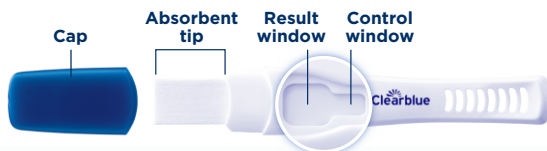


Early Detection Pregnancy Test



This home pregnancy test is an over-the-counter chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine. It is intended for use as an aid in early detection of pregnancy, in some cases as early as 6 days before the day of the missed period, i.e. as early as 5 days before the day of the expected period.¹ A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Read this leaflet carefully before testing.

- With DualSense™ Technology. See Q7.
- Don't drink lots of liquid before testing. See Q4.
- If testing early use first urine of the day. Otherwise test any time. See Q2.



Precautions

- For *in vitro* diagnostic use only
- Use once
- Store at 36°F-86°F (2°C-30°C)
- Do not use the test after its expiration date
- Not for internal use
- Keep out of the reach of children
- Discard with normal household waste
- Do not use if the foil wrapper containing the test stick is damaged
- Allow to reach room temperature for 30 minutes prior to testing if stored refrigerated

1 Take the test

Remove the test from the foil, take off the cap, and use immediately. Hold the test with the absorbent tip pointing downward, and place just the tip in either:

your urine stream



or

in a urine sample collected in a clean, dry container up to where the tip meets the plastic housing



IMPORTANT: avoid getting the plastic housing wet during sampling.
Replace the cap and lay the test stick flat.

2 Wait



Red lines will start to develop. If not, see 'Test errors'.

Wait 5 FULL MINUTES before reading your result.

IMPORTANT! Read your result within **10 minutes** of testing. Do not read results after 10 minutes.

3 Results

Pregnant

See Q5 for more information.



Two lines on the test indicates a positive result (pregnant). It does not matter how faint or dark the lines are.

A red line must be present in the control window for your result to be valid. If not, see 'Test errors'.

Not Pregnant

See Q6 for more information.



Result line
Control line



Questions and answers

1 How accurate is Clearblue®?

Early Detection Pregnancy Test is over 99% accurate in laboratory tests from the day you expect your period.²

2 What time of day can I test?

If testing before you expect your period always use the first urine of the day, as any pregnancy hormone will be more concentrated. If testing from the day you expect your period, hormone levels will be higher if you are pregnant, so you can test with urine collected from any time of the day.

3 How early can I test?

You can test from 6 days before your missed period (5 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 the expected period	-1	-2	-3	-4	-5
Pregnancies detected	>99%	>99%	98%	93%	77%

4 Does drinking liquid affect the test?

You should not drink too much liquid, including water, before testing, as it can dilute the level of any pregnancy hormone present in your urine and may affect the result.

5 My result is Pregnant. What should I do?

See your doctor as soon as possible who may confirm your pregnancy, after all clinical and laboratory findings have been evaluated.

6 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 tested before your expected period, test again when your period is due.

If you get a 'Not Pregnant' result on or after the day you expect your period, but still think you might be pregnant, see your doctor.

7 How does DualSense™ Technology work?

Though known as the 'pregnancy hormone', a very small number of non-pregnant women may have low levels of hCG in their urine. If these women use a very sensitive pregnancy test, they have a very small risk of a false positive result. This test may prevent false positives in some of these women.

8 Can any medication or medical conditions affect the result?

Always read the drug label instructions for any medication you are taking before testing. If you get unexpected results you should discuss them with your doctor.

Medications containing hCG or FSH and other hormone therapies may affect the result. Ectopic or recent pregnancy, even if not carried to full term, can cause misleading results.

The test should NOT be affected by hormone therapies containing Clomiphene citrate, common painkillers, alcohol, antibiotics, or the contraceptive pill.

9 What if I get a test error (invalid result)?

See 'Test errors' section for more information on what to do next.

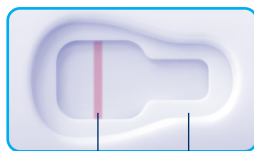
Do not disassemble device. Contains small parts. Do not eat any component of this device. If accidentally swallowed, seek medical attention.



Test errors

No red 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.



