

Menopause Strip Test

Instructions for use



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

General information:

Have I already reached the menopause? Using this test, you will be able to reliably identify whether you have gone through the menopausal transition phase. This phase, meaning the time after your last monthly period, is known as the post menopause. The post menopause occurs at around 50 years of age.

Hormones are essentially responsible for the onset of the menopause. Changes in hormone production lead to the typical menopausal symptoms, such as hot flushes, vaginal itching, sweating, insomnia, depression, heart problems, reduced libido, dry eyes, painful joints and sluggish digestion.

This test measures levels of the hormone FSH (follicle-stimulating hormone). Before the menopause, the level of this hormone in urine ranges between 10 and 20 IU/L (International Units per litre). During post menopause, the level rises above 25 IU/L and remains permanently elevated. This Menopause Test enables you to ascertain whether your FSH level is above 25 IU/L. In order to be certain of your test result, you should perform a second test one week after the first.

When to perform the test:

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

Further information:

This Menopause Test identifies the start of post menopause. However, since post menopause is influenced by many factors, it is not possible to be entirely sure that you have indeed reached post menopause. You should not therefore make any healthcare decisions based on this test alone, (e.g. whether to take particular medicines), but please refer to your doctor.

Any medication you are taking containing FSH may distort the test result. Testing the urine when pregnant may also yield a false result. Finally, oral contraceptives will influence your FSH level artificially, resulting in an unreliable result.

This is an immunological test for the detection of FSH (follicle-stimulating hormone) in urine. An increased level of FSH in urine indicates that the post menopause has probably been reached, though the result of the test is not definitive. Conversely, the absence of a rise in FSH does not always mean that the post menopause has not yet been reached. The test materials used (e.g. antibodies) are potentially infectious, but present no risk to health provided that all test components are used in accordance with instructions.

Test components:

- 2 foil packs, each with 1 test strip and desiccant, instructions

Materials required but not provided:

- Watch with a second hand to perform the test and a clean container for your urine.

IMPORTANT INFORMATION:

This is an immunological test for the detection of FSH (follicle-stimulating hormone) in urine. Although this test is extremely accurate, in very rare instances a false result may arise. 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.

Read instructions carefully before use!

Keep out of reach of children.
Do not use the test after expiry date.
(See box flap)
Store at 4° - 30°C (39° - 86°F).
Use test only once.
Do not take the test strip apart.
For external use only.
In-vitro diagnostic device for self-testing.
Copy Prepared by VailiMedix Ltd, May 2010

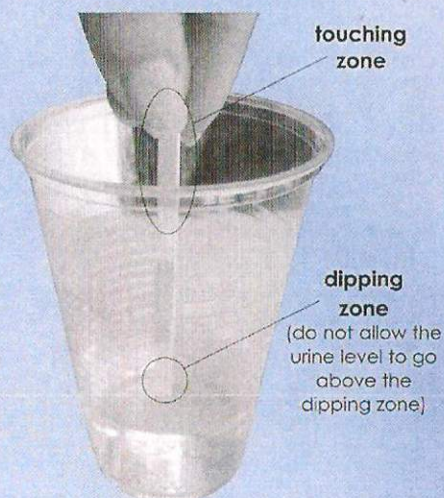
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Instructions for use

1 Preparation

Initially place the foil pack to one side unopened, since you will not need it until having collected your urine. Prepare a watch and a clean and suitable container for your urine. Then collect a sample of your urine (it is recommended to use the first urine of the day) into the container that you have selected (it is enough if the container is filled about 1-2 cm deep).



2 Incubate the test strip with urine

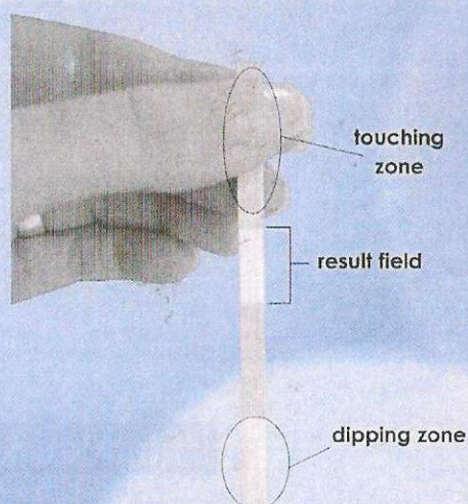
Now open the foil pack and take out the test strip. NOTE: You should touch / hold the test strip only within the "touching zone" (do not touch the strip on its white part or result field). Discard the attached desiccant (small white pouch), that protects the test from humidity, unopened with your regular household waste.

Now dip the "dipping zone" of the test strip into the collected urine for 10 - 15 seconds. NOTE: Do not allow the urine level to go above the dipping zone!

3 Put down the test strip for result development

After a few seconds remove the test strip's "dipping zone" from the urine and put it down with the coloured part up on a flat surface (the test box or the foil pack material are suitable surfaces for resting the strip).

Now wait 10 minutes before reading out the test result.



4 Interpretation of results



Positive

If two purple lines appear in the result window, and the lower line is the same shade or darker than the upper line, then your test result is positive.

You should repeat the test with the second test strip after exactly one week.

Only if both tests yield a positive result can you assume that you have reached post menopause.



Negative

If two purple lines appear in the result window and the upper line is a significantly darker shade than the lower line, this means that the test has been correctly performed, but you have not reached post menopause. The same applies if only one line appears. In this case, you do not need to use the second test strip.

Invalid

The test should be considered invalid if no purple line appears in the result window after 10 minutes. Possible causes of an invalid result include a damaged foil pack, improper storage or a mistake when performing the test. If your test has not worked, please keep all test components and contact the manufacturer.

- After 15 minutes it is no longer possible to reliably evaluate the test result.

After you have interpreted your test result successfully, you can discard most test components with your regular household waste. Please dispose of your urine into the toilet. In case you have used a reusable container please do not forget to clean it properly before you use it for further tests or something else.