PreventID[®] hCG

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Intended Use

The **PreventID**[®] **hCG** (<u>test strips</u>) 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 rapid formation of hCG and therefore quick rise in concentration make 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 the fluid travels along the test membrane. A gold-labelled conjugate aggregates with the hCG present in the sample 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 strips, individually packed TEST
- manual

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

Storage and Stability

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

Precautions

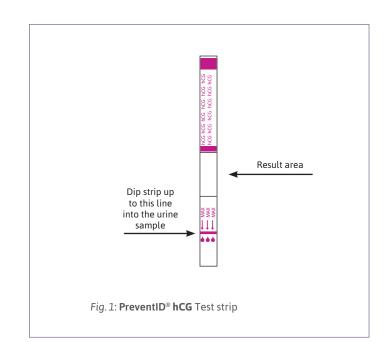
- 1. For in vitro diagnostic use only.
- 2. Do not use beyond the expiry date.
- 3. Read the manual carefully before performing the test.
- 4. Perform the test immediately after removing the test strip from the pouch.
- 5. During performing the test do not eat or smoke.
- 6. Wear protective gear such 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 strip.
- 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 strip from the pouch. Hold the test strip at the upper end.
- 2. Dip the test strip up to the maximum line into the urine sample (Fig. 1).
- 4. Remove the test strip from the urine sample as soon as the purple line runs through the result area (after a few seconds).
- 4. Place the test strip on a dry surface.
- Interpret test result after 3–5 minutes, but no later than after 5 minutes.





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Test Interpretation (*Fig. 2*)

For test interpretation place the test strip as shown in *Fig. 2* (sample area at the bottom). A colored line appears in the upper part of the result area to indicate that the test is working properly (**C**= control line).

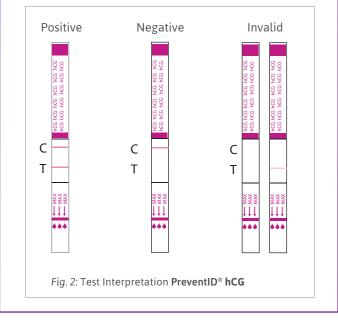
The test result appears in the lower part of the result area. If a colored line appears here, it is the **test line (T)**.

Depending on the coloured lines, the following results are possible:

Positive result: If two lines appear in the result area, an elevated hCG-level has been detected and the test result is positive.

Negative result: If only one coloured line appears in the result window, an elevated hCG-level has not been detected and the test result is negative.

Invalid: The test is considered invalid if no line or only the test line appears in the result area. For example, the control line does not appear if the strip membrane has not soaked enough sample fluid. The test should be repeated with a new test strip.



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** test kits.

Test Limitations

The **PreventID**[®] **hCG** is not reusable. Although the **PreventID**[®] **hCG** is highly reliable, a low incidence of false results (both positive or negative) may 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 strips)

- 1. Remove test strip from the pouch.
- 2. Dip test strip up to the maximum line into the urine sample. Remove the test strip from the sample as soon as the colored line is visible in the result area.
- 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.

X	Temperature limitation	m	Manufacturer
IVD	<i>In vitro</i> diagnostic device	LOT	Lot number
REF	Catalogue number	8	Expiry date
→REF	To be used with	8	Do not reuse
	Read user instructions	Σ n	Contains sufficient for <n> tests</n>
Keep away from sunlight			

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