

EasyCheck[®] Pregnancy Test

INSTRUCTIONS FOR USE



Over 99% Accurate*
Sensitivity of 25mIU/mL

Overview:

The EasyCheck Pregnancy Test works by measuring the pregnancy hormone hCG (human chorionic gonadotropin) in your urine. The body starts to produce the pregnancy hormone when the fertilised egg implants in the uterus. The pregnancy hormone can be detected in the urine from as early as about 13-16 days after fertilisation in up to 90% of woman.

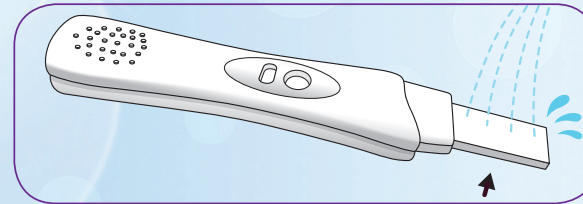
EasyCheck Pregnancy Tests have a sensitivity of 25mIU/mL and are over 99% accurate* from the day after the missed period.



EasyCheck[®] Pregnancy Test

HOW TO USE: QUICK GUIDE - PLEASE read detailed instructions overleaf before testing.

- 1 When to Test.** You can test at any time of the day, but first morning urine is preferred as it contains the highest levels of hCG and will give the most accurate result.
- 2 EITHER** Urinate on the Absorbent Tip directly until it is thoroughly wet (for at least 10 seconds) with the Absorbent Tip facing downwards. Be careful not to splash in results window.



OR If you choose, you may collect your urine in a clean, dry cup, then place the midstream Absorbent Tip in the urine for at least 15 seconds. NOTE: No urine should come in direct contact with the plastic midstream wand, only urinate on, or immerse, the Absorbent Tip.



- 3** Lay the midstream on a flat surface with the Result Window facing up, and then begin timing.
- 4** Read your results at 3-5 minutes.

READING THE RESULT WINDOW

Positive (Pregnant)

Note: One line may be lighter than the other



Negative (Not Pregnant)



RESULTS INTERPRETATION: See overleaf

Testing Early?

Studies show that only 32% of women had regular monthly cycles and were certain of their LMP.



Inter cycle differences in women have been observed to vary by more than 13 days in 30% of women.



The usual time from ovulation to implantation can vary by up to 6 days in naturally conceived pregnancies.



hCG levels rise by about 50% every day in early pregnancy, typically doubling every 2 days.



Limit fluid before testing.



Use first morning urine.



If in doubt, see your GP for a blood test.



EasyCheck Pregnancy Tests have a sensitivity of 25mIU/mL and are 99% accurate from the day of your missed period. You can test early, i.e. before your period is due, however as with all urine hCG tests the accuracy rate drops the earlier you test. If testing early ALWAYS use first morning urine as this contains the highest levels of hCG. Pregnancy tests with a sensitivity of 25mIU/mL can detect pregnancy up to 3 days before the period is due. If you receive a negative result when testing early, and still suspect pregnancy, retest 48 hours later with your first morning urine. When testing early a multi pack is recommended for this purpose of retesting. If in doubt, visit your GP.

EasyCheck® Pregnancy Test

Over 99% Accurate*
Sensitivity of 25mIU/mL

INTENDED USE

The hCG Pregnancy Test Midstream is a rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid for the early detection of pregnancy. The test is intended for in vitro diagnostic self-testing.

SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. Healthy men and healthy non-pregnant woman do not have detectable hCG by the hCG Pregnancy Test Midstream. However, healthy pregnant woman have hCG in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals. In normal pregnancy, hCG can be detected in serum as early as 7 days following conception. The concentration of hCG continues to rise rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period and peaking in the 100,000 – 200,000 mIU/mL range by 10 – 12 weeks into pregnancy. The appearance of hCG soon after conception and its subsequent rise in concentration during early gestational growth make it an excellent marker for the early detection of pregnancy. The hCG Pregnancy Test Midstream has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed period.

WARNINGS AND PRECAUTIONS

1. Read all the information in this leaflet before performing the test.
2. Do not use the kit beyond the expiration date.
3. The test stick should remain in the sealed foil pouch until use. Do not use if pouch is damaged or opened.
4. Do not touch the membrane located within the result window.
5. As with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a doctor after all clinical and laboratory findings have been evaluated.
6. Do not reuse the test midstream. Discard it in the dustbin after single use.
7. All urine specimens and used midstream should be considered potentially infectious. Avoid contact with skin.

STORAGE AND STABILITY

1. Store as packaged in the sealed pouch at room temperature (4-30 °C or 40-86 °F). The kit is stable within the expiry date printed on the labelling.
2. Once the sealed pouch is opened, the test midstream should be used within one hour. Prolonged exposure to ambient humidity will cause product deterioration.
3. DO NOT FREEZE.

ADDITIONAL EQUIPMENT REQUIRED

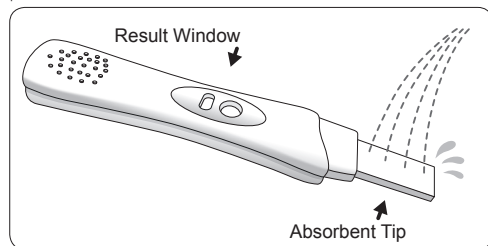
1. Timing Mechanism (such as a watch or clock).

SPECIMEN COLLECTION

The first morning urine is preferred since it generally contains the highest concentration of hCG. However, urine at any time of the day may be used.

