

Methods of performing the test

Please read both sides of these instructions carefully before performing the test.

Do not open the foil pack until you are ready to perform the test.

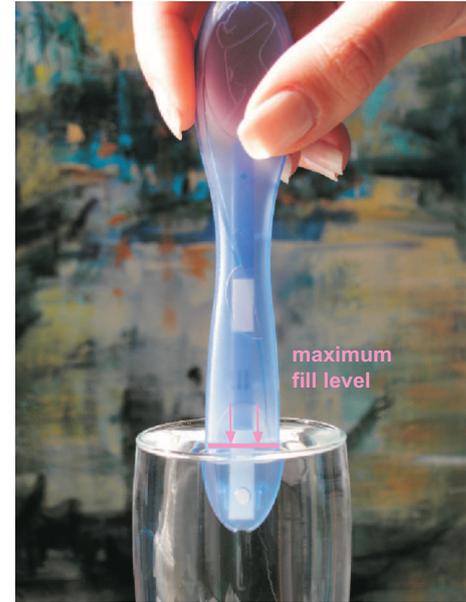
It is recommended that an early-morning urine sample be used, since this is the time of day when the concentration of hCG is highest.

DIRECTLY



Hold the end of the test stick under a light flow of urine for about 3 seconds.

WITH CUP



Dip the test stick in a collected urine sample for about 3 seconds, observing the maximum fill level.



Early Pregnancy Test with Week Determination

Put the stick aside onto the foil pack and evaluate your test result after exactly **5 minutes**. Please have the instruction for the test interpretation (week estimation) ready in order to be able to interpret the result correctly. For more information please see reverse side.

Evaluation



If **two purple lines** appear in the result window, hCG has been detected. You can assume that you are **pregnant**, even if the lower of the two coloured lines is only very faint. Please use the enclosed instruction for test interpretation after **exactly 5 minutes** in order to estimate your pregnancy week.

If the test line is faint, this can indicate a very early stage of pregnancy, or can result from an improperly implanted embryo. Antenatal care is important, so please visit your doctor promptly in order to safeguard both your own health and that of your baby. Avoid any potential risks to the embryo, such as x-rays.



If there is only **one purple line** in the upper half of the result window, this means that the test was performed correctly, but that no hCG could be detected. You can assume that you are **not pregnant**.

If your period is more than one week late, we would recommend that you see your doctor. If your period is overdue, you should avoid potential risks such as x-rays.

The test is considered **invalid** if the result field shows **no purple line** after 5-10 minutes, or if only the test line appears.

A positive or negative test result cannot be evaluated reliably after more than 20 minutes.

Possible reasons for an invalid result could be damaged foil packaging, incorrect storage, or an application error (for example, low urine volume). If this happens, please retain all test materials and contact CARE diagnostica.

Information

Many changes in the female body are essential to a normal pregnancy and normal fetal development. Essentially, it is hormones which cause the body to adapt to pregnancy. The most important pregnancy hormones are oestrogen, progesterone and hCG (human chorionic gonadotropin).

The hCG level in the urine of a healthy, non-pregnant woman is below 3 IU/L (international units per litre). At the onset of pregnancy, hCG levels increase right from the first few days following conception. Up to the 10th week of pregnancy, hCG levels rise up to 230,000 IU/L. After childbirth, these levels fall back to normal within a couple of weeks. This is why hCG is a very good marker for diagnosing pregnancy. This *viola* Pregnancy Test, which has been successfully used in a similar form for many years by doctors and clinics, offers you a rapid and reliable test result.

The test will confirm pregnancy as soon as an hCG concentration of 12 IU/L and above is detected in your urine, and is therefore a suitable test to be used even BEFORE your period is due (i.e. about 10 days after sexual intercourse).

The test may be performed at any time of the day, but it is recommended that an early-morning urine sample be used, since this is the time of day when the concentration of hCG is highest.

This is an immunological test for the detection of hCG (human chorionic gonadotropin) in urine. The test materials used (e.g. antibodies) are potentially infectious materials, but these are not hazardous as long as all test components are used according to the instructions provided.

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Further Hints

Although this test is extremely accurate, in very rare instances a false result may arise.

If the concentration of hCG in the urine is too low (e.g. because the urine is very diluted or because the test was conducted too soon), the test may show a negative result, even though you may be pregnant. A considerable number of pregnancies fail particularly during the first four weeks. This may create a misleading result.

The test cannot distinguish between normal and ectopic pregnancies. In both cases, positive test results may occur.

Medication or illness (e.g. trophoblastic disease) affecting your hCG levels may also lead to an incorrect result. The contraceptive pill does not however affect the test result in any way.

Test components:

Box, foil pack with test stick and desiccant, instructions for use and test interpretation

In addition, you will need:

a watch with a second hand to perform the test and, optionally, a clean container for your urine.



Read instructions carefully before use!
Keep out of reach of children.
Do not use the test after the expiration date.



Store at 39° to 86°F (4° to 30°C).
Use the test only once.



Do not dismantle the test stick.
For external use only.
In-vitro diagnostic device for self-testing.

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