

Self Diagnosis Test for the detection of the follicle stimulating hormone (FSH) in urine

SUMMARY AND EXPLANATION

The menopause is caused by a modification of the hormonal balance in woman body. This change arises generally when close to 45 years old. But true signs are observed around 55 years old. A menstrual cycle duration getting irregular is the early indication of the beginning menopause (peri-menopause). The follicle stimulating hormone (FSH) is an hormone which increases during menopause. MENO-CHECK® can detect the presence of FSH in urine as soon as the concentration goes up from 25 mIU/mL and over.

KIT CONTENT

The kit contains two MENO-CHECK® along with one leaflet.

Each test is packaged in a sealed aluminium pouch containing one desiccant sachet.

The device should remain in the sealed pouch until use.

Do not use the desiccant sachet.

PRECAUTIONS

1. This test is designed for *in vitro* diagnostic use only. For external use only. DO NOT SWALLOW.
2. Carefully read the directions for use before performing the test. The test is reliable only if the directions for use are carefully respected.
3. Store between +4°C and +30°C. Do not freeze.
4. Do not use beyond expiration date (printed on the tag and on the protective pouch), and if the pouch is damaged.
5. Do not reuse MENO-CHECK®.
6. Keep out of reach of children.
7. Do not use urine of pregnant or hormone-treated women.
8. After use, all components can be discarded in a dustbin.

DIRECTIONS FOR USE

1. Remove the MENO-CHECK® device from the protective pouch by tearing along the split. Discard the small pouch of desiccant.

2. Remove the cap of the MENO-CHECK® device. Turn MENO-CHECK® device so that the side, without the display window, is facing towards you and the absorbent tip is directed down wards.

3. Hold the absorbent tip directly in your urine stream for 5 to 10 seconds. **Make sure that no drop of urine penetrate into the window of the test and Control areas.**

If you prefer, it is possible to collect your urine in a clean and dry container (not provided), without any residual and dip the absorbent tip into the urine for 10 seconds.



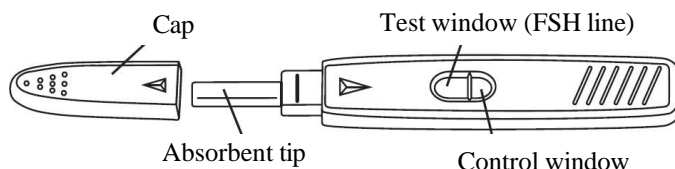
4. **Replace the cap** on the MENO-CHECK® device. The urine sample thus comes into contact with the specific reagents which starts the test.

5. Place the MENO-CHECK® device on a dry flat surface with the window facing up.

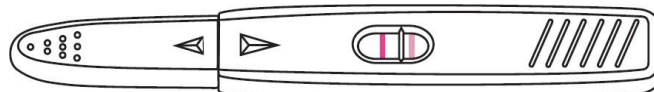
6. Read the results after 10 minutes. Do not interpret the results after 15 minutes.

RESULT INTERPRETATION

To interpret the results, it is necessary to compare the coloration of the FSH line (Test window) with the coloration of the Control line (Control window).

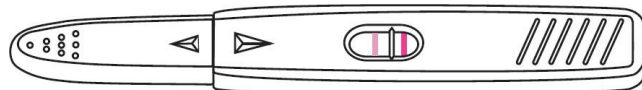


1. Positive result :



The result is positive if the FSH line is darker than the Control line. This result means that the FSH level is equal or higher than 25 mIU/mL. In this case, a second test must be performed 5 or 7 days later as the concentration of FSH can change during the menstrual cycle. If the positive result is confirmed, you could be under menopausal process and you are advised to consult your gynaecologist for a definitive diagnostic.

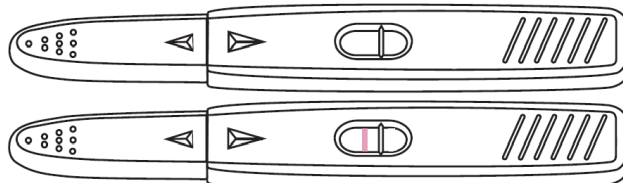
2. Negative result :



The result is negative if the Control line is darker than the FSH line. This results means that the concentration of FSH is lower than 25 mIU/mL and that you are probably **not** under menopausal process.

Caution: in some cases, the FSH line may not develop at all.

3. Invalid result :



When no Control line develops, it is not possible to interpret the test, which must be considered as invalid. In this case, it is recommended to repeat the test with a new MENO-CHECK® and a fresh urine sample.

