

Clearblue®

Pregnancy Test with Weeks Indicator

These instructions are for the Clearblue Pregnancy Test with Weeks Indicator packed in a foil wrapper which has 'DIGITAL' printed on it. Separate instructions are provided on the other side of this leaflet for the Clearblue Ultra Early Pregnancy Test which should be read prior to use.

- If testing from the day of your expected period, you can test at any time of the day to find out if you are pregnant.
- If testing before the day of your expected period, use the first urine of the day.
- For an accurate Weeks Indicator result, you must use the first urine of the day.
- Don't drink lots of liquid before taking the test.
- **Read this leaflet carefully before taking a test.**

1 Take the test

When you are ready to test, remove the test stick from the foil wrapper and take off the blue cap. Use the test stick straight away.



Throughout testing **never** hold the test stick with the absorbent sampler pointing upwards.

EITHER Test in your urine stream

- Place just the absorbent tip pointing downwards in your urine stream **for 5 seconds only**.
- Take care not to get the rest of the test stick wet.
- You may wish to replace the cap and lay the test stick flat.



OR

Collect a sample of your urine in a clean, dry container

- Place just the absorbent tip pointing downwards in the urine, as shown, **for 20 seconds only**.
- You may wish to replace the cap and lay the test stick flat.



2 Wait...

- The wait symbol will flash to show the test is working.
- When the wait symbol stops flashing your result will appear. If the wait symbol does not appear after you have used the test, see Q6.



3 Read your result

- The **Weeks Indicator** provides an estimate of when you conceived. This information is shown on the display together with a 'Pregnant' result.
- Within **3 minutes**, the display will show your result.
 - A 'Pregnant' result may appear on the display **before** the Weeks Indicator result. **Continue to wait** until the wait symbol stops flashing to see your Weeks Indicator result. This may take up to 3 minutes.
 - Some results may be shown in as little as 1 minute.
 - Your result will remain on the display for approximately 24 hours.
 - If your result is 'Pregnant' you should see your doctor who can advise you on what steps you should take next. Your doctor will calculate your stage of pregnancy based on the first day of your last period.
 - Conception occurs around 2 weeks before your next period is due. The Weeks Indicator provides an estimate of when you conceived.

- The Weeks Indicator is 93% accurate at detecting when you conceived. The estimate is based on the level of the pregnancy hormone, hCG (human Chorionic Gonadotrophin), in your urine. The level of hCG varies from woman to woman, and it is therefore possible that the Weeks Indicator might occasionally give misleading results. The accuracy of the 'Pregnant'/'Not Pregnant' result is over 99% when testing from the day of your expected period.

Test Errors

Please read the section 'Test errors' if you have used the test stick and the display does not show any of the results on this page.

How to interpret the results

Results	Time since conception	How your doctor will date your pregnancy (based on a 28 day cycle)*
Not Pregnant Pas Enceinte	Your result is Not Pregnant see Q13.	-
Pregnant Enceinte 1-2	Your result is Pregnant and you conceived approximately 1-2 weeks ago.	3-4 weeks
Pregnant Enceinte 2-3	Your result is Pregnant and you conceived approximately 2-3 weeks ago.	4-5 weeks
Pregnant Enceinte 3+	Your result is Pregnant and you conceived more than 3 weeks ago.	5+ weeks

*Your doctor will date your pregnancy from the first day of your last period, not from when you conceived.

Questions and Answers

1 How does Clearblue with Weeks Indicator work? When you are pregnant your body produces the pregnancy hormone hCG (human Chorionic Gonadotrophin). The amount of hCG in your body increases in the early stages of pregnancy. This test can detect tiny amounts of this hormone in your urine (the sensitivity of this test is 25mIU/ml). Based on the level of hCG in your urine, the Weeks Indicator provides an estimate of when you conceived.

2 How accurate is Clearblue with Weeks Indicator in detecting pregnancy? In laboratory tests Clearblue with Weeks Indicator is more than 99% accurate in detecting whether or not you are pregnant, when used from the day of your expected period. If you test before the day of your expected period and get a 'Not Pregnant' result, there is still a chance that you may be pregnant. See Q4.

3 How accurate is the Weeks Indicator? The Weeks Indicator is 93% accurate at detecting when you conceived. The estimate is based on the level of hCG in your urine. The level of hCG varies from woman to woman, and it is therefore possible that the Weeks Indicator might occasionally give misleading results. The Weeks Indicator has been shown to be 97% in agreement with the later ultrasound dating scan (11-13 weeks). Based on studies of 187 women comparing results (1-2, 2-3, 3+ weeks since conception) to ultrasound dating. If you are testing more than 6 weeks after conception the Weeks Indicator may give unexpected results. This is because the level of hCG in the urine is too high for the test to provide an accurate estimate of the time since conception.

4 When can I use Clearblue with Weeks Indicator? You can test up to 5 days before your missed period (which is 4 days before your expected period). If you test before the day of your expected period and get a 'Not Pregnant' result, there is still a chance that you may be pregnant. See the chart below for results from clinical testing with early pregnancy samples.

Testing Early				
Number of days before the expected period	-1	-2	-3	-4
% of samples from pregnant women giving a 'Pregnant' result	98%	97%	90%	65%

If the result is 'Not Pregnant', and pregnancy is still suspected see Q13. 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.

