

Clearblue[®]

Digital Ultra Early Pregnancy Test

Unmistakably clear **6 days** early^a



^a 78% of pregnant results can be detected 6 days before the missed period (5 days before the expected period).



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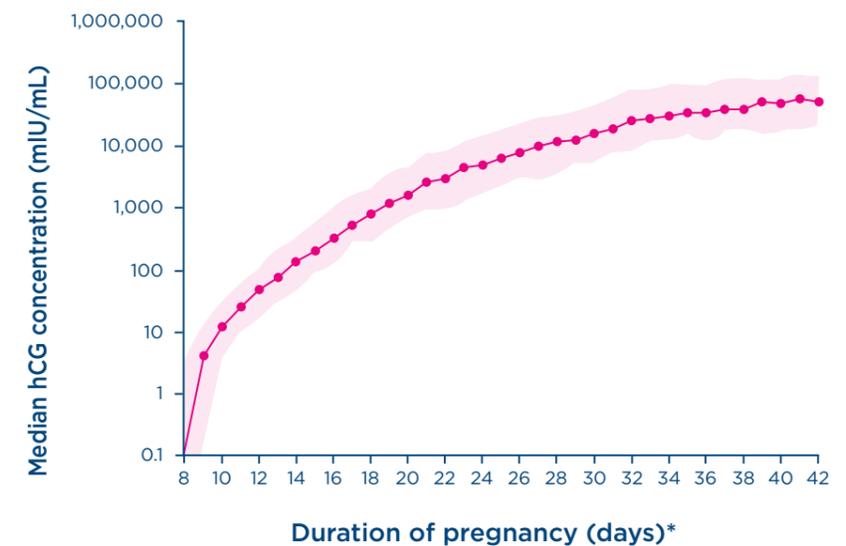


hCG in early pregnancy

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 foetal/maternal boundary.¹ The hormone is initially produced by the embryo and therefore also acts as a marker for its presence.²

The levels of hCG in the serum and urine rise rapidly during the first days of pregnancy,³⁻⁷ doubling about every 2 days (Figure One).³ In the first 3 weeks of pregnancy, estimates of gestational age based on hCG concentrations are highly comparable to ultrasound-dated pregnancy,⁸ making hCG an ideal urinary marker for quickly and accurately assessing whether a woman is pregnant or not.³⁻⁸

Figure One: Reference ranges for intact urinary hCG for each day of pregnancy (median, 10th and 90th centiles; data from 109 UK volunteers)⁸



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

About Clearblue[®]

Clearblue is the world's number one selling brand for 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.

Results 6 days before the missed period



The Clearblue Digital Ultra Early Pregnancy Test can detect pregnancy up to 6 days before the missed period.⁹ However, as the rise in hCG produced by an embryo can vary between women, not all pregnant women who test this 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 Digital Ultra Early Pregnancy Test when testing on the days leading up to the day of the missed period⁹

Days before missed period	Pregnancies detected
-1	>99%
-2	>99%
-3	>99%
-4	99%
-5	93%
-6	78%

The Clearblue Digital 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.

Benefits of knowing pregnancy status early

Early knowledge of pregnancy enables women to make informed choices about their health and obtain timely antenatal advice from healthcare professionals to make positive changes.¹⁰ The advice provided by healthcare professionals should be followed prior to conception; however, an estimated 44% of pregnancies were reported to be unplanned.¹¹ The earlier a woman finds out she is pregnant, the earlier she can make positive lifestyle changes.

Smoking

It is recommended that women stop smoking during pregnancy. There is a dose-dependent association between smoking and outcomes, such as abortion, stillbirth and recurrent pregnancy loss. Evidence suggests that those who do stop smoking are likely to permanently quit.¹²



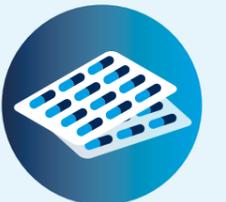
Alcohol

There is no safe alcohol limit in pregnancy. Women are advised to stop consumption of alcohol, ideally before a planned pregnancy.¹²



Folic acid

For pregnant women, dietary supplementation with folic acid before conception and throughout the first 12 weeks of pregnancy reduces the risk of the baby developing neural tube defects.^{12,13} If a woman has not taken folic acid preconception, a 6 day-early pregnancy test permits folic acid supplements to be taken at a time prior to the closure of the neural tube, potentially helping to reduce the risk of neural tube defects.^{14,15}



Exercise

Regular aerobic exercise during pregnancy appears to improve physical fitness, but the evidence is insufficient to suggest risks or benefits for the mother or baby. Owing to the effects of prenatal obesity, the advice is to continue with moderate exercise during pregnancy.^{12,16}



