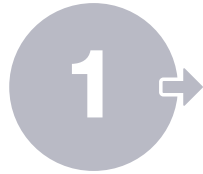


QUICK START GUIDE



Remove the Digital Pregnancy Test Stick from the foil pouch. Hold the Test Stick by the pink arrow. **DO NOT** touch the Absorbent Tip.

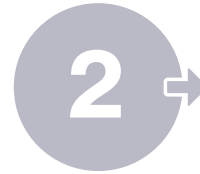
DIGITAL
PREGNANCY TEST
INSTRUCTIONS FOR USE



Or Alternative Use:

Hold the Test by the thumb grip with the exposed Absorbent Tip pointing downwards directly into your urine stream for at least 5 seconds until it is thoroughly wet.

NOTE: Do not get the Digital Reader Wet. If the Digital Reader should get wet refer to Question 4.



Insert the Test Stick into the Digital Reader by lining up the Digital Reader & the Test Stick pink arrows, until it clicks. A 🕒 symbol will appear on the Display Screen. **DO NOT** use until the 🕒 symbol is displayed.

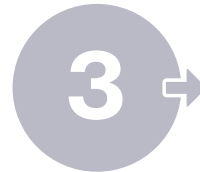
NOTE: Do not drink excess liquid or urinate for 2 hours before you start the test.



The Recommended Use:

Urinate into a clean, dry container. Then holding the Test upright, dip only the Absorbent Tip into the urine for 15 seconds.

NOTE: Do not get the Digital Reader Wet. If the Digital Reader should get wet refer to Question 4.



After removing the Test from your urine, lay the Test on a flat surface with the display screen facing upwards. The 🕒 symbol will start blinking in a few moments to show that the test is in progress & results will appear in a few minutes.

NOTE: Do not eject the test stick while waiting for the results.



If the display screen does not show a blinking 🕒 the test has not worked properly.



Please **turn over** to continue...



DIGITAL PREGNANCY TEST

INSTRUCTIONS FOR USE

PLEASE READ THIS LEAFLET CAREFULLY BEFORE BEGINNING YOUR TEST



Contents

- 1x Digital Reader
- 2x Digital Pregnancy Test Sticks (each in foil pouch)
- 1x Instruction for Use

Reading The Results



YES+

hCG has been detected, this means you may be pregnant. Refer to Question 5.



NO-

No hCG has been detected, this means that you are probably not pregnant. Refer to Question 6.



?

The result is invalid, an error has occurred. Refer to Question 7.

Questions & Answers

Q1: How does the test work?

A: The Digital Pregnancy Tests unique technology can be used to identify human Chorionic Gonadotropin (hCG) in your urine which can be an indicator of pregnancy. Human Chorionic Gonadotropin (hCG) is a hormone produced by the developing placenta shortly after fertilisation. In normal pregnancy, hCG can be detected as early as 7 days following conception. Levels of hCG rise rapidly, frequently exceeding 100mIU/mL by the first missed menstrual period & peaking at 100,000-200,000mIU/mL about 10-12 weeks into pregnancy.

Q2: What time of day should I use the test?

A: You may test at any time of the day but the test is most sensitive with first morning urine. Note: The Test Strip must be performed as the clock symbol appears, if opened & unused immediately the Test Strip should be discarded.

Q3: I have assembled the test, but the Display Screen has remained blank. What does it mean?

A: Eject the Test Stick & start again from Step 1. Otherwise, please contact our Customer Careline: 0800 0430318.

Q4: What if the Digital Reader gets wet?

A: You should wipe it dry but if it becomes very wet, it may be damaged & you should purchase a new test kit.

Q5: What should I do if I get a Positive result (YES+)?

A: It means that your urine contains hCG & you are probably pregnant. See your doctor to confirm this result & to discuss your next step.

Q6: What should I do if I get a Negative result (NO-)?

A: There is a possibility that you are not pregnant or your hCG levels are not high enough yet to be detected. If your period does not start, repeat the test in 3 days' time, using first morning urine. If you still receive a Negative result & your period does not start within a week you should consult your doctor.

Q7: Why have I received an Invalid result?

A: ? symbol indicated that an error has occurred during testing. You should re-test with a new Test Stick. Eject the Test Stick & dispose of it. Wait at least 10 minutes or until the Display Screen is blank.

Q8: I have done a test, but the clock symbol has not started blinking. What does this mean?

A: The test has not been done correctly. Eject the Test Stick & dispose of it. Wait at least 10 minutes or until the Display Screen is blank. You should test again, using a new Test Stick & following the directions carefully.

Q9: I have done a test, but the Display Screen is blank. What is wrong?

A: It can either mean that you have not applied enough urine to the Test Stick or missed the result display time. You should re-test with a new Test Stick. Eject the Test Stick & dispose of it. Wait at least 10 minutes or until the Display Screen is blank.

Q10: How long will my results show on the Display Screen?

A: Test results are displayed for approximately 6 minutes & then goes blank.

Q11: Do any medical conditions or drugs affect the test?

A: Ectopic pregnancy, ovarian cysts, menopause & some rare medical conditions can give misleading results. Alcohol may interfere with the test result. Do not use the test after drinking alcohol. Fertility drugs containing hCG can give misleading results. These fertility drugs are usually given by injection & testing too soon after administration may give a false "Pregnant" result. Other fertility therapies, painkillers & hormonal contraceptives (e.g. contraceptive pill) should not affect the results.

Q12: How accurate is the test?

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

Q13: How sensitive is the test?

A: The Digital Pregnancy Test detects hCG in urine at a concentration of 25mIU/mL or greater.

Q14: Can I reuse the Digital Reader?

A: The Digital Reader should only be used with the tests supplied. Once activated & stored the device may lose power & the test may not operate as required.

If you have any questions about the instructions or your result, call our Helpline: 0800 0430318

Limitations

- Alcohol may interfere with the test result. Do not use the test after drinking alcohol.
- Recent pregnancies, (even if not carried to full term), may give a false Positive result.
- Ectopic pregnancy, ovarian cysts, menopause & some very rare medical conditions can give misleading results.
- Fertility drugs containing hCG can give misleading results. Testing too soon after administration may give a false Positive result.
- 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 & lung cancer, or trophoblastic disease).
- A Positive result should be confirmed by a physician who will evaluate all clinical & laboratory findings.
- Do not take any medical decisions based on the results of this test without consulting your doctor.
- The Digital Pregnancy Test Sticks are not reusable.

Warnings

- Keep out of the reach of children.
- For in vitro diagnostic use only.
- Not to be taken internally.
- Do not eat the desiccant in the test foil.
- Open the test foil pouch when ready to begin testing.
- Do not touch the absorbent tip of the Test Stick.
- Do not use if pouch is torn or damaged.

- Dispose of Test Sticks with domestic waste.
- Dispose of the Digital Reader battery in accordance with Directive 2012/19/EC or local Waste Disposal Regulations.
- This device is for self-testing.

Storage

- Do not use the test after the printed expiration date.
- Store in a dry place at 4-30°C. Do not freeze.

| | | | |
|--|---|--|----------------------|
| | 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 |
| | Dispose in accordance with Directive 2012/19/EC | | |
| | CIGA Healthcare Ltd Kilcran House, Kildowney Rd, Ballymena, BT44 9EY, UK | Website: suresign.com Email: info@suresign.com REF: IFU RSDFHCI08-25 REV: 12/17 | |