

Early Digital Pregnancy Test



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

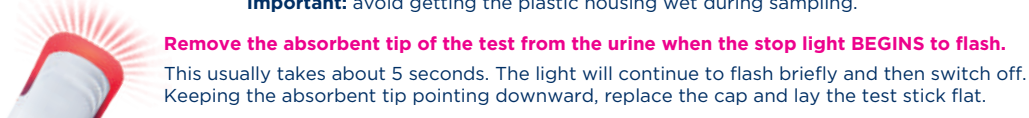
- For *in vitro* diagnostic use only
- Do not use the test after its expiration date
- Do not use if the foil wrapper containing the test stick is damaged
- Allow to reach room temperature for 30 minutes prior to testing if stored refrigerated
- Use once
- Not for internal use
- Do not freeze
- Store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

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:



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 Gonadotropin) 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 period².

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

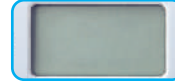


Book error

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.

Distributed by Procter & Gamble, Cincinnati, OH 45202.

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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.

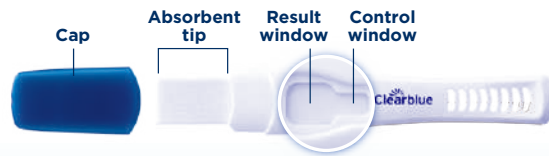
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(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

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.

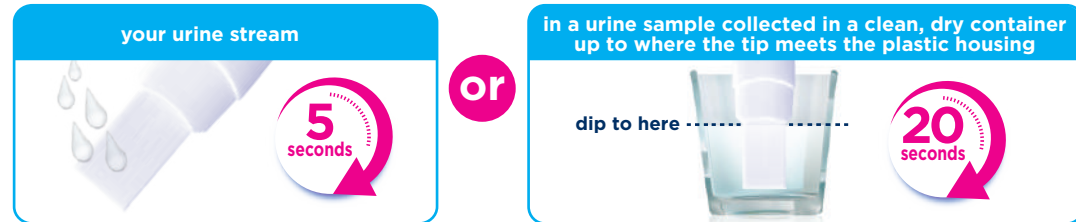
- With DualSense™ Technology. See Q7.
- Don't drink lots of liquid before testing. See Q4.
- If testing early use first urine of the day. Otherwise test any time. See Q2.

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:



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)?

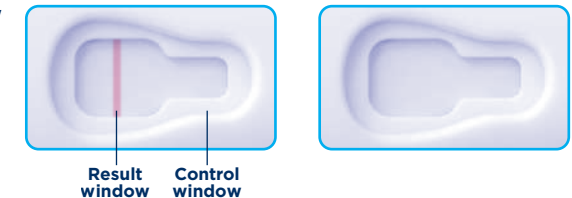
See 'Test errors' section for more information on what to do next.

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**

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