PreventID® **hCG**

Manual (FOR PROFESSIONAL USE)

→REF KST04112G10
KST04112GP

Intended Use

The **PreventID® hCG** (test devices) is a rapid test for the detection of the pregnancy hormone human chorionic gonadotropin (hCG) in urine and is used for the early detection of a pregnancy. For professional use only.

Introduction

hCG is a glycoprotein which is produced by the placenta shortly after conception. The appearance and therefore rapid increase in the concentration of hCG in the mother's urine makes it a reliable parameter for the early detection of a pregnancy. The detection limit of this test is at 20 mlU/ml.

Test Principle

After application of the urine sample to the sample application window of the test device the fluid travels along the test membrane. A gold-labelled conjugate aggregates with the hCG present in thesample to form an antibody-antigen complex. This complex binds to the anti-hCG-antibody in the test zone which results in a purple line (T = test line) if the hCG-concentration equals or is higher than 20mlU/ml. If the hCG is below this level, no test line is visible. A control line (C = control line) appears on the left side of the result window if the test has run correctly.

Materials

Materials Provided:

- test devices (with sample droppers), individually packed TEST
- manual

Materials Required but not Provided: Timer or stop watch, sample container

Storage and Stability

Store at room temperature or refrigerated (4–30 °C). The test device is sensitive to humidity and heat. Therefore, perform the test immediately after removing the test device from the pouch. If the test device 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 device 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. Do not use test if the pouch is torn or if the membrane of the test device is visibly damaged.
9. If you have any questions please contact Preventis GmbH.

Specimen Collection

1. The first urine in the morning contains the highest hCG-concentration and is therefore ideal for the test. However, the test can be performed with any other urine.
2. Collect the urine in a clean and dry sample container.
3. If the sample is not immediately tested, store up to 48 h at 2–8 °C and bring back to room temperature before testing. If the sample is to be tested after 48 h, freeze it at -20 °C. Before testing, the sample has to be thawed completely, mixed thoroughly and brought back to room temperature.

Test Procedure

1. Remove the test device and the sample dropper from the pouch and place it on a flat dry surface.
2. Place the test device with the sample application window to the right.
3. Apply **2 hanging drops of urine** with the sample dropper into the sample application window of the test device *(Fig. 1)*.
4. The result should be interpreted after **3–5 minutes** but not later than 5 minutes.

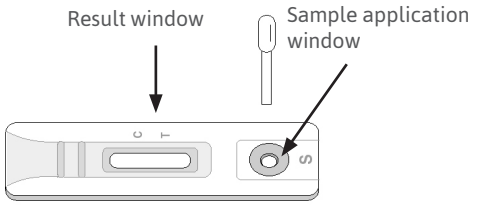

Fig. 1: Test device **PreventID® hCG**

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Test Interpretation *(Fig. 2)*

A purple line appears at the left side of the result window as a control that the test is working properly **(C = Control line)**.

A positive test result is indicated by the appearance of a purple test line **(T = Test line)** on the right side of the result window.

Upon running the test and depending on the visible lines, the following conclusions can be can be made:

Positive result: If two coloured lines appear in the result window (C- and T-line), an elevated hCG-concentration has been detected and the test result is considered positive *(Fig. 2a)*.

Negative result: If only the C-line appears in the result window, no elevated hCG-level has been detected. The test result is considered negative *(Fig. 2b)*.

Invalid: If no line or merely the test line appears in the result window, the test is invalid *(Fig.2c)*. The control line does not appear if the membrane has not absorbed enough sample fluid. The test should then be repeated with a new test device.

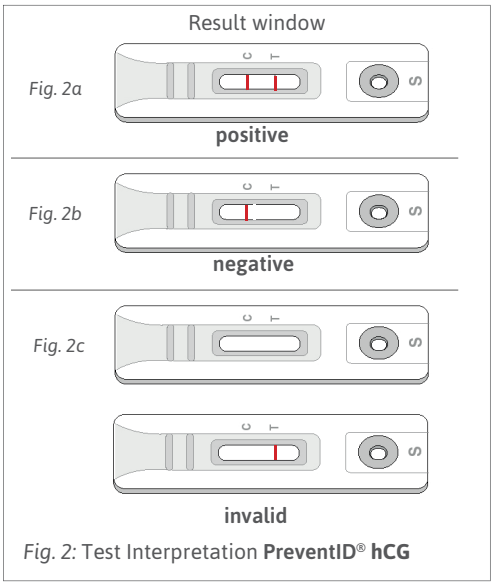

Fig. 2: Test Interpretation **PreventID® hCG**

Test Characteristics

Sensitivity: The **PreventID® hCG** test will detect hCG in urine at concentrations of 20mIU/ml or greater. This sensitivity level has been confirmed with internal hCG standards in urine, calibrated against the World Health Organization First International Standard.

Specificity: The ability of the **PreventID® hCG** test to specifically detect hCG was challenged through cross-reaction studies on urine samples containing known quantities of structurally and physiologically related hormones. Urine samples spiked with 500 mIU/ml LH (human Luteinizing Hormone), 1000 mIU/ml FSH (Follicle Stimulating Hormone) and 1000 µIU/ml TSH (Thyroid Stimulating Hormone) showed negative results only.

Interference Data: Potentially interfering drugs, protein and glucose were supplemented to normal urine specimens devoid of hCG. Baseline urine levels, as well as 20 mIU/ml hCG standards were then analyzed and compared with all samples containing a specific concentration of an interfering substance.

Substances:
Acetaminophen, 20 mg/dl
Acetylsalicylic acid, 20 mg/dl
Ascorbic acid, 20 mg/dl
Atropine, 20 mg/dl
Caffeine, 20 mg/dl
Gentistic acid, 20 mg/dl
Glucose, 2000 mg/dl
Hemoglobin, 500 mg/dl
Mestranol, 3 mg/dl
Penicillin, 40,000 U/dl
Tetracycline, 20 mg/dl

Conclusion: All of the above substances do not interfere with the results of the **PreventID® hCG** urine test kits.

Test Limitations

Test results are only reliable if you follow the instructions for use carefully. The test is limited to the detection of hCG in human urine. Use the test only once. Although the test is very accurate, a low incidence of false results can occur. The test can not distinguish between a normal and an ectopic pregnancy. Spontaneous or induced abortion can lead to misinterpretation of the test result.

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.

The test result may be negative at a very early stage of pregnancy. If a pregnancy is assumed, the test should be run again after 2 days with a fresh urine sample.

If the urine is highly diluted (i. e. low spec. weight), the hCG concentration may be below the detection limit and lead to a negative test result. If a pregnancy is assumed, the test should be re-run with first morning urine.

Short instructions PreventID® hCG (Test devices)

1. Remove test device and sample dropper from the pouch. Place test device with the sample application window to the right on a flat and dry surface.
2. Using the sample dropper, squeeze **2 drops of urine** into the sample application window.
3. Interpret test result after **3–5 minutes** but not later than 5 minutes.

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Status: 2018-11-30

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
→REF 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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