Result window Control window



www.clearblue.com

Clearblue® Helpline

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

Toll-free: **1-800-321-3279**

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

¹77% of pregnant results can be detected 6 days before your missed period (5 days before you expect your period).

²>99% accurate at detecting typical pregnancy hormone levels. Note that hormone levels vary. However, some pregnant women may not have detectable amounts of pregnancy hormone in their urine on the first day of the missed period or may have miscalculated the first day of their missed period.

The US Surgeon General 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.surgeongeneral.gov

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This home pregnancy test is intended for use as an over-the-counter integrated digital self-testing device for the qualitative detection of human chorionic gonadotropin (hCG) in a woman's urine for the determination of pregnancy. The test is indicated for use from 6 days before the day of the missed period (5 days before the day of the expected period).¹ A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Read this leaflet carefully before testing.

- Never hold test with absorbent tip pointing upwards.
- Don't drink lots of liquid before testing. See Q4.
- If testing before you expect your period use first urine of the day. See Q3.

Precautions

- For *in vitro* diagnostic use only
- Use once
- Do not freeze
- Do not use the test after its expiration date
- Not for internal use
- Store at 36°F-86°F (2°C-30°C)
- Do not use if the foil wrapper containing the test stick is damaged
- Keep out of the reach of children
- Allow to reach room temperature for 30 minutes prior to testing if stored refrigerated

1 Take the test

Remove the test from the foil, take off the cap and use immediately. Holding the test with the absorbent tip pointing downward, **either** place just the tip in:



or



Important: avoid getting the plastic housing wet during sampling.



Remove the absorbent tip of the test 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. Keeping the absorbent tip pointing downward, replace the cap and lay the test stick flat.

2 Wait

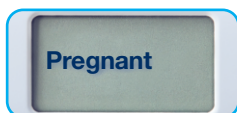
The Smart Countdown will appear on the display and each segment will appear in sequence to show the test is progressing.



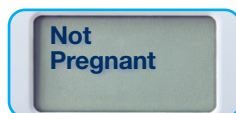
If no Smart Countdown appears see 'Test errors'.

3 Read your result

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



See Q6 for more information.



See Q7 for more information.

Questions and answers

1 How does Clearblue® work?

It detects the pregnancy hormone hCG (human Chorionic Gonadotrophin) in urine.

2 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 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 the expected period	-1	-2	-3	-4	-5
Pregnancies detected	>99%	>99%	99%	93%	78%

3 What time of day can I test?

If testing before you expect your period, always use the first urine of the day, as any pregnancy hormone will be more concentrated. If testing from the day you expect your period, hormone levels will be higher if you are pregnant, so you can test with urine collected from any time of the day.

4 Does drinking liquid affect the test?

You should not drink too much liquid, including water, before testing, as it can dilute the level of any pregnancy hormone present in your urine and may affect the result.

5 How accurate is Clearblue®?

It's over 99% accurate in laboratory tests from the day you expect your period.²

6 My result is Pregnant. What should I do?

See your doctor as soon as possible who may confirm your pregnancy, after all clinical and laboratory findings have been evaluated.

7 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 tested before your expected period, test again when your period is due.

If you get a 'Not Pregnant' result on or after the day you expect your period, but still think you might be pregnant, see your doctor.

8 How long will my result be shown on screen?

A 'Pregnant' result will be shown for up to 1 month. Read your result as soon as the result is displayed. See Q6.

A 'Not Pregnant' result will be shown for approximately 24 hours. See Q7.

Promptly dispose of the test according to local regulations.

9 Can any medication or medical conditions affect the results?

Always read the manufacturers' instructions for any medication you are taking before testing. If you get any unexpected results you should discuss them with your doctor.

Medications containing hCG can affect the result. The test should NOT be affected by hormone therapies containing Clomiphene citrate, common painkillers, alcohol, antibiotics, or the contraceptive pill.

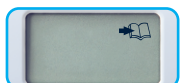
10 What if I get a test error (invalid result)?

See 'Test errors' section for information on what to do next.

Dispose of according to local regulations.

Caution: device contains batteries. Do not disassemble device, recharge or dispose of batteries in fire. Contains small parts. Do not eat any component of this device. If accidentally swallowed, seek medical attention.

