

Clearblue[®]

Digital Early Detection
Pregnancy Test

Accurate reading
in early pregnancy¹



Professional Series
Pregnancy



About Clearblue[®]

Clearblue is the world's number one selling brand in home pregnancy and fertility tests.^a 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.

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

Clearblue Digital Early Detection Pregnancy Test

Accurate reading in early pregnancy¹



The Clearblue Digital Early Detection Pregnancy Test is an easy-to-use pregnancy test that is over 99% accurate from the day of the expected period,¹ and has a unique 'Smart Countdown' progression indicator that 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 the user every step of the way until her result is displayed.

The Clearblue Digital Early Detection Pregnancy Test has the following innovative features:

- Smart Countdown - a unique progression indicator to reassure the user that the test is working, and to provide a countdown to the result
- A wide absorbent tip, for easy sampling
- Integrated Floodguard™ Technology, which helps women use the test correctly

Reassuringly easy to use

To perform a test, the user simply removes the one-piece test stick from its individual foil wrapper, takes off the blue cap and places the absorbent tip in their urine stream for 5 seconds.

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

Wide absorbent tip for easy sampling

The test has a wide, 18mm absorbent tip. This helps the user to easily and confidently obtain an adequate sample directly from their urine stream, with minimal splashing or mess.



Integrated Floodguard™ Technology helps to prevent user error

Occasionally with some home pregnancy tests, when users fail to follow instructions correctly, excess urine can enter the device, resulting in a test error; this is the No. 1 source of user error. The innovative and unique integrated Floodguard™ Technology absorbs excess urine, reducing the No. 1 reported source of usage error by over 70%,^b thereby increasing the accuracy of the test in users' hands.



The only pregnancy test that counts down to the result



The Clearblue Digital Early Detection Pregnancy Test 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). This Smart Countdown helps reassure the user that the test is working and indicates 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 will count down more quickly.

Displays a clear result in words



The test has an 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 misread traditional line pregnancy test results.² The Clearblue Digital Early Detection Pregnancy Test contains an optical reader and micro-processor that converts the test signal into a clear digital result in words, eliminating the human error that can occur when reading traditional line tests. The display will show a 'Pregnant' or 'Not Pregnant' result within 3 minutes of use.

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 Early Detection Pregnancy Test.²

Reassuring accuracy in a home-based test

A quick and accurate pregnancy assessment

The test detects the presence of urinary human chorionic gonadotrophin (hCG), a clinically accurate marker of pregnancy. It is over 99% accurate at detecting hCG when used from the day of the expected period.¹

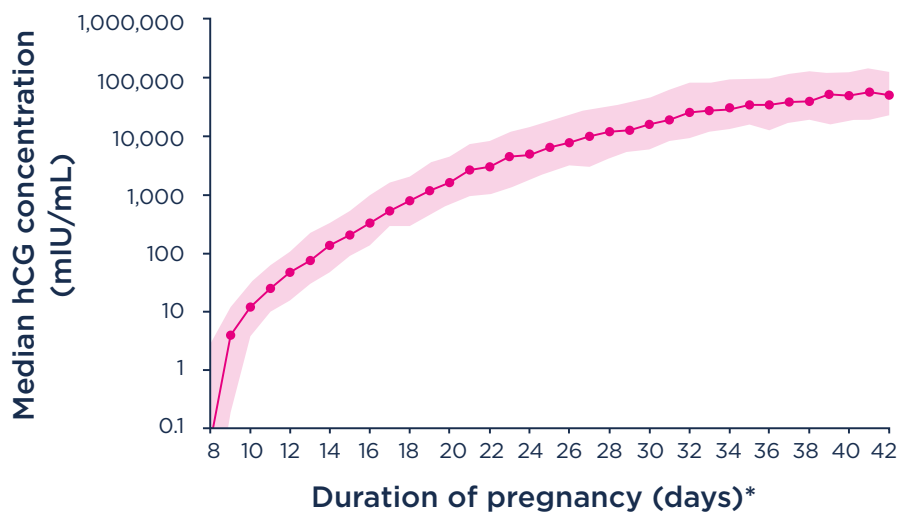
The hormone hCG is produced in the earliest stages of pregnancy, where it plays a role in the survival of the corpus luteum.³ Initially hCG is produced by the embryo, and it therefore acts as a marker for its presence.⁴ Levels of hCG rise rapidly and predictably in the earliest days of pregnancy⁵ and 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, and can be used up to 5 days before the missed period⁷

Published literature shows that the level of hCG in pregnant women reaches at least 50mIU/mL on the day of the expected period.⁸ 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 starting from the first day when it is commonly detectable in early pregnancy.⁵ 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: Reference ranges for urinary intact hCG for each day of pregnancy (median, 10th and 90th centiles; data from 109 UK volunteers)⁵



* from calculated day of ovulation (lutensising hormone surge + 1 day).

The Clearblue Digital Early Detection Pregnancy Test is sensitive enough to be used up to 5 days before the missed period (4 days before the day of the expected period).⁷ Table One shows the results of clinical testing on daily urine samples taken from 100 pregnant women.

Table One: Results from clinical testing with early pregnancy urine samples.⁷

Days before the expected period	4	3	2	1
Pregnancy detection rate (%)	51	82	90	95

Highly accurate for all women, regardless of age

Importantly, although the Clearblue Digital Early Detection Pregnancy Test is sensitive enough to be used up to 5 days before the missed period, the proportion of false-positive results associated with the device is extremely low.

Concentrations of hCG in non-pregnant women increase with age, meaning that in non-pregnant peri- or post-menopausal women, some ‘ultra-sensitive’ pregnancy tests could provide a false-positive result.⁹ In a study of non-pregnant peri-menopausal and menopausal women tested with different lots of the Clearblue Digital Early Detection Pregnancy Test, an average of 0.3% of the results were positive, with a range from 0% to 1% for different lots. All false results were from women aged over 50 years.¹⁰

Limitations

- The manufacturer's instructions regarding any medication being taken should be read before conducting the test
- When testing on or after the day of the expected period, it is not necessary to test with a first morning urine sample. When testing before the period is due, a first morning urine sample should always be used
- 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
- 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 '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
- Ectopic pregnancy,¹¹ 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 giving birth¹² and after a miscarriage or termination¹³
- If a positive 'Pregnant' result is obtained and the woman later obtains a 'Non-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^{14,15}
- Women should discuss any unexpected results with a healthcare professional

References

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Clearblue Digital Early Detection Pregnancy Test is:

Accurate – over 99% accurate from the day of the expected period¹

Unique – the only pregnancy test that counts down to the result

Unmistakably clear – digital results in words for greater accuracy in consumers' hands²

Sensitive – can be used up to 5 days before the missed period⁷

Easy to use – a quick and easy urine test, with a 'no mess' wide absorbent tip and integrated Floodguard™ Technology to help reduce the No. 1 reported source of usage error by over 70%^b

^a Based on international sales compiled using independent market research data (data on file).

^b Vs our previous visual test design. Based on calls to Helpline throughout 2010 and 2017.

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