QUESTIONS AND ANSWERS

How does MENO-CHECK® test work?

In women, the average hormonal cycle lasts 28 days. The FSH (Follicle Stimulating Hormone) secretion induces the follicle maturation, and LH (Luteinizing Hormone) secretion induces ovulation. The determination of FSH and LH level is indicated for the detection of amenorrhea and anovulatory cycles. Menopause arises at the mean age of 51 years old, i.e. between 45 and 55 years old depending on the female individuals.

Menopause is caused by a significant change in the balance of hormones. An irregular menstrual cycle duration is often the first sign of a beginning menopause. Other signs like hot flush, insomnia, palpitations, mouth ulcers, gingivitis, hair loss, dry vagina, osteoporosis, chills or excessive sweating could indicate menopause. The MENO-CHECK® is a test for the determination of high levels of Follicle Stimulating Hormone in urine which is an indicator of menopause.

The MENO-CHECK® uses a pair of antibodies for the specific detection of the human FSH. A control line capturing the excess of reagent appears in the control zone of the test. In case of positive result, it means that the FSH concentration is higher of 25 mIU/mL (as determined against W.H.O.* reference).

*World Health Organisation

When the test could be used?

The test could be used at any time of the menstrual cycle.

What is the best moment to use the test?

You can perform the test at any moment of the day; however, the first urine in the morning contains a large quantity of FSH and allows the best results to be obtained.

Is it possible to get incorrect results?

The results are accurate as long as the directions for use are carefully followed. Nevertheless, the result can be incorrect if the MENO-CHECK® is damp before performing the test. Moreover, the MENO-CHECK® could be exceptionally distorted (positive result for a young woman). In case of unexpected or contradictory results, it is recommended to consult a gynaecologist, as some health problems can induce incorrect diagnosis.

I left the absorbent tip in urine for more than 10 seconds. Will I get an accurate result?

Yes. A few more seconds will not affect the results.

I left the absorbent tip in urine for less than 5 seconds. Will I get an accurate result?

No, because the sample volume might be insufficient.

What should I do if the result is positive?

If the result is positive with the first MENO-CHECK®, a second test should be performed 5 or 7 days later. If a positive result is again obtained with a second test, the FSH level was elevated over an unusual period and could therefore indicate you are under menopausal process. You should consult your gynaecologist to confirm or not the diagnosis of menopause.

What should I do if the result is negative?

If the result is negative, the FSH level is lower than 25 mIU/mL which means you are not probably under menopausal process.

However, if you feel signs of menopause as indicated above, it is recommended to perform another test 40 to 60 days later or consult your gynaecologist.

Should the test be used as contraception method?

No, the test has not been designed for this purpose and should not be used for this purpose.

Will discontinuing my hormonal contraception (pill) affect the result?

If you use a contraceptive and that you have just discontinued it, it is possible that your cycles may be irregular for some time, which may affect the result. It is recommended to wait for two cycles before using the MENO-CHECK®.

I have reached the age to be menopausal. I have performed the test which result was positive but my menstrual cycle duration is still regular. Why?

A positive test indicates that the FSH level is equal or higher than 25 mIU/mL which means that you are possibly under menopausal process. The menopause is defined as the cease of menstruation over a period of 12 months. However this biological change in a woman life is gradual and is preceded by a sooner or later period which is named peri-menopause. So the test result could be positive while your menstrual cycle duration is still regular. This means that maybe you are in peri-menopause phase.

What is the accuracy of MENO-CHECK®?








The MENO-CHECK® is very accurate and has been used for more than 10 years by professionals in the field. Evaluation reports show an overall agreement of 92.8% with reference method. Although this test is reliable, false positive or false negative results could be obtained.

Information on menopause and the follicle stimulating hormone (FSH):

1. Web information:

http://www.doctissimo.fr/html/sante/femmes/sa_604_menopause02.htm

2. Web information: <https://fr.scribd.com/document/359925965/55-Poly-1-Menopause>

	Read the instructions before use		For <i>in vitro</i> diagnostic use		Do not reuse
	Store between +4°C and +30°C		Batch number		Expiry date
	Manufacturer				



PHARMA SOUTHERN AFRICA

95 Aberdeen Street – Westdene, Johannesburg 2092, Republic of South Africa

(+27) 079 625 2452, www.pharmasa.co.za



VEDALAB

Rue de l'Expansion - ZAT du Londeau - Cerisé

BP 181 - 61006 ALENCON Cedex (France)

+33 2 33 27 56 25, www.vedalab.com



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MENO-CHECK®

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