Caffeine

Pregnant women should be advised to limit their caffeine intake to 150 mg/day, which is equivalent to two cups of normal coffee or three cups of black tea.¹² There is a dose-related effect on pregnancy, with an increased risk of miscarriage at higher levels of caffeine.¹²



Diet

Pregnant women should be offered information on how to:

- Adopt a balanced diet, involving a variety of foods, such as fruits and vegetables¹³
- Reduce the risk of listeriosis by only drinking pasteurised/ultra-high-temperature processed milk and avoiding soft cheeses, pâté and uncooked/undercooked ready-prepared meals¹³
- Avoid an intake of over 700 µg of vitamin A supplements as it may be teratogenic. High levels of vitamin A are found in liver products, so they should be avoided¹³
- Reduce the risk of salmonella infection by avoiding raw or partially cooked eggs or meat¹³



Prescription and over-the-counter medicines

Only a few prescription and over-the-counter medicines have been established as safe to use in pregnant women, and should be used as little as possible during pregnancy. Use of prescription medicines should be limited to circumstances in which the benefit outweighs the risk.¹³ Women should seek advice from their healthcare professional.



Vaccinations

Vaccinations should be offered against:

- **Pertussis** (whooping cough) if a pregnant woman has not been immunised during the course of the current pregnancy¹³
- **Influenza** if a pregnant woman has not already been vaccinated in the current influenza season¹³



Benefits of the Clearblue Digital Ultra Early Pregnancy Test



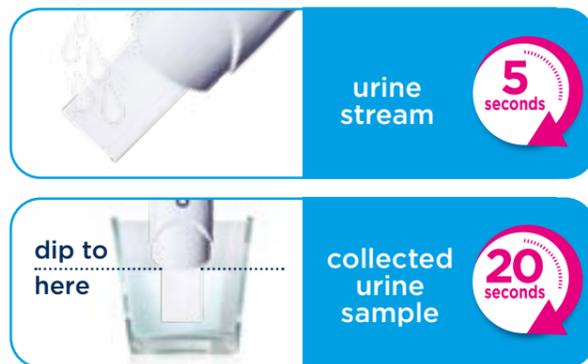
Over 99% accurate from the day of expected period

The Clearblue Digital Ultra Early Pregnancy Test is more than 99% accurate if used 4 days before the missed period.

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 tip for easy sampling

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

FIRST and ONLY test with a unique stop light

The stop light begins to flash to indicate when there is enough urine sampled to run the test. This usually takes about 5 seconds. The tip should then be removed from the urine. After a few more seconds, the flashing will stop.



Smart Countdown reassures her the test is working

For more reassurance throughout the testing process, the Clearblue Digital Ultra Early Pregnancy Test counts down to the result. It has a unique progression indicator, displayed in a four-segment format on a liquid crystal display. This Smart Countdown helps reassure the user that the test is working and helps her know when her result is coming.



Floodguard™ Technology makes it easy to test correctly

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 reported user error. The innovative and unique integrated Floodguard™ Technology absorbs excess urine and helps dramatically reduce reported user error.^c

Easy to read

The Smart Countdown will finish in 1–5 minutes and a 'Pregnant' or 'Not Pregnant' result will be displayed on screen. A 'Pregnant' result remains on the screen for up to 1 month and a 'Not Pregnant' result for approximately 24 hours.



If the user gets a 'Pregnant' result, she can be over 99% certain of the result, no matter when she tests. If the result is 'Not Pregnant', she might not be pregnant, or the level of hCG may not yet be high enough to be detected. If she has missed her period, she should test again in 3 days' time. In such cases, if the result is negative but she still suspects she might be pregnant, she should see a healthcare professional.

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 an injection. 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 negative result, or her period starts, it may be due to natural loss during the early stage of pregnancy. This is not uncommon as approximately one in four pregnancies end in early pregnancy loss^{17,18}
- 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 - this may lead to a false-negative 'Not Pregnant' result. However, other symptoms are likely to be experienced and if an ectopic pregnancy is suspected, immediate medical advice must be sought
- Ovarian cysts, menopause and certain rare medical conditions can give misleading results
- A recent pregnancy, miscarriage or termination can give misleading results, as hCG can be detected in the body several weeks after giving birth¹⁹ and after a miscarriage or termination²⁰
- 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 highly diluted urine sample may give a false-negative 'Not Pregnant' result
- 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 testing before the expected period, a first morning urine sample should always be used

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Clearblue Digital Ultra Early Pregnancy Test is:

Accurate – over 99% accurate from 4 days before the missed period

Ultra early – results 6 days before the missed period^a

Ultra sensitive – our most sensitive digital pregnancy test^d

Easy to use – with wide tip and unique stop light

Easy to read – unmistakably clear results in words

^a 78% of pregnant results can be detected 6 days before the missed period (5 days before the expected period).

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

^c Data on file.

^d Test sensitivity is 10mIU/mL.

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