

Clearblue[®]

CLEARBLUE EARLY DETECTION PREGNANCY TEST

Results 6 days before the missed period^a



Clearblue Professional Series

PREGNANCY

^a 'Missed period' refers to the day after the expected period; 79% of pregnant results can be detected 6 days before.



About Clearblue

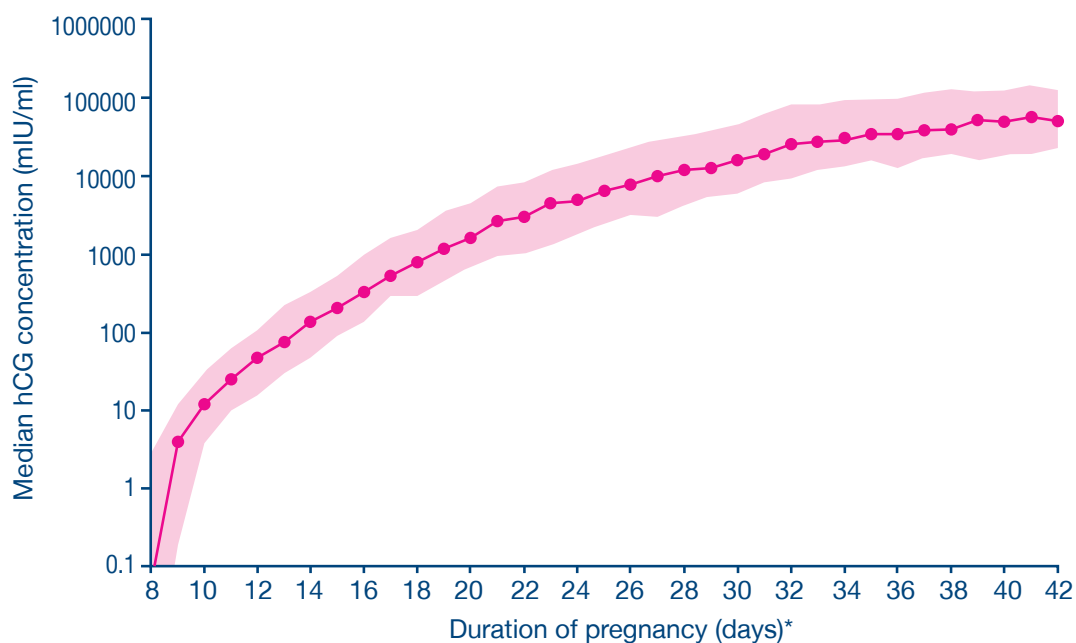
Clearblue is the world's No.1 selling brand in home pregnancy and fertility tests.^b Consumers trust the Clearblue brand because it delivers the accurate information they want. The Clearblue product range is built on a strong foundation of peer-reviewed science and consumer understanding, supported by over 30 years of expertise, quality and innovation in consumer diagnostics.

Over 99% accurate at detecting pregnancy from the day of the expected period

The Clearblue Early Detection Pregnancy Test detects urinary levels of human chorionic gonadotrophin (hCG), a clinically accurate marker of pregnancy that is produced by the embryo during the earliest stages of pregnancy.¹

Levels of hCG in serum and urine rise rapidly during the first days of pregnancy,²⁻⁶ by approximately 50% per day (Figure One).⁷ In the first 3 weeks of pregnancy, estimates of gestational age based on hCG concentrations are highly comparable with ultrasound-dated pregnancy,^{5,7} making hCG an ideal urinary marker for quickly and accurately assessing whether a woman is pregnant or not.²⁻⁷

If used on or after the day of the expected period, the Clearblue Early Detection Pregnancy Test is more than 99% accurate at detecting pregnancy.⁸



* from calculated day of ovulation (LH surge + 1 day)

Figure One: Reference ranges for urinary intact hCG for each day of pregnancy (median, 10th and 90th centiles; data from 109 UK volunteers).⁷

Results 6 days before the missed period^a



The Clearblue Early Detection Pregnancy Test can detect pregnancy from 6 days before the missed period.^a However, as the rise in hCG produced by an embryo can vary between women, not all pregnant women who test early will receive a positive (pregnant) result. Table One shows the likelihood that a pregnant woman will get a positive (pregnant) result on each test day before the day of her missed period.

Table One: Likelihood that a pregnant woman will get a positive (pregnant) result with the Clearblue Early Detection Pregnancy Test when testing in the days leading up to the day of the missed period.⁸

| The level of hCG increases rapidly in early pregnancy. In clinical testing with early pregnancy samples, the Clearblue Early Detection Pregnancy Test gave the following results: | |
|---|--|
| Number of days before the day of the missed period | Percentage of samples from pregnant women giving a pregnant result |
| -1 | >99% |
| -2 | >99% |
| -3 | >99% |
| -4 | >99% |
| -5 | 96% |
| -6 | 79% |

Data from a minimum of 102 cycles.

The Clearblue Early Detection Pregnancy Test product pack and instructions for use contain clear information regarding early testing, allowing women to make an informed choice about when to test. Women who test early and receive a non-pregnant result are advised to test again on the day of their expected period.

