HCG STRIP RAPID TEST

(Urine)

INTENDED USE

hCG One Step Pregnancy Test Strip (Urine) 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 AND EXPLANATION OF THE TEST

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

hCG One Step Pregnancy Test Strip (Urine) 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, hCG One Step Pregnancy Test Strip (Urine) shows no cross-reactivity interference from the structurally related glycoprotein hormones FSH, LH and TSH at high physiological levels.

TEST PRINCIPLE

hCG One Step Pregnancy Test Strip (Urine) 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 test strip 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-coiored conjugate and 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.

MATERIALS PROVIDED

- Test Str ips
- Package Inser t

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container
- Timer

PRECAUTIONS

- For professional and in vitro diagnostic use only. Do not use after the expiration date.
- The test strip should remain in the closed 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 closed pouch at 2-30°C.
- The test strip is stable through the expiration date printed on the sealed pouch.
- The test strip must remain in the closed pouch until use.
- Do not freeze.
- Does not use beyond the expiration date.

SPECIMEN COLLECTION AND 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

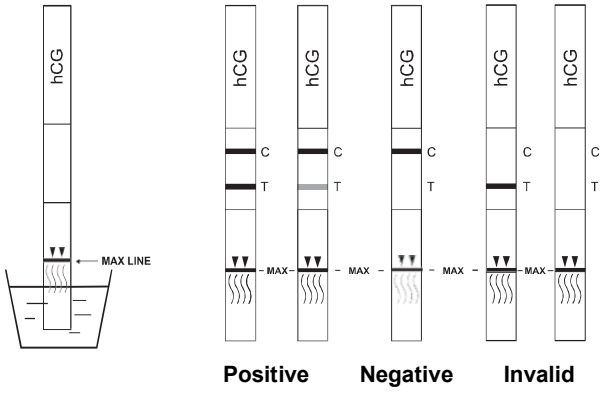
Urine specimen may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

DIRECTION FOR USE

Allow the test strip, 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 strip from the sealed pouch and use it as soon as possible.
2. Place the test dipstick into urine (**Note:** Surface of urine sample can't exceed the Maximum line on the lower tape).
3. Take the test dipstick out of urine sample after **15 seconds** or keep the test dipstick staying in the urine sample, start the timer immediately.
4. Read the result at **3-5 minute.**

Note: Don't interpret the result after 10 minutes.



READING THE RESULTS

(Please refer to the illustration below)

POSITIVE: Two distinct colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T).One line may be lighter than the other; they do not have to match. This means that you are probably pregnant.

NEGATIVE: One colored line appears in the control line Region (C) .No line appears in the test line region(T).This means that you are probably not pregnant

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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 strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

EXPECTEDVALUES

- Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine specimens. The amount of hCG will vary greatly with gestational age and between individuals.
- hCG One Step Pregnancy Test Strip (Urine) has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

QUALITY CONTROL

- A procedural control is 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 also required.
- 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 when a new shipment of test devices are received.

LIMITATIONS

- 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.
- 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.
- Very low levels of hCG (less than 50 mIll/mL) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
- 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. Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
- 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.
- False Negative results may occur to samples of women who are pregnant for more than 5 weeks. This is due to excess hCG variants in the urine that had been noticed in some uncommon cases of 10 weeks of pregnancy. If such cases are suspected, a dilution of 1:10 of the samples need to be retested to confirm the negative results.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using hCG One Step Pregnancy Test Strip (Urine) to another commercially available urine membrane hCG test. The urine study included 155 specimens and both assay identified 76 negative and 79 positive results.The results demonstrated a 100% overall agreement (for an accuracy of > 99%) of hCG One Step Pregnancy Test Strip (Urine) in comparison to the other urine membrane hCGtest.

SENSITIVITY AND SPECIFICITY

hCG One Step Pregnancy Test Strip (Urine) 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 mIU/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.

SUBSTANCE	CONCENTRATION
Acetaminophen	20 mg/mL
Adetylsalicylic Acid	20 mg/mL
Ascorbic Acid	20 mg/mL
Atropine	20 mg/mL
Bilrubin (urine)	2 mg/dL
Caffeine	20 mg/mL
Gentisic Acid	20 mg/mL
Glucose	2 g/dL
Hemoglobin	1 mg/dL

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

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