

hCG One Step Pregnancy Test Strip (Urine)

One Step Pregnancy Test is a rapid, one step test for the qualitative detection of human chorionic gonadotropin in urine.

For professional in vitro diagnostic use.

INTENDED USE

The hCG One Step Pregnancy Test Strip is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid for 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 serum and urine 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 100-200 IU/ml range about 10-12 weeks into pregnancy. The appearance of hCG in both the 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 hCG One Step Pregnancy Test Strip is a rapid urine test to qualitatively detect the presence of hCG in urine specimens at the sensitivity of 25mIU/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 hCG One Step Pregnancy Test Strip shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at physiological levels.

PRINCIPLE

The hCG One Step Pregnancy Test Strip is a qualitative, solid phase, two-site sandwich immunoassay (5-6) for the detection of human chorionic gonadotropin (hCG) in urine. The membrane is pre-coated with anti-hCG antibodies on the test band region and anti-mouse antibodies on the control band region. During testing, the urine sample reacts with the colored conjugate (mouse anti-hCG antibody colloidal gold conjugate) which has been

pre-coated on the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action to react with anti-hCG antibodies on the membrane and generate a red band. Presence of the red band indicates a positive result, while its absence indicates a negative result. Regardless of the presence of hCG, as the mixture continues to migrate across the membrane to the immobilized goat anti-mouse region, a red band at the control band region will always appear. The presence of this red band serves as verification for sufficient sample volume and proper flow and as a control for the reagents.

Reagents

The test strip 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 strip 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 strip should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature (2-30 °C). The test strip is stable within the expiration date printed on the labeling. **DO NOT FREEZE** or use beyond the expiration date.

MATERIALS PROVIDED

- hCG One Step Pregnancy Test Strip.
- Desiccant
- Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

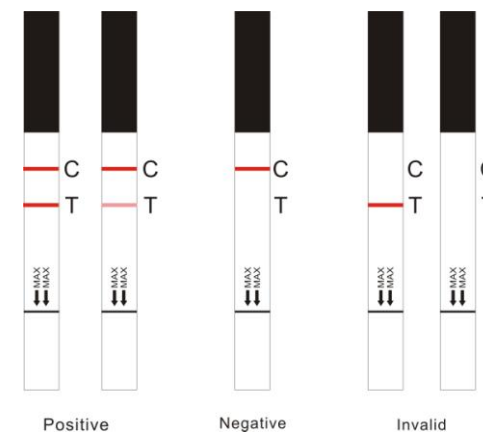
SPECIMEN COLLECTION

The urine specimen must be collected in a clean, dry plastic or glass container. The first morning urine is preferred since it generally

contains the highest concentration of hCG. However, urine collected at any time of day may be used. Urine samples exhibiting visible precipitates should be centrifuged, or allowed to settle to obtain clear supernatant for testing. Urine specimens may be stored at 2-8 °C for up to 48 hours prior to assay. Urine containing excessive bacterial contamination should not be used as this may cause spurious results.

TEST PROCEDURE

Read the entire procedure carefully prior to performing any tests. **Allow test strip and urine samples to equilibrate to room temperature (20-30 °C) prior to testing.**



1. Remove the hCG one step pregnancy test strip from foil pouch (bring the test to room temperature before opening the pouch). Use strip as soon as possible but within 1 hour after removal from pouch especially if the room temperature is more than 30°C and in high humidity environment.
2. Immerse the test strip in the urine sample with printed sample end pointing toward the urine for at least 5 seconds. Be sure the sample level is below the marked sample line on test strip.
3. Wait for red bands to appear. The test should be read in approximately 3-5 minutes for urine. It is significant that the background is clear before reading the test, specially when samples have low hCG concentration, and only a weak line appears in the test band region(T). Do not interpret results after 10 minutes.

QUALITY CONTROL

A procedural control is included in the test. A red band appearing in the control region (C) is considered an internal positive procedural control. A clear background in the results window is considered an internal negative procedural control.

It is recommended that a positive hCG control (containing 25-100 mIU/ml hCG) and a negative hCG control (containing "0" mIU/ml hCG) be included in each day testing to verify proper test performance.

INTERPRETATION OF RESULTS

POSITIVE Two distinct red bands will appear, one in the test region (T) and one in the control region (C).

NEGATIVE Only a single red band appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID Control band fails to appear which means improper testing procedures or deterioration of reagents probably occurred. In any event, repeat the test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

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

LIMITATION OF THE PROCEDURE

Very dilute urine specimens as indicated by low specific gravity may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine sample should be obtained 48-72 hours later and tested.

Very low levels of hCG (less than 50m IU/ml) are present in urine shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons (7), a test result that is weakly positive should be interpreted in conjunction with other clinical and laboratory data.

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 (8-9). Therefore, the presence of hCG in urine as determined by using hCG One Step Pregnancy Test Strip should not be used to diagnose pregnancy unless these conditions have been ruled out.

As with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Urine and serum hCG concentration of pregnant women rise very rapidly after implantation, reaching a peak concentration in excess of 100 IU/ml about 2-3 months after the last menstrual period (3).

The hCG One Step Pregnancy Test Strip has a sensitivity of 25 mIU/ml and is capable of detecting pregnancy as early as 1 day after the first missed menses. Reportedly, a level of 25 mIU/ml or more, is present 7-10 days after conception or 4-5 days prior to the first missed menses (3).

Test results which appear as a very light line in the test region are not definitive for the diagnosis of pregnancy. It is strongly recommended that an additional urine specimen be obtained after 48-72 hours and tested again.

Negative test results in patients suspected to be pregnant should be re-tested with the first morning specimen obtained 48-72 hours later.

PERFORMANCE CHARACTERISTICS

Sensitivity

The analytical sensitivity of the hCG One Step Pregnancy Test Strip is 25mIU/ml. The sensitivity was established by repetitive testing of samples containing 25mIU/ml hCG during a period of several weeks.

Specificity

The specificity of the hCG One Step Pregnancy Test Strip was determined from cross-reactivity studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH). Negative results were obtained from all tests conducted with 500 mIU/ml hLH, 1000 mIU/ml hFSH and 1000 μ IU/ml hTSH.

Precision

A study was conducted which consisted of performing a series of replicate assays using 4 different concentration of hCG in urine. The results were as followed:

hCG Conc. mIU/ml	Result	
	Pos.	Neg.
0	0	50
5	0	50
25	50	0
100	30	0
200,000	20	0

Studies were performed which consisted of testing 218 positive and 300 negative specimens using the hCG One Step Pregnancy Test Strip versus a reference hCG immunoassay. Both of these studies demonstrate 100% (relative) correlation.

		Reference hCG Method	
		positive	negative
hCG	positive	218	0
Method	negative	0	300

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