hCG Pregnancy Rapid Test Strip (Urine) Package Insert

REF L031-20111/20171	English

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 Pregnancy Rapid Test Strip (Urine) is a one step, rapid chromatographic immunoassay for in vitro 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. 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 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 hCG Pregnancy Rapid 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 two monoclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the hCG Pregnancy Rapid Test Strip (Urine) shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The hCG Pregnancy Rapid Test Strip (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 utilizes a combination of antibodies including two monoclonal hCG antibody to selectively detect elevated levels of hCG. The control line is composed of goat polyclonal antibodies and colloidal gold particles. The assay is conducted by immersing the test strip in a urine specimen and observing the formation of colored line. 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.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use the kit after the expiration date.
- The test should remain in the sealed pouch or closed canister until ready to use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Use appropriate precautions in the collection, storage, handling and disposal of patient samples and used kit contents
- Dispose of containers and used contents according to Local requirements.

STORAGE AND STABILITY

- Store as packaged at room temperature or refrigerated (2-30°C).
- The test is stable through the expiration date printed on the sealed pouch or label of the closed canister.
- **NOTE:** Once the canister has been opened, the remaining test(s) are stable for 90 days only.
- **DO NOT FREEZE**.

SPECIMEN COLLECTION AND PREPARATION

Urine Collection

Urine specimen must be collected in a clean and dry container. 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 can 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.

REAGENTS

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

MATERIALS

Materials Provided

- Test strips
- Package insert

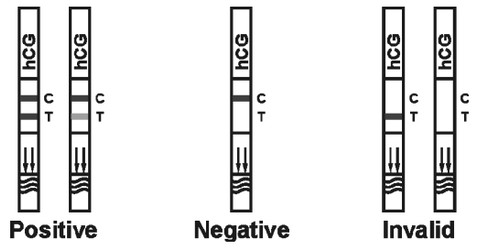
Materials Required But Not Provided

- Specimen collection containers
- Timer

DIRECTIONS FOR USE

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

1. Remove the test strip from the sealed pouch or closed canister. Use the test strip as soon as possible.
   NOTE: For canister packaging, immediately close the canister tightly after removing the required number of the test strip(s). Record the initial opening date on the canister. Once the canister has been opened, the remaining test strip(s) are stable for 90 days only.
2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line on the test strip when immersing the strip. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. The result should be read at 3 minutes.



NOTE: A low hCG concentration might result in a weak line appearing in the test line 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 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:** The intensity of the color in the test line region (T) may vary depending on the concentration of hCG present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

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 sample application to the specified specimen well. But the appearance of C line does not indicate whether correct type of specimen (urine) has been added for the testing; Use only appropriate specimen type. 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 is received.

LIMITATIONS

1. The hCG Pregnancy Rapid Test Strip (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, 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 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. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. 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.
6. 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 Pregnancy Rapid 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.

PERFORMANCE CHARACTERISTICS

Accuracy

A clinical evaluation was conducted comparing the results obtained using the hCG Pregnancy Rapid Test Strip (Urine) to another commercially available urine membrane hCG test. The study included 200 urine specimens, and both assays identified 150 negative and 50 positive results.

The results demonstrated >99% overall accuracy of the hCG Pregnancy Rapid Test Strip (Urine) when compared to the other urine membrane hCG test.

Method		Other hCG Rapid Test		Total Results
hCG Test Strip	Results	Positive	Negative	
	Positive	50	0	50
	Negative	0	150	150
Total Results		50	150	200

Sensitivity: 100% (92.9%-100%)* Specificity: 100% (97.6%-100%)*

Accuracy: 100% (98.2%-100%)* *95% Confidence Intervals

Cross-Reactivity

The hCG Pregnancy Rapid Test Strip (Urine) can detect hCG at a concentration of 25 mIU/mL or greater. The addition of LH (500 mIU/mL), FSH (1,000 mIU/mL) and TSH (1,000 µIU/mL) to hCG negative and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

Interference

No Interference was detected with the performance of the hCG Pregnancy Rapid Test Strip (Urine) upon addition of substances with concentrations in the table below.

Substances	Concentration	Substances	Concentration
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
Bilirubin	2 mg/dL	Hemoglobin	1 g/dL

BIBLIOGRAPHY

1.Batzer FR. Hormonal evaluation of early pregnancy, Fertil. Steril. 1980; 34(1): 1-13.

2.Catt KJ, ML Dufau, JL Vaitukaitis Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte, J. Clin. Endocrinol. Metab. 1975; 40(3): 537-540.

3.Braunstein GD, J Rasor, H. Danzer, D Adler, ME Wade Serum human chorionic gonadotropin levels throughout normal pregnancy, Am. J. Obstet. Gynecol. 1976; 126(6): 678-681.

Index of Symbols

	Manufacturer	Σ	Tests per kit	2°C 30°C	Store between 2-30°C
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
LOT	Lot Number	REF	Catalog #	EC REP	Authorized Representative

***ACON* Laboratories, Inc.**
10125 Mesa Rim Road,
San Diego, CA 92121, USA

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1150875003
Effective date: 2016-09-11