

Clearblue[®]

Pregnancy Tests

Over 99% accurate
from the day of the expected period^a



Professional Series
Pregnancy



About Clearblue®

Clearblue® is the world's #1 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.

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

Pregnancy

A range of tests offering important benefits to suit the needs of different women

Clearblue® Digital Pregnancy Test



Clearblue® Rapid Detection Pregnancy Test



Clearblue® Reassurance Pregnancy Test



Table One. Clearblue® pregnancy tests have a variety of features designed to make the tests accurate, rapid, and easy to use

	Clearblue® Pregnancy Test		
	Digital	Rapid Detection	Reassurance
As accurate as a doctor's urine test	✓	✓	✓
Over 99% accurate from the day of the expected period ^a	✓	✓	✓
Can be used up to 5 days before the missed period (which is 4 days before the expected period)	✓ ¹	✓ ²	
Result as fast as 1 minute ^c		✓	
Easy-to-read ⊕ or ⊖ result		✓	✓
Unmistakably clear result in words	✓		
Red Dot Award Winner 2012: ^d Designed to be the easiest home pregnancy test to use ³		✓	
Ergonomic handle designed to help women to hold the device correctly in the urine stream		✓	
Extra-wide 18mm tip: To help obtain an adequate sample from the urine stream	✓	✓	
Color Change Tip: Lets the user know that urine has been absorbed		✓	✓
Floodguard™ Technology: Helps women use the test correctly	✓	✓	
Smart Countdown: Unique progress indicator to reassure the user that the test is working	✓		

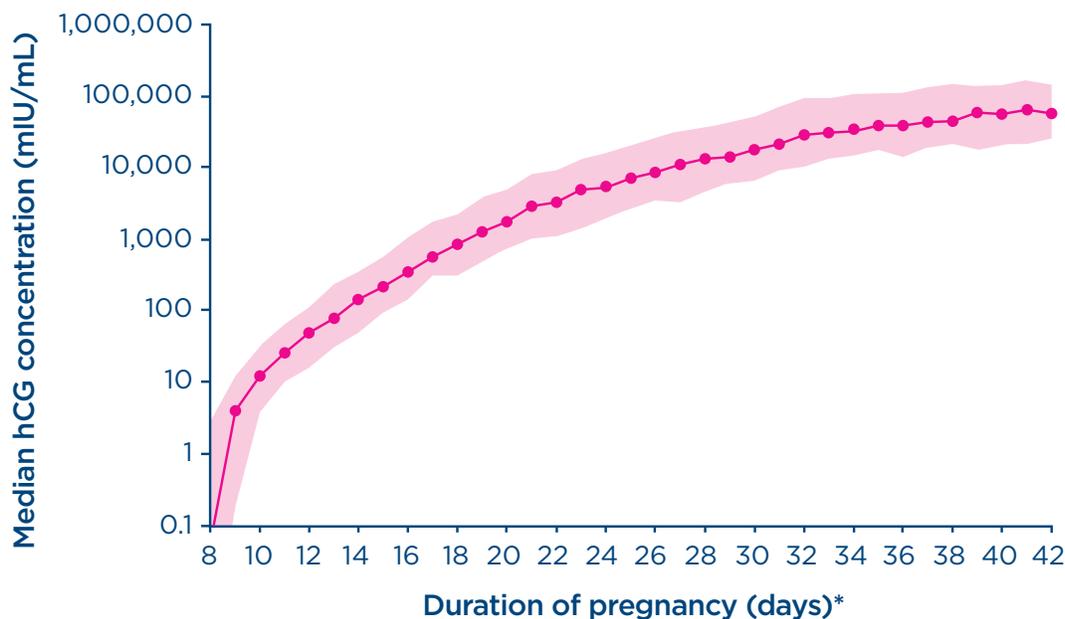
Clearblue® pregnancy tests are over 99% accurate from the day of the expected period^a

Clearblue® pregnancy tests detect the presence of urinary levels of human chorionic gonadotropin (hCG), a clinically accurate marker of pregnancy. The production of hCG occurs in the earliest stages of pregnancy, where it plays a role in the survival of the corpus luteum, implantation of the blastocyst, and protection of the embryo against immune attack at the fetal/maternal boundary.⁴ The hormone is initially produced by the embryo and therefore also acts as a marker for its presence.⁵

Levels of hCG in serum and urine rise rapidly during the first days of pregnancy,⁶⁻¹⁰ by approximately 50% per day.¹¹ The rise in hCG levels is also consistent between different ethnicities, making it an ideal urinary marker for quickly and accurately assessing whether a woman is pregnant or not.⁵⁻¹¹

Figure One shows a typical rise in urinary hCG from the first detection of pregnancy.¹¹

Figure One: Reference ranges for urinary intact hCG for each day of pregnancy (median, 10th and 90th centiles; data from 109 UK volunteers)¹¹



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

Published literature shows that the level of hCG reaches at least 50mIU/mL on the day of the expected period.¹² If a Clearblue® pregnancy test is used on or after the day of the expected period, it is more than 99% accurate at telling a woman she is pregnant or not pregnant.

