



Early Detection Pregnancy Test 6 day early*

INSTRUCTIONS FOR USE

PLEASE READ ALL INFORMATION IN THE INSTRUCTIONS FOR USE BEFORE USING THE TEST!

For Over-the-Counter use.

REF: 01001-1

*This test can be used as early as six (6) days before the day of the missed period.

INTENDED USE

The SureSign Early Detection Pregnancy Test is used for qualitative detection of human chorionic gonadotropin (hCG) in human urine. This test is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period (i.e. as early as five (5) days before the day of the expected period). It is intended for use by people who would like to find out whether they are pregnant in a home environment. **This device is intended for home-use only. Only for use outside the body. For over-the-counter use.**

Important note regarding positive results:

Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

COMPONENTS OF THE TEST KIT

Materials provided

1. One or more test pouches each containing a test and a desiccant.
2. Leaflet with instructions for use.

What else do you need?

1. Urine collection cup.
2. Timer or clock.

STORAGE CONDITIONS AND SHELF LIFE

1. Store in a dry place at 35.6 - 86°F (2 - 30°C), **DO NOT** freeze.
2. The product is stable until the expiration date printed on the foil pouch and outer packaging.
3. Use the test within 1 hour of removing from the foil pouch.

WARNING AND PRECAUTIONS

1. This product is only for *in vitro* testing of human urine. **NOT** for internal use.
2. **DO NOT** make any decision of medical relevance without first consulting your doctor.
3. This product is for single-use. **DO NOT** reuse.
4. Keep out of the reach of children.
5. The desiccant in the foil pouch is for storage purposes only. **DO NOT** swallow.
6. **DO NOT** use the product if damaged or its pouch is punctured or not well sealed.
7. **DO NOT** use the product after the expiration date.
8. Please follow local regulations to discard used product.

LIMITATIONS

1. Low levels of hCG may be present in non-pregnant people. Because this test detects low levels of hCG, positive results may occur even if you are not pregnant. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.
2. This device is intended for home-use and not intended for clinical-care settings.
3. A confirmed pregnancy diagnosis should only be made by a doctor.

SAMPLE REQUIREMENTS

Collect your urine in a clean, dry urine collection cup, or directly urinate on the absorbent tip of the test. It is preferable to collect the urine sample first thing in the morning, however, urine samples collected at any time of the day can be used for the test. Please perform the test immediately after urine collection.

TAKE THE TEST

The test should be performed at room temperature 59 ~ 86°F (15 ~ 30°C).

1. Remove the test from foil pouch, take off the cap and use immediately.

Test in urine stream: Hold the test with the absorbent tip pointing downwards into your urine stream (Fig.2). Keep the absorbent tip in the urine stream for at least 5 seconds.

Caution: Make sure that only the absorbent tip is wet during sampling and that other parts of the test remain dry.

Or Test in a urine collection cup: Dip the entire absorbent tip into the collected urine for at least 5 seconds (Fig.3). **Caution:** Make sure that only the absorbent tip is wet during sampling and that other parts of the test remain dry.

2. After removing the test from your urine, immediately replace the cap, lay test flat with the result window facing upwards, and then begin timing (Fig.4). **Caution:** Never hold the test with the absorbent tip pointing upwards during testing.
3. The result should be read within 3-10 minutes. Do not read result after 10 minutes.

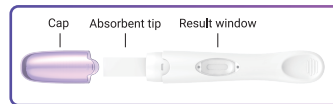


Fig.1 Test



Fig.4 Lay the test flat with the result window facing upwards.

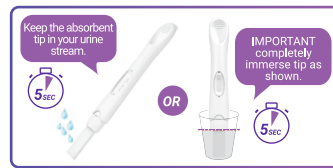
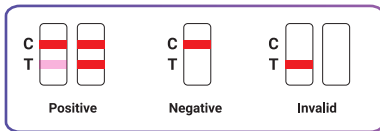


Fig.2 Test in urine stream Fig.3 Test in a urine collection cup



Fig.5 WAIT 3 mins before checking results. Do not read results after 10 minutes.

READ YOUR RESULT



Positive (pregnant): TWO distinct colored lines appear. A colored line is visible in both the Control Zone (C) and the Test Zone (T), the test result is positive and valid. It indicates you are pregnant (See Q1).

Negative (not pregnant): Only ONE colored line appears in the Control Zone (C), and no apparent line in the Test Zone (T), the result is negative and valid. It indicates you are not pregnant (See Q2).

Invalid: No colored line appears in the Control Zone (C), even if a colored line appears in the Test Zone (T), it indicates that the test is invalid (See Q5).

NOTE: If the color in the Test Zone is very faint, it is recommended to repeat the test in 48 hours or if the test shows a negative result, but you suspect that you may be pregnant, repeat the test after a few days.

QUESTIONS & ANSWERS

1. My result is Pregnant. What should I do?

The positive test result may indicate pregnancy. See your doctor to confirm, who can advise you on your next steps.

2. My result is Not Pregnant. What does this mean?

When the test result is negative, it indicates that you may not be pregnant. If pregnancy is still suspected, test again using a new device with morning urine 48-72 hours later. If you still get a negative result and your period is late, you should see your doctor.

3. How does the Suresign™ Early Detection Pregnancy Test work?

The Suresign™ Early Detection Pregnancy Test detects a very small concentration of the hCG in your urine, your body produces hCG during pregnancy. The amount of hCG increases as pregnancy progresses.

4. Can any medication or conditions affect the results?

Medications containing hCG can affect the result. A number of conditions other than pregnancy cause elevated levels of hCG and could cause incorrect results. Unclean urine collection cup or improper operation will also produce incorrect results.

5. How do I know that the test was run properly?

The appearance of a colored line in the Control Zone (C) indicates that the test was performed properly. If no colored line appears in the Control Zone (C), even if a colored line appears in the Test Zone (T), it indicates that the test result is wrong or invalid. Please make sure that the test instructions are followed, and retest with a new device.

6. Can test results be interpreted after more than 10 minutes?

Test results must be read in 10 minutes. A negative result may change to a false positive within minutes after the end of the 10-minute testing period, which would not be an accurate reading. It is always best to read the result at 3 minutes and then discard the test to avoid confusion.

7. How early can I test?

You can test from 6 days before your missed period (5 days before your expected period). See the chart below for test results:

Days Before Missed Period	-1	-2	-3	-4	-5	-6
% Samples Positive for hCG	>99%	>99%	>99%	>99%	97%	77%

ASSISTANCE



KINGSWAY
PHARMACEUTICALS

Distributed by

Kingsway Pharmaceuticals dba NFI, LLC
636 Shelby Street, Suite 300, Bristol, TN 37620

Questions or Comments?

1.800.432.9334 (Monday to Friday 8:45am - 4:45pm Eastern)

info@kingswaypharma.com US.SURESIGN.COM

MADE IN CHINA

SS-PRD-25-090-IFU