

Clearblue[®]

Ultra Early Pregnancy Test

Results **6 days**
before the missed period^a



Professional Series
Pregnancy

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



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 35 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

Clearblue Ultra Early Pregnancy Test

Results 6 days before the missed period^a



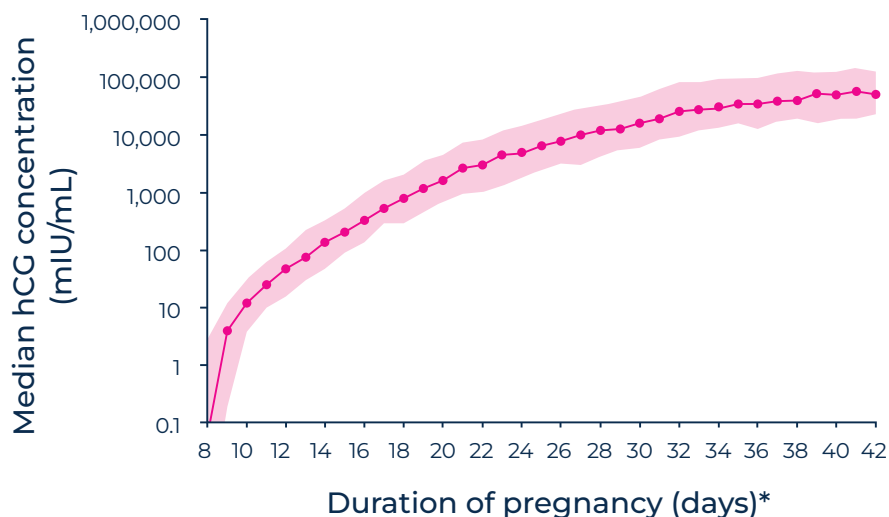
Over 99% accurate at detecting pregnancy from the day of the expected period

The Clearblue Ultra Early 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 Ultra Early Pregnancy Test is more than 99% accurate at detecting pregnancy.

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



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

Results 6 days before the missed period^a



The Clearblue Ultra Early Pregnancy Test can detect pregnancy 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 result on each test day before the day of her missed period.

Table One: Likelihood that a pregnant woman will get a positive result with the Clearblue Ultra Early Pregnancy Test when testing in the days leading up to the day of the missed period^b

Day relative to the day of the missed period	Samples from pregnant women giving a positive result (%)
-1	>99
-2	>99
-3	>99
-4	>99
-5	96
-6	79

Data from a minimum of 102 cycles.

The Clearblue Ultra Early 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 negative ('Not Pregnant') result are advised to test again on the day of their expected period.

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

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

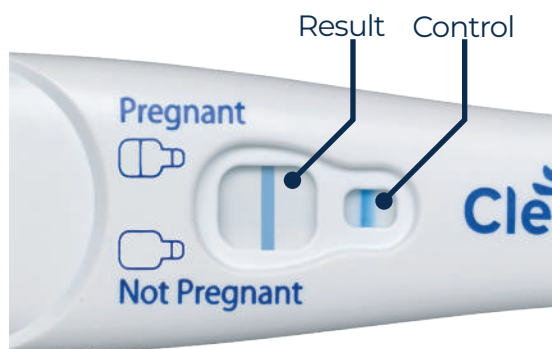
- A long easy-grip handle with an ergonomically designed stick to help the user hold the device correctly in the urine stream
- A wide 18mm tip to help obtain an adequate sample from the urine stream
- A colour change tip (changes from white to pink) to let the user know that urine has been absorbed, helping her perform the test more easily
- Unique integrated Floodguard™ Technology to help reduce the No. 1 reported source of usage error by over 70%^c
- A large easy-to-read result window



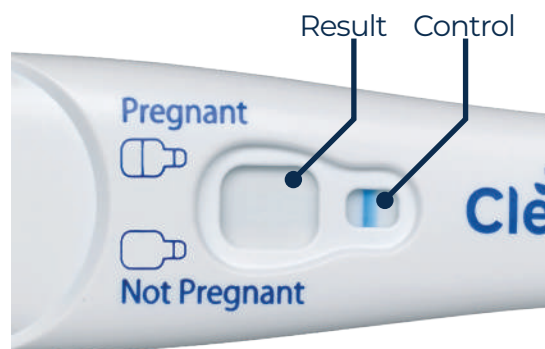
Integrated Floodguard™ Technology helps women to use the test correctly

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

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 'positive' result no matter how faint or dark the line is.



