

Clearblue

Pregnancy Test

Digital Ultra Early



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

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

Warnings and Precautions

Instructions for device with 'CB15002' 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. This product contains batteries. Dispose of in accordance with local regulations. 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*



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



Don't drink
lots of liquid
before testing



Never hold
the test stick
with tip pointing
upwards

1 Take the test

Materials required but not provided: Clean, dry container if dipping test stick. Remove the test stick from the foil, take off the cap and use immediately. **Either** test in:



your
urine
stream

or



a collected
urine
sample

Remove the absorbent tip from the urine when the stop light BEGINS to flash.

This usually takes about 5 seconds. The light will continue to flash briefly and then switch off. Keep the absorbent tip pointing downward, replace the cap and lay the test stick flat.

2 Wait

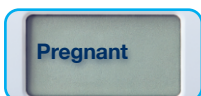
The Smart Countdown will be shown on the display and each segment will appear in sequence to show the test is progressing.



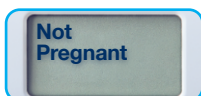
If the Smart Countdown has not appeared see "Test errors".

3 Read your result

The Smart Countdown will finish in 1-5 minutes and your result will appear on screen.



You can be over 99% certain that you are pregnant, no matter when you test. See Q1 for more information.



If you tested early there's still a chance you may be pregnant as the amount of hormone increases rapidly in early pregnancy. See Q2 for more information.

Questions and answers

1 My result is Pregnant. What should I do?
See your doctor who can advise you on what steps to take next. It is possible to get a positive result and find out later that you are no longer pregnant, see Q6.
A 'Pregnant' result stays on screen for up to 1 month.

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 result is 'Not Pregnant' 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).
If your result is 'Pregnant' you can be over 99% certain that you are pregnant, no matter when you test.
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%	93%	78%

4 How does Clearblue work?
It detects the pregnancy hormone hCG in women's urine. Following sample application, device electronics measure, interpret and display the progress of the assay and then end result. It's over 99% accurate 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 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 that you are no longer pregnant. This is called "early pregnancy loss" which is sadly not uncommon, affecting around 1 in 4 pregnancies. Happily, most women can have a healthy pregnancy afterwards.

Disposing of your test
Remove the batteries prior to test stick disposal. Battery disposal should be in accordance with the appropriate recycling scheme. To remove, insert the **curved edge of the cap** into the side of the test stick and twist to break open the stick. **Caution:** Do not disassemble, recharge or dispose of batteries in fire. Dispose of the rest of the stick according to the appropriate recycling scheme for electrical equipment. Do not dispose of electrical equipment in fire.

Test errors



Book error
An error has occurred during testing. It may be that:
• the absorbent tip was not kept pointing downward
• the test was not laid flat after urine was applied
• too much or too little urine was applied to the tip
Test again using a new test, carefully following the instructions.



Blank error
If the Smart Countdown didn't appear after testing or started to run and then the screen went blank, you will need to perform another test. Test again using a new test, carefully following the instructions.

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.

The following preventive warnings apply to EN 61326-2-6 compliant equipment.
a) Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
b) Do not use this instrument in close proximity to sources of strong electromagnetic radiation (e.g., mobile phones), as these may interfere with the proper operation.

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 514 women across two studies).
• In a study testing 831 early pregnancy urine samples, the device was >99% accurate from the day of expected period.
• Clinical specificity testing with pre-, peri- and post-menopausal samples (450 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 10mIU/ml.
This IVD digital device meets the emissions and immunity requirements of EN 61326-2-6. The EMC countermeasures employed within the electronic instrument will provide reasonable protection against electromagnetic interference effects likely to be encountered in the home environment.

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Distributed by P & G South African Trading (Pty) Ltd, 15 Alice Lane, Sandton 2196 Gauteng South Africa. RSA Consumer
Caroline 0800 555 454 (free from landlines).

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.
*78% of pregnant results can be detected 6 days before your missed period (5 days before you expect your period).

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