

Package Insert

Pregnancy Test Strip

REF

SFHC 101-1&2 (1&2 Tests) English

For Self Testing

PRINCIPLE

The Pregnancy Test Strip is a rapid, one-step lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the detection of pregnancy. The test utilises a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by dipping the end of the strip in a sample of urine and obtaining the result from the formation of coloured lines on the strip.

Human chorionic gonadotropin (hCG) is a hormone produced by the developing placenta shortly after fertilisation. In normal pregnancy, hCG can be detected in urine as early as 7 days following conception. Levels of hCG rise rapidly, frequently exceeding 100mIU/mL by the first missed menstrual period, and peaking at 100,000-200,000mIU/mL about 10-12 weeks into pregnancy.

PRECAUTIONS

Please read all the information in this package insert before performing the test. Pay particular attention to the position of the C and T lines

- Do not use after the expiration date printed on the foil pouch
- Store in the sealed pouch in a dry place at 4-30°C. Do not freeze.
- Do not use if pouch is torn or damaged. or
- Do not open the foil pouch until you are ready to start the test.
- Do not reuse the test device. Dispose of hygienically in domestic waste.
- Do not touch the membrane.
- Treat urine samples and used devices as potentially infectious. Avoid contact with skin.
- 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.

KIT CONTENTS

- 1 or 2 Pregnancy Test Strips (each in foil pouch)
- Package insert

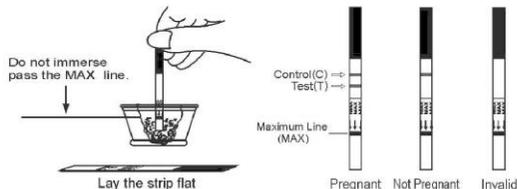
MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Sample container
- Disposable gloves (optional)

SPECIMEN

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG. However, urine specimens collected at any time of the day may be used.

INSTRUCTIONS



1. Allow the Pregnancy Test Strip and urine sample to reach room temperature (15-30°C) before opening the foil pouch
2. Remove the Pregnancy Test Strip from the pouch and use it as soon as possible.
3. With the arrows pointing towards the urine specimen, immerse the test strip vertically in the urine for at least 5 seconds. **Do not pass the maximum line (MAX) on the test strip when immersing the strip.**
4. Lay the test strip down on a flat, non-absorbent, clean surface, start the timer and wait for the red line(s) to appear.
5. Read the result after 5 minutes. Do **not** read the result after 15 minutes.

READING THE RESULTS

POSITIVE

Two red-purple coloured lines appear. One line should be in the Control region (C) and another line should be in the Test region (T). This means that you are probably pregnant.

NEGATIVE

One red-purple coloured line in the Control region (C). No apparent red or pink line appears in the Test region (T). This means that you are probably not pregnant.

INVALID

The result is invalid if the Control Line (C) fails to appear. Insufficient volume of urine or incorrect procedure are the most likely reasons for an invalid result. Review the procedure and repeat the test with a new test strip. If the problem persists, discontinue using the test kit and contact the Customer Care Line below.

QUALITY CONTROL

A red-purple line appearing in the control region (C) confirms that the test is performing properly. It indicates that sufficient urine has been applied to the strip and that the correct procedure has been carried out.

LIMITATIONS

1. Alcohol may interfere with the test result. Do not use the test after drinking alcohol.
2. If a woman has recently been pregnant, (even if not carried to full term), a false “Pregnant” result may be obtained. Occasionally, urine specimens containing less than 25mIU/mL hCG can also give a positive result.
3. Ectopic pregnancy, ovarian cysts, menopause and some very rare medical conditions can give misleading results.
4. In cases where very high levels of hCG are present (>500,000mIU/mL), a false negative result can occur due to a “prozone” effect
5. Excessive fluid intake should be avoided before testing. A “Not Pregnant” result may be obtained if the urine sample is too dilute.
6. 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.
7. Other fertility therapies (e.g. clomiphene citrate), painkillers and hormonal contraceptives (e.g. contraceptive pill) should not affect the results.
8. A number of conditions other than pregnancy including trophoblastic disease and certain non-trophoblastic neoplasms, including testicular tumours, prostate cancer, breast cancer and lung cancer, cause elevated levels of hCG. Therefore the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
9. A diagnosis of pregnancy by this test should be confirmed by a physician who will evaluate all clinical and laboratory findings.
10. Do **NOT** take any medical decision based on the results of this test without consulting your doctor.
11. The Pregnancy Test Strip is not reusable.

QUESTIONS & ANSWERS (Call our Customer Care Line 0800 0430318)

1. **Q: How does the test work?**
A: The Pregnancy Test Strip detects a hormone (hCG) in your urine that your body produces during pregnancy. The amount of hormone increases as pregnancy progresses.
2. **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 after you miss your period.
3. **Q: Do I have to test with first morning urine?**
A: Although you can test at any time of the day, your first morning urine is usually the most concentrated and likely to have the most hormone (hCG) in it. Do not drink excessively before taking the test.
4. **Q: How accurate is the test?**
A: Clinical evaluations have shown that the Pregnancy Test Strip is more than 99% accurate at 25mIU/mL of hCG.
5. **Q: How sensitive is the test?**
A: The Pregnancy Test Strip detects hCG in urine at concentrations of 15mIU/mL or greater. The presence in the urine sample of LH (300mIU/mL), FSH (1,000mIU/mL) or TSH (1,000mIU/mL) did not interfere with the expected test result.
6. **Q: Do common medications affect the test?**
A: At the concentrations shown, none of the following substances affected the test results: Acetaminophen (Paracetamol 20mg/dL), Acetylsalicylic acid (Aspirin 20mg/dL), Ascorbic acid (Vitamin C 20mg/dL), Atropine (20mg/dL), Caffeine (20mg/dL), Gentamic acid (20mg/dL), Glucose (2g/dL), Haemoglobin (1mg/dL), Ampicillin (20mg/dL) and Tetracycline (20mg/dL).
7. **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.
8. **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 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 Pregnancy Test Strip. If you receive the same result after repeating the test and you still do not get your period, you should see your doctor.
9. **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 correctly and the proper amount of urine was absorbed.

	Attention, see instructions for use		Tests per kit		Manufacturer
	For <i>in vitro</i> use only		Use by		Do not re-use
	Store between 4 - 30°C		Lot Number	REF	Catalogue #

Manufacturer

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Customer Care Line 0800 0430318

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