

Information Leaflet

Please read all the information in this package insert before performing the test.

- Fast, easy to read result.
- Accurate Result: 99% accurate at first day of missed period.
- Convenient: You can test at any time of the day but the test is most sensitive with first morning urine.
- Can be used as early as 4 days before your missed period. Most accurate on the first day of the missed period.

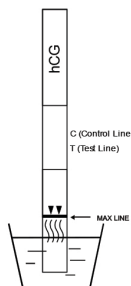
Kit Contents

- Either 1 or 2 Pregnancy Tests (each in foil pouch)
- Package insert
- Timer (Not Provided)
- Specimen Collection Cup (Not Provided)

How to use

Allow Pregnancy Test to reach room temperature (15-30°C).

- 1 Remove the Pregnancy Test Strip from the foil pouch (USE WITHIN 1 HOUR).
- 2 Urinate into a clean, dry cup or container.
- 3 Place the Pregnancy Test Strip into the urine (Note: Do Not dip past the MAX line) for 10 seconds.
- 4 Remove the Pregnancy Test Strip after 10 seconds and start the timer immediately.
- 5 Read the results at 3 minutes, do not read after 10 minutes.



Reading the Results

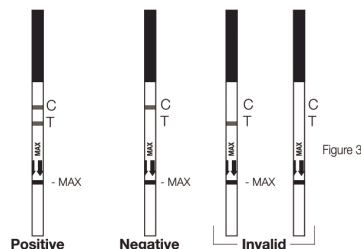


Figure 3

PREGNANT

Two distinct coloured lines appear. One line should be in the Control Region (C) and another line should be in the Test Region (T). One line may be lighter than the other; they do not have to match. This means you are probably pregnant.

NOT PREGNANT

One coloured line appears in the Control Region (C). No line appears in the Test Region (T). This means that you are probably not pregnant.

INVALID

The result is invalid if no coloured line appears in the Control Region (C), even if a line appears in the Test Region (T). Insufficient volume of urine or incorrect procedure are the most likely reasons for an invalid result. You should repeat the test with a new Pregnancy Test.

Questions and Answers

Q: How does the test work?

A: The Pregnancy Test detects a hormone in your urine that your body produces during pregnancy (hCG-human chorionic gonadotropin). The amount of pregnancy hormone increases as pregnancy progresses.

Q: How soon after I suspect that I am pregnant can I take the test?

A: You can test your urine as early as 4 days before your missed period, however the test is most accurate on the first day of the missed period.

Q: Do I have to test with first morning urine?

A: Although you can test at any time of the day, your first morning is usually the most concentrated of the day and would have the most hCG in it. Do not drink excessively before taking the test.

Q: How will I know that the test worked?

A: The appearance of a coloured line in the Control Region (C) tells you that you followed the test procedure properly and the test has worked.

Q: Do I have to wait the full 3 minutes before reading my results?

A: Yes. It is important that you wait to see if a line appears in the Test Region (T) before reading the result. Although the line in the Control region (C) may appear quickly, a line in the Test Region (T) may take up to 3 minutes to become visible.

Q: If I see a line in both the Test and Control Regions, but one line is darker than the other, am I pregnant?

A: Yes. Even if one line is darker than the other, this result indicates that you are probably pregnant.

Q: How accurate is the test?

A: Clinical evaluations have shown that the Pregnancy Test is more than 99% accurate from the day your missed period is due.

Q: How sensitive is the test?

A: The Pregnancy Test detects hCG in urine at a concentration of 25mIU/mL or greater. The presence in the urine sample of LH (300mIU/mL), FSH (1,000mIU/mL) and TSH (1,000pIU/mL) did not interfere with the expected result.

Q: What should I do if the result shows that I am pregnant?

A: It means that your urine contains hCG and you are probably pregnant. See your doctor to confirm that you are pregnant and to discuss the steps you should take.

Q: What should I do if the result shows that I am not pregnant?

A: It means that no hCG has been detected in your urine and probably you are not pregnant. If you do not start your period within a week of its due date, repeat the test with a new Pregnancy Test. If you obtain a negative result after repeating the test and you still do not start your period, you should see your doctor.

Q: Do common medications or metabolites affect the test?

A: At the concentrations shown, none of the following substances affected the test results: Acetaminophen (Paracetamol 20mg/dL), Acetoacetic acid (2g/dL), Acetylsalicylic acid (aspirin 20mg/dL), Albumin (2G/dL), Bilirubin (2mg/dL), Caffeine (20mg/dL), Codeine (10mg/dL), Ephedrine (20mg/dL), Ethanol (1%), Gentisic acid (20mg/dL), Glucose (2g/dL), Haemoglobin (1mg/dL), Methadone (10mg/dL), Methanol (10%), Phenylpropanolamine (20mg/dL), Phenothiazine (20mg/dL), Salicylic acid (20mg/dL).

If you have questions about the instructions or your results, call our Helpline 0800 0430318.

The Pregnancy Test is a rapid lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG.

Limitations

- If a woman has recently been pregnant (even if not carried to full term), a false "Pregnant" result may be obtained.
- A number of conditions other than pregnancy, including trophoblastic diseases and certain non-trophoblastic neoplasms including testicular tumours, prostate cancer, breast cancer and lung cancer cause elevated levels of hCG.
- In cases where very high levels of hCG are present (>500,000mIU/mL), a false negative result can occur due to a "prozone" effect.
- Excessive fluid intake should be avoided before testing, as a "Not Pregnant" result may be obtained if the urine sample is too dilute.
- 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 (e.g. clomiphene citrate), painkillers, alcohol, antibiotics and hormonal contraceptives (e.g. contraceptive pill) should not affect the results.
- A false positive test result can be caused by a number of conditions other than pregnancy which produce raised levels of hCG (e.g. breast and lung cancer, or trophoblastic disease).
- A diagnosis of pregnancy by this test should be confirmed by a physician who will evaluate all clinical and laboratory findings.
- Do NOT take any medical decision based on the results of this test without consulting your doctor.
- The Pregnancy Test is not reusable.

Warnings

- Keep out of the reach of children.
- For in vitro diagnostic use.
- Not to be taken internally.
- Do not eat the desiccant in the package.
- The Pregnancy Test is not reusable.
- Do not open the test foil pouch until you are ready to start the test.
- Do not use if pouch is torn or damaged.
- Dispose of the used test hygienically in domestic waste.

Storage

- This device is for self-testing.
- Do not use after the expiration date printed on the foil pouch.
- Store in a dry place at 4-30°C.
- Do not freeze.

Index of Symbols		Attention, see instructions for use		Tests per kit		Manufacturer
		For in vitro diagnostic use only		Use by		Do not reuse
		Store between 4 - 30°C		Lot Number		Catalog #
		Do not use if packaging is damaged		Authorised representative		Consult Instructions For Use