5 Can any medication or medical conditions affect the result?

- Always read the manufacturers' instructions for any medication you are taking before conducting a test.
- Fertility drugs containing hCG can give misleading results (these fertility drugs are usually given by injection, and testing too soon after administration may give a false 'Pregnant' result).
- Other fertility therapies (such as clomiphene citrate), painkillers and hormonal contraceptives (e.g. contraceptive pill) should not affect the result.
- If you have recently stopped using hormonal contraception or are using fertility therapies like clomiphene citrate, your periods may be irregular, leading you to test too soon.
- If you have recently been pregnant (even if not carried to full term) you may get a false 'Pregnant' result.
- If you are approaching the menopause you may obtain a false 'Pregnant' result even though you are not pregnant.
- Ectopic pregnancy and ovarian cysts can give misleading results.
- Multiple and ectopic pregnancies can give misleading Weeks Indicator results.

If you do get unexpected results you should discuss them with your doctor.

6 I have used the test, but the wait symbol has not appeared. What does this mean? The test has not worked correctly. See test errors.

7 I have used the test but no result has appeared on the display. What does this mean? Your result should appear on the display within 3 minutes. If no result appears please see test errors.

8 My test says I'm 'Pregnant'. What should I do? If your result is 'Pregnant' you should see your doctor who can advise you on what steps you should take next. The Weeks Indicator is only an estimate as to when conception occurred. Your doctor will estimate the stage of your pregnancy based on the first day of your last period. Conception occurs around 2 weeks before your next period is expected.

9 My test says I'm pregnant but I do not think I conceived when the Weeks Indicator says I did. Is this possible? The Weeks Indicator is 93% accurate when testing with the first urine of the day. Some medication or medical conditions may affect the result. See Q5.

10 I tested yesterday and the result was 'Pregnant'. I have tested again today, and according to the Weeks Indicator the number of weeks since I conceived has reduced. What should I do? The level of hCG fluctuates as it rises and it is therefore possible that the Weeks Indicator will give unexpected results if you test on consecutive days. Test again in 5 days and if the Weeks Indicator results still show that the number of weeks since you conceived has reduced, please see Q12.

11 I previously tested 'Pregnant' but have tested again and got a 'Not Pregnant' result, or my period has started. What does this mean?

Whilst the test is over 99% accurate at detecting the pregnancy hormone from the day of your expected period, it's possible to get a pregnant result and find out later that you're not pregnant (i.e., you may later get a not pregnant result, or your period may start). This may be due to natural loss during the early stages of pregnancy, known as 'early pregnancy loss', which sadly is not uncommon, as around 1 in 4 pregnancies end in early pregnancy loss. If you do get unexpected results, ask your doctor for advice.

12 I tested a week ago and the result was 'Pregnant'. I have tested again, and according to the Weeks Indicator the number of weeks since I conceived has reduced. What should I do? If you tested according to the instructions, using the first urine of the day on both occasions, and the Weeks Indicator gave unexpected results, you should see your doctor.

13 My test says I'm 'Not Pregnant'. What should I do? You may not be pregnant, or the level of pregnancy hormone may not be high enough to be detected, or you may have miscalculated the day your period was expected.

- If you tested early, test again when your period is expected.
- If your period is overdue, test again in 3 days' time. If this test gives you a 'Not Pregnant' result and you still have not had your period, see your doctor.

Test errors

Book error - an error has occurred during testing.

- It may be that:
- The absorbent tip was not kept pointing downwards or the test was not laid flat after urine was applied.
 - Too much or too little urine was applied. You should test again using a new test taking care to follow the instructions.

Blank error - The test has not worked as expected.

This may be because the instructions for use were not followed. You will need to take another test. Please follow the instructions carefully.

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 on in the direction of the arrow to assist removal. **Caution:** Do not disassemble, recharge or dispose of batteries in fire. Dispose the rest of the stick according to the appropriate recycling scheme for electrical equipment. Do not dispose of electrical equipment in fire.

This IVD digital device complies with the Industry Canada spectrum management and telecommunications interference-causing equipment standard ICES-003. CAN ICES-3 (B)/NMB-3(B)

The EMC countermeasures employed within the electronic instrument will provide reasonable protection against electromagnetic interference effects likely to be encountered in the home environment. 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.

For self-testing at home. For *in vitro* diagnostic use. 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. This product includes 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.

Health Canada advises pregnant women to abstain from alcohol consumption as this may lead to harmful effects on the baby such as Fetal Alcohol Syndrome Disorders (FASD). More information is available at www.hc-sc.gc.ca.

www.clearblue.com

Clearblue Helpline

Monday-Friday 8:30 a.m. - 5:00 p.m. EST.

1-888-698-5039 Toll free from landlines.

Please have the product and packaging, including any foil pouches, with you when you call. Calls are recorded for training and quality control.

Manufacturer: SPD Swiss Precision Diagnostics GmbH (SPD), Route de St Georges 47, 1213 Petit-Lancy, Geneva, Switzerland.

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The Clearblue Pregnancy Test with Weeks Indicator is an over-the-counter urine hCG (human chorionic gonadotropin) test which is intended for the detection of pregnancy. The test is indicated for use from 4 days before the date of the expected period (5 days before missed period).