Clearblue® Digital Pregnancy Test

Unmistakably clear result in words

It has been shown that one in four women misread traditional line pregnancy test results.¹³ The Clearblue® Digital Pregnancy Test contains an optical reader and micro-processor that converts the test signal into a clear digital result in words, eliminating the need to interpret lines that are often faint. The LCD 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 Pregnancy Test.¹³

The only test with a Smart Countdown feature

The Clearblue® Digital Pregnancy Test is an easy-to-use pregnancy test that is over 99% accurate from the day of the expected period.¹⁴ It has a unique 'Smart Countdown' progression indicator that appears after sampling and counts down to the result.



The only pregnancy test that counts down to the result

The Smart Countdown feature helps reassure the user that the test is working and indicates when they can expect their result to appear on the 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.



Highly sensitive, and can be used up to 5 days before the missed period

Published literature shows that the level of hCG in pregnant women reaches at least 50mIU/mL on the day of the expected period.¹² This means that most women who test a few days before they expect their period will have sufficient urinary hCG to provide a positive result with the most sensitive home pregnancy tests.

The Clearblue® Digital 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). Table Two shows the results of clinical testing on daily urine samples taken from pregnant women.¹

Table Two: Results from clinical testing with early pregnancy urine samples¹

Number of days before the expected period	Samples from pregnant women giving a pregnant result (%)
1	95
2	90
3	82
4	51

Clearblue® Rapid Detection Pregnancy Test

Award-winning design and Floodguard™ Technology

The innovative Clearblue® Rapid Detection Pregnancy Test is the first pregnancy test to win the prestigious Red Dot Design Award.



Color Change Tip

helps women to perform the test more easily

Easy to read

⊕ or ⊖ result in just 1-3 minutes^c

Ergonomically designed handle

Red Dot Award Winner 2012:^d Designed to be the easiest home pregnancy test to use³

Floodguard™ Technology

The Clearblue® Rapid Detection Pregnancy Test is equipped with unique integrated Floodguard™ Technology, which collects excess urine and helps reduce the #1 reported usage error by over 70%.^e Clearblue® aims to provide all women with the best products to help them test correctly and obtain the accurate information that they need.



Highly sensitive, and can be used up to 5 days before the missed period

The Clearblue® Rapid 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). Table Three shows the results of clinical testing on daily urine samples taken from pregnant women.²

Table Three: Results from clinical testing with early pregnancy urine samples²

Number of days before the expected period	Samples from pregnant women giving a 'pregnant' ⊕ result (%)
1	98
2	97
3	88
4	56

Provides an easy-to-read result in just 1-3 minutes^c



As the test begins to work, blue lines will start to develop in the test and control windows. If testing from the day of the missed period, a 'Pregnant' ⊕ result may appear within 1 minute.

If testing early and to confirm a 'Not Pregnant' ⊖ result, the user should wait 3 minutes.

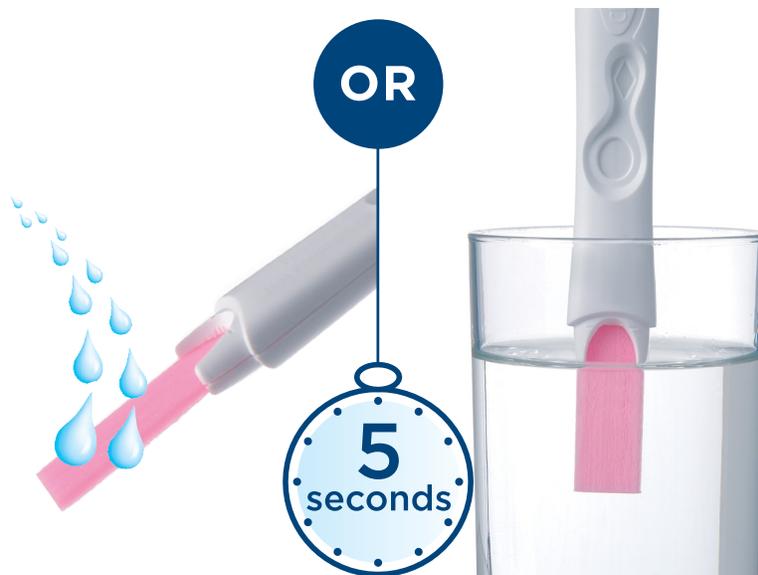
The test window must be read between 3 and 10 minutes after performing the test.

