

Clearblue®

Ultra Early ADVANCED
Pregnancy Test



For self-testing. Read this leaflet carefully before testing.

This product is a non-automated, at home, self-testing device for the qualitative detection of human chorionic gonadotrophin (hCG) in a woman's urine for the determination of pregnancy. Intended for use from 6 days before the missed period (5 days before expected period).

Warnings and Precautions

Instructions for device, with 'CB16003' printed on the wrapper. For self-testing at home. For in vitro diagnostic use only. Not for internal use. Do not reuse. Keep out of reach of children. Store between 2° – 30°C. Allow to reach room temperature for 30 minutes prior to testing if stored refrigerated. Do not use if the foil wrapper is damaged. Do not use after the 'use by' date. Once foil is opened, use immediately. Discard with normal household waste. Contains small parts. Do not eat any component of this device. If accidentally swallowed, seek medical attention. Report any injury caused by the use of this product to Clearblue and the Competent Authority of the member state.



Test from
6 days
before
your missed period*



with
DualSense
Technology



Don't drink
lots of liquid
before testing



If testing early use
first urine of the day
Otherwise test
any time. See Q2

1 Take the test

Materials required, but not provided: Clean, dry container and a stopwatch.

Remove from foil, take off the cap, and use immediately. Hold the absorbent tip pointing downward, and place just the tip in **either**:

your urine stream



or

a collected urine sample



Replace the cap and lay the test stick flat.

2 Wait



Red lines will start to develop. If not, see 'Test errors'.

Wait 5 FULL MINUTES before reading your result.

3 Results

Pregnant

See Q4 for more information.

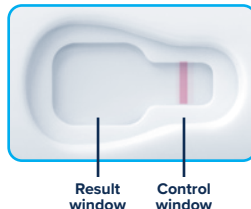


If you see two lines you are pregnant.
It does not matter how faint or dark the lines are.

A red line must be present in the control window for your result to be valid. If not, see 'Test errors'.
IMPORTANT! Read your result within 10 minutes of testing. Disregard any changes after this time.

Not Pregnant

See Q5 for more information.



Questions and answers

1 How accurate is Clearblue?

Ultra Early ADVANCED Pregnancy Test is over 99% accurate in laboratory tests from the day you expect your period.

2 What time of day can I test?

If testing before you expect your period always use the first urine of the day, as any pregnancy hormone will be more concentrated. If testing from the day you expect your period, hormone levels will be higher if you are pregnant, so you can test with urine collected from any time of the day.

3 How early can I test?

You can test from 6 days before your missed period (5 days before you expect your period).*

However, as hormone levels vary from woman to woman, and in early pregnancy can be very low, you may be pregnant but still get a negative result.

The chart below shows the percentage of pregnancies detected in lab testing of early pregnancy urine samples:

Days before the missed period	-1	-2	-3	-4	-5	-6
Pregnancies detected	>99%	>99%	>99%	98%	93%	77%

4 My result is Pregnant. What should I do?

See your doctor who can advise you on your next steps. It is possible to get a positive result and find out later you are no longer pregnant.

5 My result is Not Pregnant. What does this mean?

You may not be pregnant, or the level of pregnancy hormone may not yet be high enough to be detected.

If you tested before your expected period, test again when your period is due.

If you get a 'Not Pregnant' result on or after the day you expect your period, but still think you might be pregnant, see your doctor.

6 How does DualSense Technology work?

Though known as the 'pregnancy hormone', a low level of hCG can be present in a very small number of women's urine without them being pregnant (usually women nearing or in menopause). This could mean there may be a very small risk these women might get a false positive result if they use a high sensitivity pregnancy test, i.e., one that can be used very early, because it has to be capable of detecting low levels of hCG.

However, research shows these women might also have a high level of associated FSH (follicle stimulating hormone). Clearblue's DualSense Technology is a unique system that captures hCG when there are high levels of FSH present in urine, and is designed to help avoid the possibility of false positives within this group of women.

7 Can any medication or medical conditions affect the result?

Always read the manufacturers' instructions for any medication you are taking before testing. If you get unexpected results you should discuss them with your doctor.

Medications containing hCG or FSH and other hormone therapies may affect the result. Ectopic or recent pregnancy, even if not carried to full term, can cause misleading results.

The test should NOT be affected by hormone therapies containing Clomiphene citrate, common painkillers, alcohol, antibiotics, or the contraceptive pill.

8 Is there anything I should do if I am planning to get pregnant?

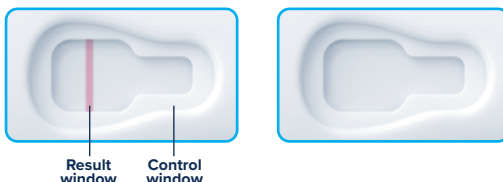
It's a good idea to speak to your doctor before you try to get pregnant. Many doctors advise taking folic acid or prenatal vitamin supplements, avoiding alcohol, stopping smoking, and that trying to maintain a healthy weight can be beneficial. You may also want to consider using an ovulation test to identify your most fertile days.

Clearblue offers a range to help maximise your chances of conceiving.

Test errors

No red line appears in the control window within 10 minutes of testing.

The test has not worked, possibly because too much or too little urine was used. Test again using a new test, following the instructions carefully.



Result window Control window

Performance Characteristics

Clinical performance:

Clinical performance testing demonstrated the device is >99% accurate in determining pregnancy status from the day of expected period.

- Device was >99% accurate in the hands of the lay users when compared to their pregnancy status (tested by 302 women).
- In laboratory testing of 708 samples, the device was >99% accurate from the day of expected period.
- Clinical specificity testing with pre-, peri- and post-menopausal samples (501 samples) confirmed ≥99% specificity

Analytical performance:

Analytical specificity was established by testing the device with potentially interfering or cross-reacting substances. The results confirmed that high concentrations of the same do not affect device performance. Nor is it by high levels of beta core hCG fragment, very high levels of intact hCG, a range of specific gravities, or pH of urine. A Precision Study demonstrated the analytical sensitivity of the device is 10 mIU/ml.

www.clearblue.com

Advisors available 07:00 – 15:00hrs Mon-Fri, excluding Bank Holidays.

UK 0800 917 2710 • IE 1800 812 607 Freephone.

Calls are recorded and may be monitored for quality purposes. Please have the product, packaging and foil pouches with you when you call.

IVD	In vitro diagnostic medical device	LOT	Batch code
	Manufacturer		Use-by date
	Do not re-use		Temperature limit 2°C – 30°C
	Authorised representative in the European Union		

Literature

1. Perrier d'Hauterive S, et al. Gynecol Obstet Invest 2007; 64(3): 156–60.
2. Gnoth C and Johnson S. Geburtshilfe und Frauenheilkunde 2014; 74(7):661-669.
3. Gronowski A, et al. Clin Chem 2008; 54: 652-656

*77% of pregnant results can be detected 6 days before your missed period (5 days before you expect your period).

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