



**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**).

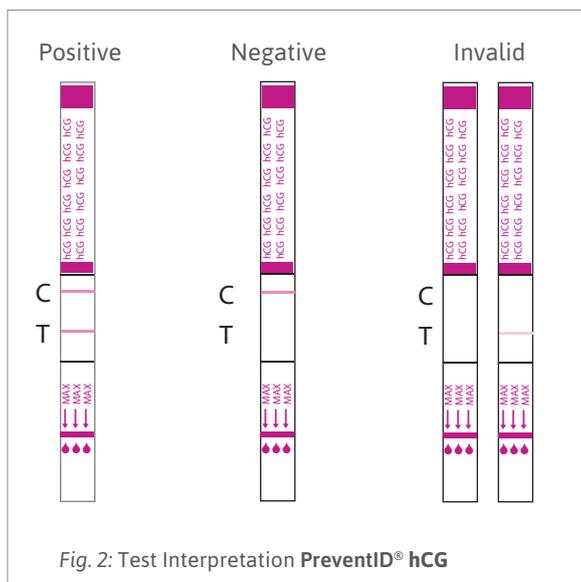
The test result appears in the lower part of the result area. If a colored line appears here, it is the **test line (T)**.

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.



Status: 2018-11-30

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

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

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

Imundiagnostik AG  
Stubenwald-Allee 8a  
64625 Bensheim, Germany

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