Clearblue® Reassurance Pregnancy Test

With Color Change Tip for added reassurance^f

The Clearblue® Reassurance Pregnancy Test is an easy-to-use pregnancy test offering several important features.

Color Change Tip helps women perform the test correctly



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 Color Change Tip in her urine stream (or a sample of her urine collected in a clean, dry container).

The Color Change Tip will instantly turn pink, showing that urine is being absorbed; however, the user should continue to hold the tip in her urine for a full 5 seconds.

Throughout testing, the test stick should be held with the Color Change Tip pointing downwards or laid flat until the user is ready to read the results.



Simple and easy to use

The result is displayed clearly as a ⊕ or ⊖, providing reassurance, confidence, and trust in the accuracy of the result. In comparison to cassette and strip tests, 90% of women rate tests where the results are displayed visually as ⊕ or ⊖ as easy to use.¹⁴ Furthermore, less than 20% and 30% of women are confident reading the results of strip- or cassette-based tests, respectively.¹⁴



One easy step for a fast result in just 2 minutes

As the test begins to work, blue lines will start to develop in the device windows.

- A ⊕ result in the test window means that the user is pregnant



- A ⊖ result in the test window means that the user is not pregnant

The result must be read within 10 minutes after performing the test.

Limitations

- The manufacturer's instructions regarding any medication being taken should be read before conducting the test
- Fertility drugs containing hCG can affect the result. These are usually given by injection, and testing too soon after administration can give a false 'Pregnant' result. Other fertility therapies (such as Clomid), common painkillers, the contraceptive pill, alcohol, or antibiotics should not affect the result
- 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, which is not uncommon as around one in four pregnancies end in early pregnancy loss^{15,16}
- Ectopic pregnancy can result when the fertilized 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, as hCG can be found in the body for several weeks after giving birth¹⁷ and after a miscarriage or termination¹⁸
- Women who have recently stopped taking hormonal contraception or are using fertility therapies may have irregular periods, leading them to test too soon
- 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 the result is 'Not Pregnant' and pregnancy is still suspected, the user should wait at least 3 days before testing again
- When testing on or after the day of the expected period, it is not necessary to test with a first morning urine sample. When using Clearblue® Rapid Detection Pregnancy Test or Clearblue® Digital Pregnancy Test before the expected period, a first morning urine sample should always be used
- Women should discuss any unexpected results with a healthcare professional

References

1. SPD data on file. Clearblue® Digital Pregnancy Test can be used 5 days before the missed period (which is 4 days before the expected period). In lab testing, 95% of 'Pregnant' results were detected the day before the expected period, 90% were detected 2 days before, 82% 3 days before, and 51% 4 days before.
2. SPD data on file. Clearblue® Rapid Detection Pregnancy Test can be used 5 days before the missed period (which is 4 days before the expected period). In lab testing, 98% of 'Pregnant' results were detected the day before the expected period, 97% were detected 2 days before, 88% 3 days before, and 56% 4 days before.
3. SPD data on file. In a US study of 149 women using leading line tests, over 80% of women found the Clearblue® Rapid Detection Pregnancy Test the easiest to use in sampling.
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19. SPD data on file. When compared to a laboratory reference method, the Clearblue® Digital Pregnancy Test has been shown to be over 99% accurate from the day the period is expected when using urine samples supplied for pregnancy testing. Reference method used: Perkin Elmer DELFIA hCG.

Clearblue® Digital Pregnancy Test is:

Accurate - over 99% accurate from the day of the expected period^{19,a}

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

Unmistakably clear - digital results in words for greater accuracy in consumers' hands¹³

Sensitive - can be used up to 5 days before the missed period¹

Easy to use - wide tip for easy sampling, and unmistakably clear results in words

Clearblue® Rapid Detection Pregnancy Test is:

Accurate - over 99% accurate from the day of the expected period^a

Fast - easy-to-read ⊕ or ⊖ result in just 1-3 minutes^c

Sensitive - can be used up to 5 days before the missed period²

Easy to use - award-winning ergonomic design^d and Floodguard™ Technology

Clearblue® Reassurance Pregnancy Test is:

Accurate - over 99% accurate from the day of the expected period^a

Reliable - as accurate as a doctor's urine test

Easy to use - Color Change Tip gives the user reassurance that the test is working

Clear - ⊕ or ⊖ result in just 2 minutes

^a 99% accurate at detecting typical pregnancy hormone levels. Note that hormone levels may vary. See insert.

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

^c A 'Pregnant' ⊕ result may appear within 1 minute when testing from the day of the missed period. The user should wait 3 minutes to confirm a 'Not Pregnant' ⊖ result.

^d Red Dot Design Award winner 2012.

^e Vs our standard visual test. Based on Helpline calls in 2010 and 2014-2017.

^f To show test is working.



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