A line only in the control window indicates a negative 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.



Limitations

- 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, a first 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. Other fertility therapies (such as clomiphene citrate), painkillers and hormonal contraceptives (e.g. the contraceptive pill) should not affect the result
- Excessive fluid intake should be avoided before testing, as a urine sample that is too dilute may give a false-negative (non-pregnant) result
- Ectopic pregnancy and ovarian cysts can give misleading results⁹
- Elevated levels of hCG that are caused by an increase of pituitary hCG production in peri-menopause, 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 negative 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^{12,13}
- Women should discuss any unexpected results with a healthcare professional

References

1. 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.
2. Nepomnaschy PA, *et al.* Urinary hCG patterns during the week following implantation. *Hum Reprod.* (2008) 23: 271–277.
3. 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.
4. Johnson SR, *et al.* Analytical performance of home pregnancy test that estimates time since ovulation based on hCG threshold concentration at week boundaries. *Clin Chem.* (2013) S10: B45.
5. Johnson SR, *et al.* Agreement between the Clearblue Digital Pregnancy Test Conception Indicator and standard-of-care ultrasound dating in the assessment of pregnancy duration. *Curr Med Res Opin.* (2011) 27: 393–401.
6. Larsen J, *et al.* Human chorionic gonadotropin as a measure of pregnancy duration. *Int J Gynaecol Obstet.* (2013) 123: 189–195.
7. Gnath C and Johnson SR. Strips of hope: accuracy of home pregnancy tests and new developments. *Geburtshilfe Frauenheilkd.* (2014) 74: 661–669.
8. SPD data on file. In a laboratory study that tested a minimum of 102 cycles, pregnancy could be detected in 79% of the samples tested 6 days before the missed period (which is 5 days before the expected period).
9. Stenman UH, *et al.* The classification, functions and clinical use of different isoforms of HCG. *Hum Reprod Update.* (2006) 12: 769–784.
10. Korhonen J, *et al.* Disappearance of human chorionic gonadotropin and its α - and β -subunits after term pregnancy. *Clin Chem.* (1997) 43: 2155–2163.
11. Steier JA, Bergsjø P. and Myking OL. Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion, and removed ectopic pregnancy. *Obstet Gynecol.* (1984) 64: 391–394.
12. Chard T. Frequency of implantation and early pregnancy loss in natural cycles. *Baillieres Clin Obstet Gynaecol.* (1991) 5: 179–189.
13. Macklon NS, *et al.* Conception to ongoing pregnancy: the 'black box' of early pregnancy loss. *Hum Reprod Update.* (2002) 8: 333–343.

Clearblue Ultra Early Pregnancy Test is:

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

Sensitive – can be used 6 days before the day of the missed period^a

Early – no pregnancy test can tell women sooner^a

Reliable – integrated Floodguard™ Technology helps to reduce the No. 1 reported source of usage error by over 70%^c

Easy – innovative ergonomic design

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

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

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

This material is intended for healthcare professionals only. It is for general information only with no warranties, representations or undertakings, express or implied, and does not constitute medical advice. Product images are for illustration only. Clearblue® is a registered trade mark of SPD Swiss Precision Diagnostics GmbH ("SPD"). © 2023 SPD (except for any third-party content identified as such). All rights reserved.



For more information about the Clearblue Ultra Early Pregnancy Test, please visit our websites:

www.clearblue.com

www.swissprecisiondiagnostics.com



SPD Swiss Precision Diagnostics GmbH, 1213 Petit Lancy, Geneva, Switzerland

Clearblue Professional Series: HCP-0187.5