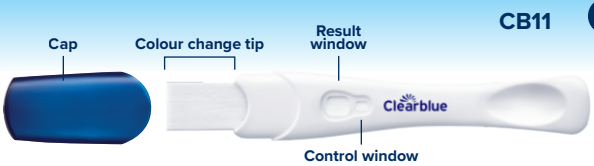
Clearblue™

Rapid Detection
Pregnancy Test

CB11 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 4 days before the period is due.

Warnings and Precautions

Instructions for device, with 'CB11012' 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. Once foil is opened, use immediately. Do not use after the 'use by' date. 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.

Over 99% accurate from the day you expect your period

+ or **–** **Easy to read results**

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 the foil wrapper, take off the cap and use immediately.
Place the colour change tip for **5 seconds:**



in your urine stream 5 seconds

or



in a collected urine sample 5 seconds

IMPORTANT: the colour change tip will instantly turn pink, which shows that it is absorbing urine, but you MUST continue to hold the tip in your urine for a full 5 seconds.

IMPORTANT: completely immerse the tip as shown

Replace the cap and lay the test stick flat. If the tip does not turn completely pink, see 'Test errors'.

2 Wait

1-3 minutes

- A Pregnant '+' result may appear in 1 minute when testing from your missed period (the day after you expect your period).
- Wait 3 minutes to confirm a Not Pregnant '-' 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.

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 yet be high enough to be detected. Test again in three days' time. If this test gives you a 'Not Pregnant' result and your period is late, see your doctor.

3 I am not sure when my next period is expected. How do I know I am testing at the right time?
To work out when your period is expected, calculate your usual cycle length by counting the number of days from the first day of your period until the day before your next period starts. If you have irregular cycles, you should allow for your longest cycle in recent months before testing.

4 How does Clearblue 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?
For your result to be 'Pregnant' there must be a blue line in the control window and a '+' in the result window within 10 minutes of testing.

Pregnant Results

Picture A: This is more likely to occur when you are pregnant and you are testing more than a few days after your missed period as hCG levels are higher.

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: This still denotes a pregnant result.

It does not matter if one of the lines that make up the '+' symbol is lighter or darker than the other; the result is 'Pregnant'.
For your result to be 'Not Pregnant' there must be a blue line in the control window and a '-' (minus) symbol in the result window within 10 minutes of testing.
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 has not turned 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 120 women).
- In a study testing 600 samples, the device was >99% accurate from the day of expected period.
- Clinical specificity testing with pre-, peri- and post-menopausal samples (600 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 25 mIU/ml.

IVD	In vitro diagnostic medical device	LOT	Batch code
	Manufacturer		Use-by date
	Do not re-use	2°C 30°C	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.

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

Market Authorisation Holder
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Manufacturing Site:
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