PreventID® **Menopause**

Manual (FOR PROFESSIONAL USE)

→REF KST17114G10
KST17114GP

Intended Use

The **PreventID® Menopause** (midstream test) is a rapid test for the detection of an elevated follicle-stimulating hormone (FSH)-concentration in urine. The body produces more FSH before and during menopause. FSH measurements are used in the diagnosis and treatment of pituitary gland and gonadal disorders. The test sensitivity is 25 mIU/ml FSH. For professional use only.

Materials

Materials Provided:

- midstream test stick, single packed TEST
- manual

Materials Required but not Provided: Timer or stop watch

Storage and Stability

Store at room temperature or refrigerated (4–30 °C). The test stick is sensitive to humidity and heat. Therefore, perform the test immediately after removing the test stick from the pouch. If the test is refrigerated, it should be brought to room temperature before use.

Precautions

1. For *in vitro* diagnostic use only.
2. Do not use beyond the expiry date.
3. Read the manual carefully before performing the test.
4. Perform the test immediately after removing the test stick from the pouch.
5. During performing the test do not eat or smoke.
6. Wear protective gear such as disposable gloves, lab coat etc. and avoid spilling of sample material. If sample material has been spilled, clean the site thoroughly with disinfectant.
7. Clean all contaminated surfaces carefully. Dispose all test components and samples in conventional garbage.
8. If the pouch has been damaged, do not use the test stick. Do not use the test after the expiry date printed on the package.
9. If you have any questions please contact Preventis GmbH.

When to begin testing?

You may do this test at any time of the day, but you should test at approximately the same time each day. Reduce your liquid intake for two hours before testing.

Test Procedure

1. Remove the test stick from the pouch *(Fig. 1)*.
2. Take the cap off the test stick *(Fig. 2)*.
3. Hold the test stick at an angle, with handle-end up and urine collection-end down as shown in *Fig. 3a*. (*Fig. 3b* shows the wrong angle), place the urine collection end in a direct stream of your urine for at least ten seconds so that adequate urine goes into the absorbent well (*Fig. 3a*).
4. After urinating, immediately recap the test stick and lay it on a flat horizontal surface with the result window facing up *(Fig. 4a)*. Do not hold the test stick up (*Fig. 4b* and *Fig. 4c*) while waiting or reading the result.
5. Interpret the test result **at 5 minutes**.

Fig. 1

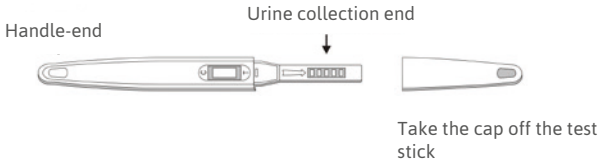

Fig. 2

Hold test stick in the urine midstream

Fig. 3a *Fig. 3b*

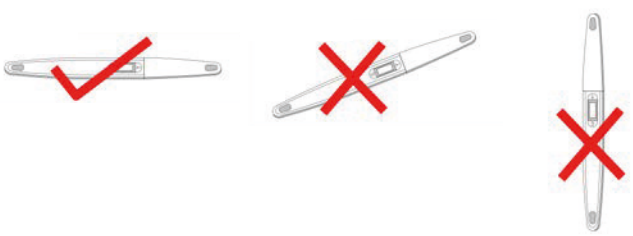

Fig. 4a *Fig. 4b* *Fig. 4c*

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Test Interpretation *(Fig. 5)*

As the test kit begins to work, a coloured line will appear at the left section of the result window to show that the test is working properly. This line is the **control line (C)**.
The right section of the result window indicates the test result. If another colour line appears at the right section of the result window, this line is **test line (T)**.
The **control line (C)** is used as a reference. If the test line (T) is similar in colour or darker than the control line (C), the test result is positive. If the test line (T) is lighter in colour than the control line (C), the test result is negative. The control line (C) is also used for procedural control to determine if the test reagentis working properly.

