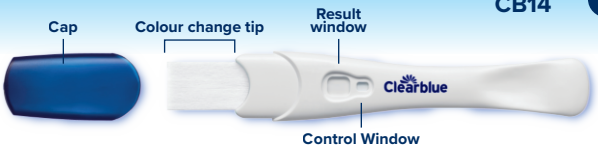
Clearblue™

Ultra Early Pregnancy Test

CB14 ENGLISH



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 'CB14005' 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. Single use.

- Test from **6 days before** your missed period*
- **If testing early use first urine of the day** Otherwise test any time
- **Don't drink lots of liquid** before testing
- **Read results within 10 minutes** (10 minutes)

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.
Place the colour change tip:

IMPORTANT: completely immerse tip as shown



or



IMPORTANT: the colour change tip will turn instantly pink, showing that urine is being absorbed. **Start timing as soon as you see the colour change tip turn pink.** Replace the cap and lay the test stick flat. If the tip does not turn completely pink, see 'Test errors'.

2 Wait

3 minutes

A line in the control window may start to appear quickly but you must **WAIT 3 FULL MINUTES** before reading your result.

If no blue lines appear, see 'Test errors'.

3 Results

Pregnant - if your result is Pregnant see your doctor (see Q1)

Picture A ***Picture B*** ***Picture C***



Not Pregnant (see Q2)



If you are unsure of your result, see Q6.

IF YOU SEE TWO LINES YOU ARE PREGNANT. IT DOES NOT MATTER HOW FAINT OR DARK THE LINES ARE.

A blue 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.

Questions and answers

1 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 (see Q7).

2 My result is Not Pregnant. What does this mean?
You may not be pregnant or the level of pregnancy hormone may not be high enough to be detected yet. Test again in three days' time. If this test gives you a 'Not Pregnant' result and your period is late, see your doctor.

3 How early can I test?
This test can be used from 6 days before your missed period (5 days before you expect your period).*
However, as hormone levels vary from woman to woman, and can be very low in early pregnancy, you may be pregnant but still get a negative result. The chart below shows the percentage of pregnancies that were detected in lab testing with early pregnancy urine samples:

Days before missed period	-1	-2	-3	-4	-5	-6
Pregnancies detected	>99%	>99%	>99%	>99%	96%	79%

4 How does this test work?
It detects hCG in urine following sample application. Visual results indicate if hCG has been detected with over 99% accuracy from the day you expect your period.

5 Can any medication or medical conditions affect the results?
Always read the manufacturers' instructions for any medication you are taking before testing. Medications containing hCG, and certain rare medical conditions, can cause false positive results.
Ectopic or recent pregnancy, even if not carried to full term, can cause misleading results. If you are in or approaching the menopause you may obtain a false pregnant result even though you are not pregnant.
The test should **NOT** be affected by hormone therapies containing Clomiphene citrate, common painkillers, alcohol, antibiotics, or the contraceptive pill. If you get any unexpected results you should discuss them with your doctor.

6 What if I am unsure of my result?
If you see two blue lines within 10 minutes of testing you are Pregnant, it does not matter how faint or dark the lines are.

Pregnant Results

Picture A: This is more likely to occur when you are testing before you expect your period when your hCG levels may be relatively low.

Picture B: You may see this if you are testing around the day you expect your period as hCG levels may be relatively low.

Picture C: You may see this if you are testing more than a few days after you miss your period as hCG levels are higher.

If you are still unsure of your result, you should wait at least 3 days before testing again, taking care to follow the instructions.

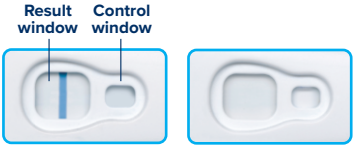
7 I previously tested Pregnant but have tested again and got a negative result, or my period has started. What does this mean?
It is possible to get a positive result and find out later you are no longer pregnant. This may be due to early pregnancy loss, which is not uncommon, affecting around 1 in 4 pregnancies. Most women can go on to have a healthy pregnancy afterwards.

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

The colour change tip does not turn completely pink.
You may not have applied enough urine. However, you can be sure the test has worked if the control line appears within 10 minutes of testing.

No blue 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.



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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 911 women).
- In a study testing 300 samples, the device was >99% accurate from the day of expected period.
- Clinical specificity testing with pre-, peri- and post-menopausal samples (1051 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.

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

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.

*79% of pregnant results can be detected 6 days before your missed period (5 days before you expect your period).

For product enquiries, please contact Customer Support at the address below:-

Market Authorisation Holder
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Manufacturing Site: Abbott Diagnostics (Shanghai) Co. Ltd.
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