Innovative features of the Clearblue Early Detection Pregnancy Test make it easy to use

The innovative design of the Clearblue Early Detection Pregnancy Test features:

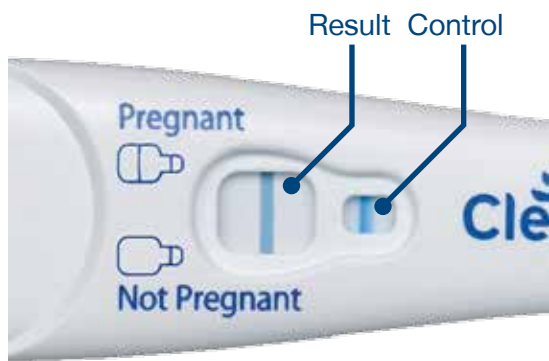
- A long easy-grip handle with an ergonomically designed stick to help the user hold the device correctly in the urine stream
- A wide 18 mm sampler to help obtain an adequate sample from the urine stream
- A colour changing tip (changes from white to pink) to let the user know that urine has been absorbed, helping her perform the test more easily
- Unique Floodguard™ Technology to help reduce the #1 reported usage error by 70%^d
- A large easy-to-read result window.



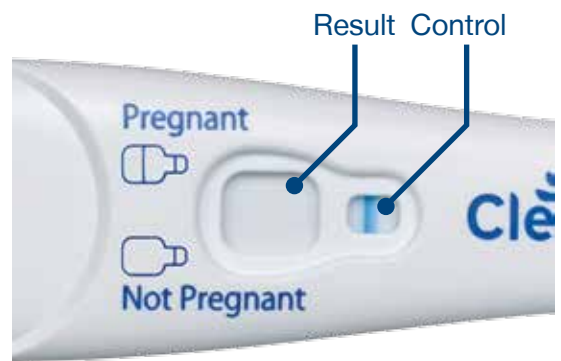
Floodguard™ Technology helps women to use the test correctly

Occasionally, excess urine can cause an incorrect pregnancy test result. The Clearblue Early Detection Pregnancy Test with Floodguard™ Technology absorbs excess urine, thereby increasing accuracy in users' hands.^d

Provides an easy-to-read result



Two lines indicates a positive (pregnant) result. The appearance of the line in the result window may vary, however, it is still a pregnant result no matter how faint or dark the line is.



A line in the control window only indicates a negative (not pregnant) result at the time of testing. Note: if the user is testing before her expected period, the level of hCG may not yet be high enough to be detected and she is advised to test again when her period is expected.

The test window must be read between 3 and 10 minutes after completing the test. If no blue line has appeared in the control window after 10 minutes, the test has not worked.



Points to remember

- The manufacturer's instructions regarding any medication being taken should be read before conducting the test
- When testing before the day of the expected period, an early-morning urine sample should always be used. This is not necessary when testing on or after the day of the expected period
- Testing within 14 days after administration of a fertility drug containing hCG can give a false pregnant result
- Excessive fluid intake should be avoided before testing, as a urine sample that is too dilute may give a false non-pregnant result
- Ectopic pregnancy can give misleading results⁹
- Elevated levels of hCG that are caused by an increase of pituitary hCG production in perimenopause and chemotherapy-induced suppression of gonadal function, or gestational trophoblastic disease, can give misleading results⁹
- A recent pregnancy, miscarriage or termination can give misleading results, as hCG can be found in the body for several weeks after giving birth¹⁰ and after a miscarriage or termination¹¹
- 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, which is not uncommon, as around one in four pregnancies end in early pregnancy loss
- Women should be encouraged to discuss any unexpected results with their healthcare professional.

References

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7. Gnoth C., Johnson SR. Strips of hope: accuracy of home pregnancy tests and new developments. *Geburtshilfe Frauenheilkd.* (2014) 74: 661–669.
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The Clearblue Early Detection Pregnancy Test is:

- Sensitive** - can be used 6 days before the day of the missed period^a
- Accurate** - over 99% accurate from the day of the expected period^c
- Reliable** - Floodguard™ Technology helps to reduce the #1 reported usage error by 70%^d
- Easy** - innovative ergonomic design
- Trustworthy** - from Clearblue, the world's No. 1 selling brand in home pregnancy and fertility tests^b

^a 'Missed period' refers to the day after the expected period; 79% of pregnant results can be detected 6 days before.

^b Based on international sales in nearly 20 countries compiled using independent market research data.

^c Over 99% accurate at detecting pregnancy from the day of the expected period.

^d Vs. our previous visual test design. Based on calls to Helpline throughout 2010 and 2014.

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The logo for Clearblue, featuring the word "Clearblue" in a bold, blue, sans-serif font. Above the letter "i" in "Clearblue", there is a stylized graphic of a fan or sunburst with multiple blue lines radiating upwards.

For more information about the Clearblue Early Detection Pregnancy Test, please visit our website:

www.clearblue.com



www.swissprecisiondiagnostics.com

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