Test errors

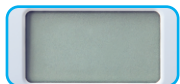


Book error

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

Clearblue® Helpline

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

Toll-free. 1-800-321-3279

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

Electromagnetic Disturbance & Compatibility: This device complies with the electromagnetic requirements specified in IEC 60601-1-2 Ed 4.0. The electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment. The device will withstand electromagnetic disturbances likely to be encountered in the home. Battery Type: Two 1.5V alkaline mercury-free LR41 button cell batteries, 41mAh capacity ea.

Caution: Risk of battery failure if exposed to temperatures above 122°F/50°C.

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Pat. - see www.swissprecisiondiagnostics.com/patents

¹78% of pregnant results can be detected 6 days before your missed period (5 days before your expected period).

²>99% accurate at detecting typical pregnancy hormone levels. Note that hormone levels vary. However, some pregnant women may not have detectable amounts of pregnancy hormone in their urine on the first day of the missed period or may have miscalculated the first day of their period.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

The US Surgeon General 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.surgeongeneral.gov



Read this leaflet carefully before testing.

Over 99% accurate 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

Read result within 10 minutes



1 Take the test

Remove from foil wrapper, take off the cap and use immediately.

Place the color change tip for **5 seconds**:



or



IMPORTANT: The color change tip will turn instantly pink showing that urine is being absorbed **but you MUST continue to hold the tip in your urine for a full 5 seconds**. Replace the cap and lay the test stick flat. If the tip does not turn completely pink, see 'Test errors'.

2 Wait



- 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 or when testing early (see Q7).

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

3 Results

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

Picture A



Result window

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 later find out you are no longer pregnant (see Q8).

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 How early can I test?

You can test from 5 days before your missed period (4 days before you expect your period). If you test before 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 of lab testing with early pregnancy samples.

Days before the expected period	-1	-2	-3	-4
Pregnancies detected	98%	97%	88%	56%

4 How does Clearblue® work?

It detects the pregnancy hormone hCG (human Chorionic Gonadotrophin) in urine. Test sensitivity is 25mIU/ml.

5 Can any medication or medical conditions affect the result?

Always read the manufacturers' instructions for any medication you are taking before testing. If you get unexpected results you should discuss them with your doctor. Medications containing hCG (e.g. Pregnyl®² and Profasi®³) can affect the result. Ectopic or recent pregnancy, even if not carried to full term, can cause misleading results. The test should **NOT** be affected by hormone therapies containing Clomiphene citrate (e.g. Clomid®⁴), common painkillers, alcohol, antibiotics, or the contraceptive pill.

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.

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'.

Pregnant Results

Picture A This is more likely 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.

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 performing the test.

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 When can I read the result?

Make sure a blue line is also present in the control window before reading your result.

A 'Pregnant' result may appear in 1 minute if testing when you have missed your period.

You **must** wait 3 minutes to confirm a 'Not Pregnant' result, or when testing before your missed period.

8 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 sadly not uncommon, affecting around 1 in 4 pregnancies. Happily, most women can go on to have a healthy pregnancy afterwards.

9 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 maximize your chances of conceiving.

Do not disassemble device. Contains small parts. Do not eat any component of this device. If accidentally swallowed, seek medical attention.

Test errors

The color 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.



Result window Control window

www.clearblue.com

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Pat. - see www.swissprecisiondiagnostics.com/patents

¹>99% accurate at detecting typical pregnancy hormone levels. Note that hormone levels vary. However, some pregnant women may not have detectable amounts of pregnancy hormone in their urine on the first day of the missed period or may have miscalculated the first day of their period.

²Pregnyl® is a registered trademark of Organon USA Inc.

³Profasi® is a registered trademark of Ares Trading S.A.

⁴Clomid® is a registered trademark of Sanofi-Aventis.

The US Surgeon General 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.surgeongeneral.gov.

Home pregnancy test. Use once. For *in vitro* diagnostic use only. Not for internal use. Keep out of the reach of children. Store at 36°F-86°F (2°C-30°C). Allow to reach room temperature for 30 minutes prior to testing if stored refrigerated. Do not use if the foil wrapper containing the test stick is damaged. Do not use the test stick after expiration date. Discard with normal household waste.