



Result window

Maximum fill level

Opening for urine sample

Super Early
Pregnancy Test
from day 8

Notes

Please read both sides of this leaflet before opening the foil pack and starting your test.

This viola test is extremely sensitive, detecting human chorionic gonadotropin (hCG) in your urine as low as 5 IU/L. It provides an indication of pregnancy at the very earliest stage and can be used even before your period is due (i.e. about 8 days after conception).

The test materials used (e.g. antibodies) are potentially infectious substances, although they present no hazard provided that all test components are used in accordance with these instructions.

Contents:

Instruction leaflet, 2 foil packs each containing a test stick and desiccant.

You will also need a watch or a clock and optionally, a clean glass to collect your urine sample.

Methods of performing the test

It is recommended that you test an early-morning urine sample, as this is when the levels of the pregnancy hormone hCG are highest

Directly



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

Using a glass



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

Put the test stick aside onto the foil pack and evaluate your test result after **10 - 15 minutes**, referring to the information overleaf.

Evaluation



If only **1 purple line** (control line) appears in the upper half of the result window, this means that the test was performed correctly but hCG was not detected. You can assume that you are **not pregnant**. Use the second test stick in a few days time to check again.

If your period is more than one week late, we would recommend that you see your doctor. If your period is overdue there is still a chance that you could be pregnant and you should avoid potential risks to the embryo, such as x-rays or alcohol abuse.



If **2 purple lines** (control and test line) appear in the result window, then hCG has been detected. You can assume that you are **pregnant**, even if the lower of the two coloured lines is very faint. A very faint line indicates the beginning of a pregnancy.

We would recommend that you see your doctor at the latest once your period is overdue. Ante-natal care is important! Avoid any potential risks to the embryo such as x-rays or alcohol abuse.

If your test result is positive but your period is not yet late, we recommend that you perform another viola Pregnancy Test or EARLY Pregnancy Test after a few days in order to confirm the result.

Further information on the test result may be found in the next column.

The test is considered invalid if the result field shows no purple line after 15 - 20 minutes or if only the test line appears. It is extremely rare to get an invalid result. Possible reasons for an invalid result could be due to damaged foil packaging, incorrect storage or mistakes made when using the test, for example, not enough urine being added. If you get an invalid result please keep all test materials and contact CARE diagnostica.

Do not rely on a result if left for longer than 20 minutes.

Discard the test stick and the packaging material with your normal household waste after your test result has been evaluated.

Information on your test result

During your pregnancy, hormones such as hCG, oestrogen and progesterone allow your fetus and pregnancy to develop normally. The hCG level in urine of a healthy, non-pregnant woman is below 3 IU/L (international units per litre). During pregnancy, the hCG level increases from the first few days following conception and reaches values of about 230000 IU/L by the 10th week of pregnancy.

This test provides an indication of pregnancy as soon as your urine contains 5 IU hCG/L. Although extremely rare, as with most medical tests, false results may occur.

Reasons for a false **negative** test result:

- hCG values may increase differently in individual cases and thus may be too low to be detected in the very early stages of pregnancy.
- If your urine is very dilute, the test result may show a negative result.

Reasons for a false **positive** test result - when your doctor confirms that you are not 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.
- In non pregnant women, hCG levels peak at the middle of the menstrual cycle and could be near the detection limit of this test in very rare instances.
- Some tumours produce hCG ("phantom hCG") and could mimic a pregnancy.
- Infertility treatment always involves hCG injections which could lead to increased levels of hCG in your urine and thus affect the test result.

Peri-menopausal women produce increased levels of hCG. However, the amounts of hCG are normally below the detection limit of this test.

Medication or illness, for example, trophoblastic disease can affect hCG levels and may also lead to an incorrect result. The contraceptive pill does not, however, affect the test result in any way.



Keep out of reach of children. Do not use the test after the expiration date. Store at 39° to 68 °F (4° to 30 °C). Do not dismantle test stick. In-vitro diagnostic device for self testing.

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Art.: ZANL0026-GB
Rev00. 2013-06