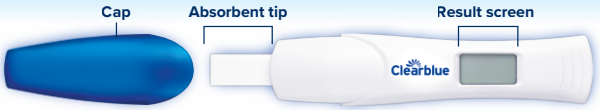
Clearblue™

Pregnancy Test with Weeks Indicator

CB9 ENGLISH



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

This product is an automated, at-home, self-testing device for the semi-quantitative detection of human chorionic gonadotrophin (hCG) in a woman's urine for the determination of pregnancy. For positive results, the product also predicts weeks since conception, categorising them as follows: 1-2, 2-3 or 3+ weeks since conception occurred. Intended for use from 5 days before the missed period (4 days before the expected period).

Warnings and Precautions

Instructions for device, with 'CB9A001C' 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. Single use.

Over 99% accurate at detecting pregnancy from the day you expect your period

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

Don't drink lots of liquid before testing

Never hold test with tip pointing upwards

1 Take the test

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



or



Replace the cap and lay the test stick flat.

2 Wait



The wait symbol will flash to show the test is working and your result will appear in 1-3 minutes.

If no wait symbol appears see 'Test errors'.

3 Read your result

A 'Pregnant' result may appear on the display before the Weeks Indicator result.



You conceived about 1-2 weeks ago.
Your doctor will date this as 3-4 weeks pregnant.



You conceived about 2-3 weeks ago.
Your doctor will date this as 4-5 weeks pregnant.



You conceived more than 3 weeks ago.
Your doctor will date this as 5+ weeks pregnant.

If your result is **Pregnant** see Q2.

The Weeks Indicator is 93% accurate at detecting when you conceived (see Q3). Your doctor will date your pregnancy using a different method based on the first day of your last period.



If your result is **Not Pregnant** see Q4.

Questions and answers

1. **When should I test?** Use the first urine of the day for an accurate Weeks Indicator result, or when testing early.
2. **My result is Pregnant. What should I do?** See your doctor who can advise you on your next steps. **Clearblue with Weeks Indicator is over 99% accurate at detecting pregnancy from the day you expect your period.**
   A 'Pregnant' result stays on the display for approximately 24 hours.
3. **How accurate is the Weeks Indicator?** The Weeks Indicator is 93% accurate at detecting when you conceived when testing with the first urine of the day. Conception occurs around 2 weeks before you expect your next period. Your doctor will date your pregnancy using a different method based on the first day of your last period (based on a 28 day cycle).
4. **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 still think you might be pregnant, test again in three days' time. If this test gives you a 'Not Pregnant' result and your period is late, see your doctor.
5. **How early can I test?** This test can be used from 5 days before your missed period (4 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 missed period	-1	-2	-3	-4	-5
Pregnancies detected	>99%	99%	99%	97%	80%

6. **How does Clearblue with Weeks Indicator work?**
   It semi-quantitatively detects the pregnancy hormone hCG in women's urine, to indicate how many weeks since you conceived. Following sample application, device electronics measure, interpret and display the end result. It's over 99% accurate at detecting pregnancy from the day you expect your period.
7. **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. Multiple and ectopic pregnancies can give misleading Weeks Indicator results.
8. **Can anything else affect the result?** The Weeks Indicator may give unexpected results if you are testing more than 6 weeks since you conceived because the level of hCG in the urine is too high for the test to provide an accurate estimate of the time since conception.
9. **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 later find out you are no longer pregnant. This is called early pregnancy loss, which is not uncommon, affecting around 1 in 4 pregnancies. Most women can go on to have a healthy pregnancy afterwards.
10. **I have tested again and the Weeks Indicator result has reduced. What does this mean?** The level of hCG can fluctuate as it rises and it is therefore possible that the Weeks Indicator will give unexpected results if you test on consecutive days. You should wait at least 5 days before testing again, using the first urine of the day. If it has been more than 5 days since you last tested and the Weeks Indicator result has reduced see your doctor.

Disposing of your test
Remove the battery prior to test stick disposal. Battery disposal should be in accordance with the appropriate recycling scheme. To remove, insert a coin into the slot at the end and twist to break open the back of the test stick. If battery is not visible, slide the battery holder out in the direction of the arrow to assist removal.
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



The test has not worked as expected, you will need to perform another test. Test again using a new test, carefully following the instructions.

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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.
- 5652 clinical samples (2727 non-pregnant samples and 2925 pregnant samples) tested across two studies showed >99% agreement between pregnancy status and pregnancy test results.
- 3076 clinical samples collected from 131 volunteers were tested demonstrating that the 'weeks indicator' result is 93% accurate when compared to ultrasound and LH surge dating.
- The 93% accuracy is based on the lowest agreement received for the 2-3 weeks band. The overall agreement (i.e. considering the average agreement across all weeks indicator bands 1-2, 2-3 and 3+) was calculated as 97%.

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.

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. 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.

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.

*80% of pregnant results can be detected 5 days before your missed period (4 days before you expect your period).

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

Market Authorisation Holder
SPD Swiss Precision Diagnostics GmbH (SPD),
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Manufacturing Site:
Abbott Diagnostics (Shanghai) Co. Ltd. Shanghai, China

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

CE 0123

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