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Self-diagnosis test for the detection of the follicle stimulating hormone in urine (at-home menopause test (FSH))















Our ambition is to make healthcare widely accessible by empowering self-care globally.

Driven by our spirit of innovation, **Advent Life** specialises in self-tests for a wide range of medical conditions, while also offering other products that allow everyone to take health into their own hands. We enable people to take the first step themselves and at their own convenience.

Advent Life focuses on bringing the best from the world while prioritising safety and easy-to-use products. We design premium brands that are delivered to pharmacies, hospitals, laboratories, public organisations and government institutions.

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MENOPAUSE

The menopause is caused by a change in the hormonal balance in a woman's body. This change generally begins when a woman approaches 45 years of age. However, the real symptoms are noticed around the age of 55. The menstrual cycle duration getting irregular is an early indication that the menopause is beginning (perimenopause).

WHAT IS FOLLICLE STIMULATING HORMONE (FSH)?

The follicle stimulating hormone (FSH) is a hormone which increases during menopause. MENO-CHECK® can detect the presence of FSH in urine as soon as the concentration goes over 25 mIU/mL.

WHAT ARE THE SYMPTOMS?

Menopause is caused by significant changes in hormonal balance. Variation in the duration of the menstrual cycle is often the first symptom of the onset of menopause. Other symptoms are:

- Hot flashes
- Insomnia
- Palpitations
- Mouth sores
- Gingivitis

- Hair loss
- Vaginal dryness
- Osteoporosis
- Chills or excessive sweating



SELF-DIAGNOSIS TEST FOR DETECTION OF THE FOLLICLE STIMULATING HORMONE IN URINE

PURPOSE

The follicle stimulating hormone (FSH) is a hormone which increases during menopause. MENO-CHECK [®] can detect the presence of FSH in urine as soon as the concentration goes over 25 mIU/mL.

The MENO-CHECK® test is used to detect high levels of Follicle Stimulating Hormone in the urine, which is an indicator of menopause.

The MENO-CHECK® test 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. If the test is positive, it means that the concentration of FSH is higher than 25 mlU/mL (as determined against World Health Organisation reference).



FAST AND RELIABLE RESULTS

Time: 10-15 minutes.

Store between +4°C and +30°C. Do not freeze!

2 tests per box.

The follicle stimulating hormone (FSH) is a hormone which increases during menopause. MENO-CHECK® can detect the presence of FSH in urine the moment the concentration exceeds 25 mIU/mL.

Easy to read results.

The MENO-CHECK® test 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 occur.

CLINICAL EVALUATION RESULTS

Sensitivity: 100 % Specificity: 100 % Accuracy: 100 %



PROVIDED MATERIALS:

2 sealed aluminium pouches, each containing:

1 test device1 desiccant bag1 instruction leaflet.

Only open the protective pouch when you are ready to use the test. The desiccant bag should not be used.

REQUIRED MATERIALS NOT PROVIDED:

Timer

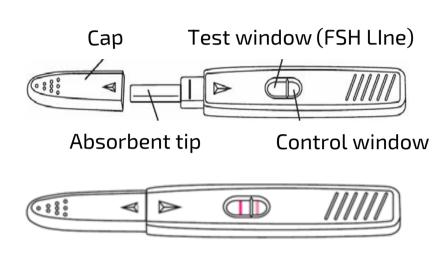




Testing procedure always starts with a good preparation. Place the contents of the box on a clean, dry and flat surface (e.g. table). Then begin the testing:

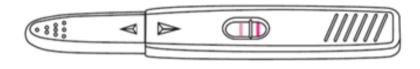
- 1. Remove the MENO-CHECK® test device from the protective pouch by tearing along the split. Discard the small desiccant bag.
- 2. Remove the cap of the MENO-CHECK® device. Turn MENO-CHECK® device so that the side, without the display window, is facing towards you and the absorbent tip is directed downwards.
- 3. Hold the absorbent tip directly in your urine stream for 5 to 10 seconds. Make sure that no drop of urine goes 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. Place the cap on the MENO-CHECK® test device. The urine sample then comes into contact with the specific reagents which starts the testing process.
- 5. Place the MENO-CHECK® test 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.



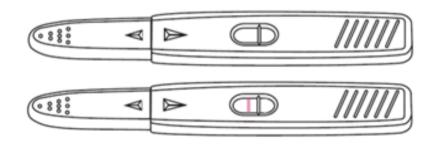


To interpret the results, it is necessary to compare the colouration of the FSH line (Test window) with the colouration of the Control line (Control window).

Positive: 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.



Negative: The result is negative if the Control line is darker than the FSH line. This result 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.



Invalid: 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.

NOTE:

The intensity and the colour of the lines do not have any importance for the interpretation of the test results.



This test is exclusively intended for in vitro diagnostics use. External use only. **DO NOT SWALLOW**.

Carefully read the instructions before performing the test. The test is only interpretable if the instructions are carefully respected.

Follow strictly the indicated time, blood and diluent quantities.

Store between +4°C and +30°C. Do not freeze.

Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.

Do not reuse the MENO-Check® test.

Keep out of reach of children.

After use, all the components can be discarded in a dustbin.

Not suitable for children under 6 years old.

