



# 6 day early\* Pregnancy Tests

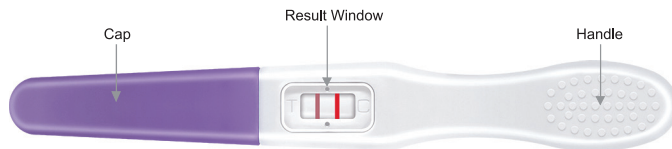
\*The test can be used as early as 6 days before your missed period (5 days before day of expected period). The test is most accurate on the day your period is due.

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## Information Leaflet

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



- **Fast and easy to read result.**
- **Accurate Result: 99% accurate on first day of expected period.**
- **Convenient: You can test at any time of the day but the test is most sensitive with first morning urine.**

## HOW TO USE

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

- 1 Remove the Pregnancy Test from the foil pouch and use within 1 hour. Hold the test by the thumb grip and remove the cap but do not discard it.

### Either

Urinate into a clean, dry glass container, then, holding the test upright; dip only the Absorbent Tip into the urine for at least 10 seconds.

**NOTE: Do not allow urine to come into contact with the Result window.**



### Or

Hold the test by the thumb grip with the exposed Absorbent Tip pointing downwards directly into your urine stream for at least 10 seconds until thoroughly wet. **NOTE: Do not allow urine to come into contact with the Result window.**



- 2 After removing the test from your urine, immediately replace the cap over the absorbent tip, lay the test on a flat surface with the test and control window facing upwards, and then begin timing.

### Note:

As the test begins to work, you will see the formation of a reddish-purple line in the Control region (C), indicating the test is working properly.



- 3 Some positive results may be observed after 1 minute depending on the concentration of hCG but leave for up to 3 minutes for a line to appear in the Test region.

### IMPORTANT!

Read results within 10 minutes. Discard the test stick after this time. After 10 minutes you should disregard any change in the result or any lines that appear after this time.



- 4 If no coloured line appears in the Control region (C) within 5-10 minutes the test has not worked properly.

## READING THE RESULTS



### 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.

**IF YOU TEST POSITIVE ON A DAY BEFORE YOUR EXPECTED PERIOD, PLEASE RE-TEST ON THE DAY OF YOUR EXPECTED PERIOD TO CONFIRM THE RESULT.**



### 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.

# 6 day early\* Pregnancy Tests

## 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 6 days before your missed period (5 days before day of expected 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 urine 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 that 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 10mIU/mL or greater. The presence in the urine sample of LH (300mIU/mL), FSH (1,000mIU/mL) and TSH (1,000µIU/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%), Gentic acid (20mg/dL), Glucose (2g/dL), Haemoglobin (1mg/dL), Methadone (10mg/dL), Methanol (10%), Phenylpropanolamine (20mg/dL), Phenthiazine (20mg/dL), Salicylic acid (20mg/dL).

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. The test is conducted by urinating on Absorbent Tip of the Pregnancy Test or immersing the Absorbent Tip in urine and obtaining the result from the coloured lines in the result window.

## CLINICAL RESEARCH DATA

A study was carried out to assess the accuracy of the Suresign Ultra Early Pregnancy Test at daily intervals prior to the day the period is due. The following table shows these results:

Number of days before expected period	5 days before	4 days before	3 days before	2 days before	1 day before	Day period is due	Day after period is due
Percentage accuracy of result	76%	96%	99%	99%	99%	99%	99%

## 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.

## WARNINGS

- Keep out of the reach of children.
- For in vitro diagnostic use.
- Not to be taken internally.
- Do not eat the desiccant.
- 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.
- This device is for self-testing.
- Do not use after the expiration date printed on the foil pouch.

## SYMBOLS

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

## STORAGE

- Store in a dry place at 4-30°C.
- Do not freeze.

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FHC-U103H  
146096101  
REV 01/20