Positive result:
The presence of two coloured lines of similar intensity within the result window indicate an FSH increase, no matter which one appears first *(Fig. 5a)*. The test line (T) may be darker than the control line (C).

Negative result:
The presence of only the control line (C) within the result window indicates that an FSH increase has not been detected. The presence of a control line (C) and a lighter coloured test line (C) also means that an FSH increase has not been detected *(Fig. 5b)*.

Invalid result:
The test is considered invalid when no coloured line appears in the result window *(Fig. 5c)*. The test directions may not have been followed correctly or the test may have deteriorated (check expiry date). In this case, the test should be repeated using a fresh test stick.

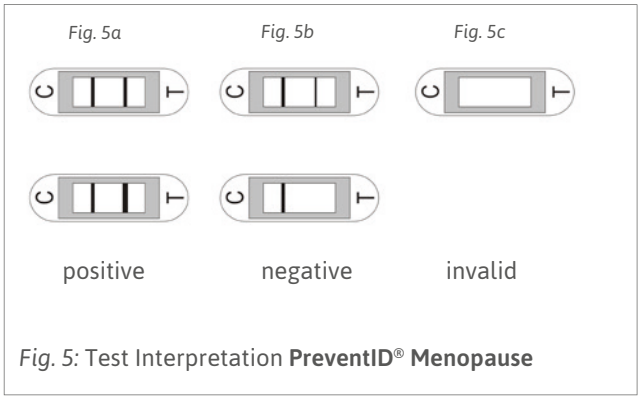

Fig. 5: Test Interpretation **PreventID® Menopause**

Test characteristics

The **analytical sensitivity** of **PreventID® Menopause** is determined to be at 25mIU/ml.
Analytical specificity: positive results are produced by only FSH at concentration levels higher than 25mIU/ml. Neither LH nor hCG showed positive results, tested with concentrations up to 500 mIU/ml. Samples were spiked with the following substances, tested with **PreventID® Menopause** and showed no cross-reactivity or interferences: Acetamiophen, Acetyl salicyl acid, Ascorbic acid, Atropine, bilirubin, caffeine, creatinine, gentesic acid, glucose, hemoglobin, ketones, Mestranol, nitrite, Penicillin, sodium and lithium heparin.

For the **clinical sensitivity and specificity** testing of the **PreventID® Menopause** a study was conducted by a comparison of collected urine samples from subjects using **PreventID® Menopause** and PHAMATECH MOMENTS MENOPAUSE (FSH) CHECK.
The **relative sensitivity** of the **PreventID® Menopause** test is 99.5 % (186/187) and the relative specificity is 98.2 % (111/113) when compared to the commercial one-step FSH test.

Test Limitations

The **PreventID® Menopause** is not reusable. The test works only if the instructions are followed precisely. Although it is highly accurate in detecting FSH, a low incidence of false results (positive when no FSH exists or negative when elevated FSH is present) can occur.
The **PreventID® Menopause** should not be used for contraception.
Some prescription drugs or certain rare medical conditions can affect the FSH level.
As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Short instructions PreventID® Menopause

1. Remove test stick from the pouch. Take the cap off the stick.
2. Hold the tip of the test stick for at least 10 seconds in the urine midstream.
3. Recap the test stick and place it on a flat surface with the cap to the right.
3. Interpret test result **at 5 minutes**.

CE

Status: 2018-06-13

US: all products: Research Use Only. Not for use in diagnostic procedures.

Temperature limitation	Manufacturer
IVD *In vitro* diagnostic device	LOT Lot number
REF Catalogue number	Expiry date
To be used with	Do not reuse
Read user instructions	Contains sufficient for <n> tests
Keep away from sunlight	

Immundiagnostik AG
Stubenwald-Allee 8a
64625 Bensheim, Germany

Distributed by:
Preventis GmbH
Stubenwald-Allee 8a
64625 Bensheim, Germany
Phone:+49 6251 70711-0
Fax: +49 6251 70711-25
info@preventis.com
www.preventis.com

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