ Table One shows the results of clinical testing on daily urine samples taken from 100 pregnant women.

Table One: Results from clinical testing of the Clearblue DIGITAL Pregnancy Test with early pregnancy urine samples.⁷

Days before the period is due	4	3	2	1
Pregnancy detection rate, %	51	82	90	95

Highly accurate for all women, regardless of age

Importantly, although the Clearblue DIGITAL Pregnancy Test with Smart Countdown is sensitive enough to be used to up 4 days before the period is due, the proportion of 'false-positive' results associated with the device is extremely low.

Concentrations of hCG in non-pregnant women increase with age such that in non-pregnant peri- or post-menopausal women, some 'ultra-sensitive' pregnancy tests could provide a false positive result.¹⁰ In a study of non-pregnant peri-menopausal and menopausal women tested with different lots of Clearblue DIGITAL pregnancy test,* an average of 0.3% of results were positive, with a range from 0% to 1% for different lots. All false results were from women aged over 50 years.¹¹

* The chemistry used in the Clearblue DIGITAL Pregnancy Test with Smart Countdown is the same as that used in the Clearblue DIGITAL pregnancy tests.

Additional points

- The manufacturer's instructions for any medication being taken should be read before conducting the test
- When testing on or after the day the period is due, it is not necessary to test with an early morning urine sample. When testing before the period is due, an early morning urine sample should always be used. Regardless of when the test is performed, excessive fluid intake should be avoided before testing as a false 'Not Pregnant' result may be obtained if the urine sample is too dilute
- If a woman receives a negative (Not Pregnant) result and she has tested before her period is due, she is advised to test again from the day her period is due. There is clear information provided on the pack and instruction leaflet about early testing, including guidance on the proportion of pregnant women that can expect a 'Pregnant' result. This allows women to make an informed decision about whether or not early testing would be the best choice for them
- Fertility drugs containing hCG can affect the result. These are usually given by injection, and testing too soon (within 14 days) after administration can give a false 'Pregnant' result
- Ectopic pregnancy can result when the fertilised egg does not reach the uterus and continues to grow in the fallopian tube. The production of hCG in an ectopic pregnancy may be lower than in a normal pregnancy and this may lead to a false 'Not Pregnant' result. However, other symptoms are likely to be experienced and if an ectopic pregnancy is suspected then immediate medical advice must be sought
- Ovarian cysts, menopause and some very rare medical conditions can give misleading results
- A recent pregnancy, miscarriage or termination can give misleading results. It is possible for hCG to be found in the body for up to 3 weeks after birth and it can remain in the body for up to 9 weeks after a miscarriage or termination. Whilst hCG remains in the body it is possible for a pregnancy test to detect it and show a false 'Pregnant' result
- If a 'Pregnant' result is obtained and the woman later finds out that she is not pregnant then it is possible that this is due to natural loss of the pregnancy which is not uncommon in the early stages, affecting around one in four pregnancies
- Women should be encouraged to discuss any unexpected pregnancy test results with a healthcare professional.

References

1. Data on file. When compared to a laboratory reference method, Clearblue DIGITAL Pregnancy Test* has been shown to be over 99% accurate from the day the period is due when using urine samples supplied for pregnancy testing. Reference method used: Perkin Elmer DELFIA hCG.
2. Tomlinson C, et al. Comparison of accuracy and certainty of results of six home pregnancy tests available over-the-counter. *Curr Med Res Opin* (2008) 24: 1645–1649.
3. Baird DD, et al. Rescue of the corpus luteum in human pregnancy. *Biol Reprod* (2003) 68: 448–456.
4. Perrier d'Hauterive S., et al. Dialogue between blastocyst hCG and endometrial LH/hCG receptor: which role in implantation? *Gynecol Obstet Invest* (2007) 64: 156–160.
5. Johnson SR, 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.
6. Wilcox AJ, et al. Time of implantation of the conceptus and loss of pregnancy. *N Engl J Med* (1999) 340: 1796–1799.
7. Data on file. Clearblue recommends that women test from the day the period is due. However, the pregnancy hormone increases rapidly in early pregnancy and Clearblue DIGITAL Pregnancy Test* can be used as early as 4 days before the period is due. In clinical testing, Clearblue DIGITAL Pregnancy Test* detected the pregnancy hormone in 51% of women when testing 4 days before their period is due, 82% at 3 days before their period is due, 90% at 2 days before their period is due and 95% at 1 day before their period is due.
8. Lenton EA, et al. Plasma concentrations of human chorionic gonadotropin from the time of implantation until the second week of pregnancy. *Fertil Steril* (1982) 37: 773–778.
9. Chard T. Pregnancy tests: a review. *Hum Reprod* (1992) 7: 701–710.
10. Snyder JA, et al. Diagnostic considerations in the management of hCG in aging women. *Clin Chem* (2005) 51: 1830–1835.
11. Data on file. Study of 261 pre- (n=60), peri- (n=101) and post-menopausal (n=100) urine samples comparing the result from the Clearblue DIGITAL Pregnancy Test* with quantitative hCG levels measured using AutoDELFIA (Perkin Elmer).

*The chemistry used in the Clearblue DIGITAL Pregnancy Test with Smart Countdown is the same as that used in the Clearblue DIGITAL pregnancy tests.

The Clearblue DIGITAL Pregnancy Test with Smart Countdown is:

- Unique** – the only pregnancy test that counts down to the result
- Accurate** – over 99% accurate from the day the period is due¹
- Easy to use** – a quick and easy urine test, with a 'no mess' wider absorbent sampler* and integrated Floodguard™ to help prevent user error during testing
- Sensitive** – can be used up to 4 days before the period is due⁷
- Unmistakably clear** – digital results in words for greater accuracy in consumers' hands.²

*50% wider absorbent sampler than the Clearblue DIGITAL Pregnancy Test



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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