

One Step hCG Single Test Card Package Insert

A rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine.

For professional in vitro diagnostic use only.

INTENDED USE

The One Step hCG Single Test Card is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception (1-4). hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period (2-4), and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

The One Step hCG Single Test Card is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the One Step hCG Single Test Card shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The One Step hCG Single Test Card is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by immersing the strip of the test card in a urine specimen and observing the formation of colored lines. The

specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific antibody-hCG-colored conjugate to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

REAGENTS

The test card contains anti-hCG particles and anti-hCG coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test card should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test card should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30°C. The test card is stable through the expiration date printed on the sealed pouch. The test card must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION & PREPARATION

Urine Assay

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

PROCEDURE

Materials Provided

- Test card
- Package insert

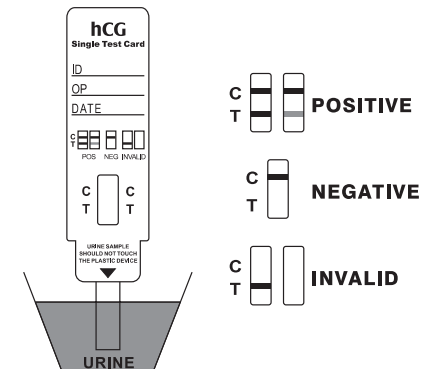
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test card, urine specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test card from the sealed pouch and use it as soon as possible.
2. Remove the cap from the end of the test card. With arrows pointing toward the urine specimen, immerse the strip of the test card vertically in the urine specimen for at least 5 seconds. Do not pass the arrow on the test card when immersing the strip. See the illustration below.
3. Place the test card on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The result should be read at 3 minutes. It is important that the background is clear before the result is read.



Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test card. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

It is recommended that a positive hCG control (containing 25-250 mIU/mL hCG) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance. It is recommended that federal, state, and local guidelines be followed.

LIMITATIONS

1. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
2. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons (5), a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.

4. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG (6-7). Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals.

The One Step hCG Single Test Card has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the One Step hCG Test to another commercially available urine membrane hCG test. The study included 150 urine specimens: both assays identified 72 negative and 78 positive results. The results demonstrated 100% overall agreement (for an accuracy of $\geq 99\%$) of the One Step hCG Test when compared to the other urine membrane hCG test.

Reference hCG Method

	Positive	Negative
One Step Method		
Positive	78	0
Negative	0	72

Sensitivity and Specificity

The One Step hCG Single Test Card detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 μ IU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen	20 mg/mL	Caffeine	20 mg/mL
Acetylsalicylic Acid	20 mg/mL	Gentisic Acid	20 mg/mL
Ascorbic Acid	20 mg/mL	Glucose	2 g/dL
Atropine	20 mg/mL	Hemoglobin	1 mg/dL
Bilirubin	2 mg/dL		

None of the substances at the concentration tested interfered in the assay.

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