Discover™

hCG Women Pregnancy Test Cassette (Urine)
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 hCG One Step Pregnancy Test Device (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin 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.[1,2,3,4] hCG levels continue to rise very rapidl frequently exceeding 100 mIU/ml by the first missed menstrual period[2,3,4] and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy.[4] 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 Device (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 double monoclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the hCG One Step Pregnancy Test Device (Urine) shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The hCG One Step Pregnancy Test Device (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy. The test uses two lines to indicate results. The test line is pre-coated with a monoclonal hCG antibody to selectively detect elevated levels of the hCG. The control line is pre-coated with goat anti-mouse IgG antibody. The test also includes a burgundy colored conjugate pad containing another monoclonal hCG antibody conjugated with colloidal gold. The assay is conducted by adding a urine specimen to the specimen well of the test device 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 in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test 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 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 used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30℃). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do 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 specimens may be stored at 2-8℃ for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20℃. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Test devices
- Droppers
- Desiccant
- Package insert

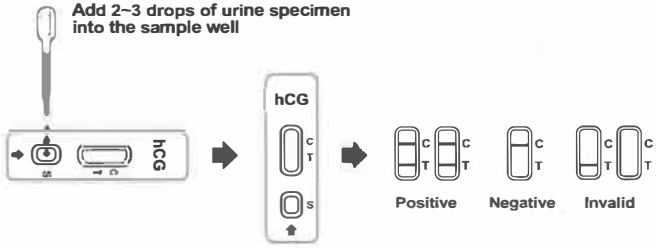
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test, urine specimen and/or controls to reach room temperature (15-30℃) prior to testing.

1. Remove the test device from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 2-3 full drops of urine** to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
3. Wait for the colored line(s) to appear. **Read the result in 5 minutes. Do not interpret results after 5 minutes.** It is important that the background is clear before the result is read.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

***NOTE:** A sample hCG concentration below the cut-off level of this test might result in a weak line appearing in the test region (T) after an extended period of time. A line in the test region (T) seen after the read time could be indicative of a low hCG level in the sample. If such results are seen, it is recommended that the test be repeated with a new sample in 48-72 hours or that an alternate confirmation method is used.

NEGATIVE: One colored line appears in the control line region (C). No apparent colored line appears in the test line 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If a background color appears in the result window and interferes with the ability to read the test result, the result may be invalid.

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 tests are received.

LIMITATIONS

1. The hCG One Step Pregnancy Test Device (Urine) is a preliminary qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. 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.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimens 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. This test reliably detects intact hCG up to 500,000 mIU/mL. It does not reliably detect hCG degradation products, including free-beta hCG and beta core fragments. Quantitative assays used to detect hCG may detect hCG degradation products and therefore may disagree with the results of this rapid test.
5. This test may produce false positive results. 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.
6. This test may produce false negative results. 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. In case pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
7. 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 hCG One Step Pregnancy Test Device (Urine) 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 hCG One Step Pregnancy Test Device (Urine) to another commercially available urine membrane hCG test. The study included 159 urine specimens, and both assays identified 88 negative and 71 positive results. The results demonstrated >99% overall accuracy of the hCG One Step Pregnancy Test Device (Urine) when compared to the other urine membrane hCG test.

hCG Reference Method

Method		Other hCG Rapid Test		Total Results
	Results	Positive	Negative	
hCG Test Device	Positive	71	0	71
	Negative	0	88	88
Total Results		71	88	159

Sensitivity: 100% (95%-100%)*
Specificity: 100% (95%-100%)*
Accuracy: 100% (98%-100%)*
* 95% Confidence Intervals

Sensitivity and Specificity

The hCG One Step Pregnancy Test Device (Urine) detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 μIU/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/dL	Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	Gentisic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL	Glucose	2 g/dL
Atropine	20 mg/dL	Hemoglobin	1 mg/dL
Bilirubin	2 mg/dL		

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

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