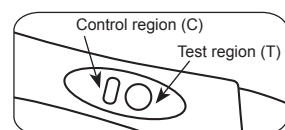
TEST PROCEDURE

Read the entire procedure carefully before performing any tests. The midstream test pouch should be brought to room temperature (15-30 °C) prior to testing. Do not open the pouches until ready to perform the test.

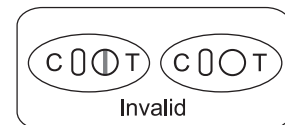


1. Remove the test midstream from its foil pouch by tearing at the notch and take the cap off the test stick.
2. To perform the test, turn the test stick so the absorbent tip is pointing in a downward direction and hold the test stick in your stream of urine so the urine makes contact with the absorbent area. Hold it for at least fifteen seconds so that adequate urine goes into the absorbent part of the tip. Do not allow urine to splash into the result window. NOTE: If you prefer, you can urinate into a clean and dry container, then dip only the Absorbent Tip of the midstream into the urine for at least 10 seconds.
3. Re-cap the pregnancy test stick and lay the test stick flat on a horizontal surface with the result window facing upwards.
4. Wait for red-colored lines to appear. The test should be read in approximately 3-5 minutes. Do not interpret results after 5 minutes.

READING THE RESULT WINDOW



NOTE: One line may be lighter than the other



INTERPRETATION OF RESULTS

PREGNANT: Two distinct red-coloured lines will appear, one in the test region (T) and one in the control region (C). You can assume that you are pregnant. You should consult your doctor.

NOTE: The intensity of the red-coloured line in the test-region (T) may vary depending on the concentration of hCG present in the specimen. Therefore, any shade of red colour in the test region should be considered positive.

NOT PREGNANT: Only one red-coloured line appears in the control region (C). No apparent red or pink line appears in the test region (T). You can assume that you are not pregnant.

INVALID: Control band fails to appear. The result is invalid if no red-coloured line appears in the control region (C), even if a line appears in the test region (T).

NOTE: Insufficient specimen volume or incorrect testing procedural techniques are the most likely reasons for control-line failure. Review the procedure and repeat the test with a new midstream test. If the problem persists, please contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A coloured line appearing in the control region (C) is considered an internal positive procedural control, indicating proper performance and reactive agents. A clear background in the Result Window can be seen as a basis for effective testing, and is considered an internal negative procedural control. If the test has been performed correctly and reagents are working properly, the background will be clear to give a discernable result. If the test line is weak, it is recommended that the test be repeated with the first morning specimen obtained 48-72 hours later.

LIMITATION

1. Drinking too much fluid before taking the test may cause a false-negative result. For the most accurate results, take the test first thing in the morning when your urine is the most concentrated.
2. Very low levels of hCG (less than 50mIU/mL) are present in urine specimens shortly after implantation. A test result that is weakly positive should be confirmed by re-testing with a first morning urine specimen collected 48 hours later.
3. Certain fertility medications which contain hCG (such as Pregnyl, Profasi, Novarel) can give a false-positive result. Alcohol, oral contraceptives, birth control pills, analgesics (pain killers), antibiotics or hormone therapies that do not contain hCG should not affect the test result.
4. A number of medical conditions other than pregnancy, including ovarian cyst, choriocarcinoma or ectopic pregnancy (pregnancy outside the uterus) can cause elevated levels of hCG.
5. Using the test midstream within 8 weeks of giving birth or having a miscarriage may also cause a positive result. You should ask your doctor for help in interpreting your test result if you have had the experience of pregnancy as described above recently.

QUESTIONS AND ANSWERS

1. Q: How soon after I suspect that I am pregnant can I take the test?
A: You can test your urine as early as the first day you miss your period.
2. Q: Do I have to test with first morning urine?
A: You can perform the test at any time of the day. However, your first morning urine is usually the most concentrated of the day and would have the most hCG in it.
3. Q: How do I know the test was run properly?
A: The appearance of a coloured line in the control region (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed.

4. Q: Can test results be interpreted after more than 5 minutes?
A: No. Test results must be read within 5 minutes. Though a positive result should not change for several days, a negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading.
5. Q: What should I do if the test result shows that I am pregnant?
A: Consult your doctor to confirm the result and for advice on pregnancy.
6. Q: What should I do if the test result shows I am not pregnant?
A: It means no hCG has been detected in your urine and you are probably not pregnant, if you do not start your period within a week of its due date, repeat the test with a new test stick. If you receive the same result after repeating the test and you do still not get your period, you should see your doctor.
7. Q: How accurate is the test?
A: The test has shown to be over 99% accurate in laboratory tests when the hCG level is 25mIU/mL or greater. This level is normally reached by the first day of the missed period.

CROSS REACTIVITY

The following potentially interfering substances were added to either hCG negative urine specimens or hCG positive urine specimens, none of the substances at the concentration tested interfered in the assay.

Acetaminophen	20mg/dl
Acetosalicic Acid	20mg/dl
Ascorbic Acid	20mg/dl
Atropine	20mg/dl
Caffeine	20mg/dl
Gentisic Acid	20mg/dl
Glucose	2g/dl
Hemoglobin	10mg/dl
Ampicillin	20mg/dl
Tetracycline	20mg/dl
Bilirubin	2mg/dl

INDEX OF SYMBOLS

	Consult instructions for use		Do not reuse		Manufacturer
	For in vitro diagnostic use		Use by		Authorized representative
	Store between 4-30 °C		Lot		Lot number

EASYCHECK® is a trade mark.

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* In laboratory tests

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