# Accu-Screen hCG Rapid Test Strip Package Insert

**A rapid test for the qualitative assessment of human chorionic gonadotropin in human urine.**
**For professional In Vitro Diagnostic Use Only.**

## INTENDED USE

The hCG Rapid Test Strip is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.
For prescription use only including at point of care sites.
For in vitro diagnostics only.

## 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 100mIU/mL by the first missed menstrual period [2-4],and peaking in the 100,000-200,000mIU/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 marker for the early detection of pregnancy.
The hCG Rapid Test Strip is a rapid test that qualitatively detects the presence of hCG in urine at the sensitivity of 25mIU/mL.The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG.The test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

## PRINCIPLE

The hCG Rapid Test Strip 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 mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. In the test Strip format, the sample pad of the strip is dipped into urine, the reaction is initiated by movement of the urine sample through the test Strip.The sample migrates via capillary action along the membrane to react with the colored conjugate. Positive samples react with the specific antibody-hCG-colored line at the test line region of the membrane.Absence of the 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 Strip contains mouse anti-beta hCG antibody conjugated to colloidal gold and goat anti-alpha hCG antibody coated on the membrane.

## PRECAUTIONS

- For prescription in vitro diagnostic use only. Do not use after the expiration date.
- The test Strip should remain in the sealed pouch until use.
- All samples 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 through the expiration date printed on the sealed pouch.The test Strip must remain in the sealed pouch until use.

## SPECIMEN COLLECTION AND PREPARATION

**Urine sample**

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

**Specimen storage**

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

## MATERIALS

**Materials provided**

- Test Strip
- Package insert

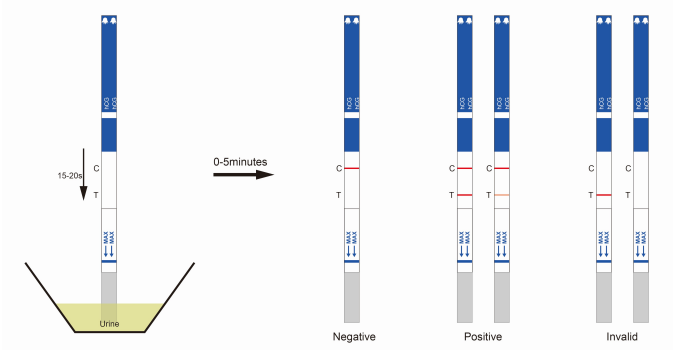
**Materials required but not provided**

- Specimen collection containers
- Timer
- External Quality Control Materials

## DIRECTIONS FOR USE

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

1. Remove the test Strip from the sealed pouch and use it as soon as possible.
2. Dip the end of the strip into the specimen for at least 15 seconds to 20 seconds or until migration occurs. Immerse the strip just below the top line of the wave line on the test strips.
3. Place the test strip on a flat dry surface.
4. Wait for the red line(s) to appear.**Read the result at 5 minutes when testing a urine specimen.Do not interpret results after the appropriate read time.** 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 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 sample 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 Strip immediately and contact your suppliers.
**Note:**The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the sample.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 positive procedural control.It confirms sufficient sample volume and correct procedural technique. 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 >25mIU/mL hCG) and a negative hCG control (containing “0”mIU/mL hCG) be evaluated to verify proper test performance.Test each new lot and shipment by using external quality control materials (positive and negative),with each new untrained operator,monthly for storage,and as otherwise required by your lab internal quality system procedures.The external quality control materials may be purchased from Bio-Rad,Biochemical Diagnostics, Inc and other qualified suppliers. It is recommended that federal, state and local guidelines be followed.

## LIMITATIONS

1.Very dilute urine samples,as indicated by a low specific gravity,may not contain representative levels of hCG. If pregnancy is still suspected,a first morning urine sample 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 sample should be collected 48 hours later and tested.
3. Very low levels of hCG are present in urine 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 sample collected 48 hours later.
4. This test detects intact hCG only.This test does not reliably detect hCG degradation products, including free-beta subunits and beta-core fragment.Therefore,this test may show reduced reactivity in urine after 8 weeks gestation. This test should not be used to monitor trophoblastic disease or post–partum patients.
5. Quantitative assays used to detect hCG may be detecting hCG degradation products,and therefore may disagree with the result of the pregnancy test.
6. 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 sample should not be used to diagnose pregnancy unless these conditions have been ruled out.
7. As with any assay employing mouse antibodies,the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen.Specimens from patients who have received preparations of monoclonal antibodies may cause false positive or false negative results.
8. 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 samples.The amount of hCG varies greatly with gestational age and between Individuals.
The hCG Rapid Test Strip has a sensitivity of 25mIU/mL and is capable of detecting pregnancy as early as the first day of the expected period.

## PERFORMANCE CHARACTERISTICS

**Accuracy**

The clinical evaluation was conducted by comparing the results obtained using the Pregnancy test and another commercially available urine hCG test.The urine study included 100 samples and both tests identified 51 negative and 49 positive results.The results demonstrated a 100% overall agreement (for an accuracy of >99%) of the pregnancy test when compared to the other urine membrane hCG test.

**Sensitivity and Specificity**

The hCG Rapid Test Strip detects hCG at concentrations of 25mIU/mL or greater.The test has been standardized to the W.H.O.Four International Standard.The addition of LH (500mIU/mL),FSH (1,000mIU/mL),and TSH (1,000μIU/mL) to negative (0mIU/mL hCG) and positive (25mIU/mL hCG) samples showed no cross-reactivity.

**Interfering Substances**

The following substances and chemicals at a concentration of 100ug/mL or above show no cross-reactivity with urine samples containing hCG at the concentration 0mIU/mL and 25μIU/mL when tested by the Home Pregnancy Test:

| Interfering Substance | Concentration | Interfering Substance | Concentration |
|---|---|---|---|
| Acetaminophen | 100 ug/ml | Hemoglobin | 100 ug/ml |
| Acetone | 100 ug/ml | Ibuprofen | 100 ug/ml |
| Albumin | 100 ug/ml | (+/-)-Isoproterenol | 100 ug/ml |
| Ampicillin | 100 ug/ml | Ketamine | 100 ug/ml |
| Ascorbic Acid | 100 ug/ml | Levorphanol | 100 ug/ml |
| Aspartame | 100 ug/ml | Lidocaine | 100 ug/ml |
| Aspirin | 100 ug/ml | (+)-Naproxen | 100 ug/ml |
| Atropine | 100 ug/ml | Niacinamide | 100 ug/ml |
| Benzocaine | 100 ug/ml | Nicotine | 100 ug/ml |
| Bilirubin | 100 ug/ml | (+/-)-Norephedrine | 100 ug/ml |
| Caffeine | 100 ug/ml | Oxalic Acid | 100 ug/ml |
| Chloroquine | 100 ug/ml | Penicillin-G | 100 ug/ml |
| (+)-Chlorpheniramine | 100 ug/ml | Pheniramine | 100 ug/ml |
| (+/-)-Chlorpheniramine | 100 ug/ml | Phenothiazine | 100 ug/ml |
| Creatine | 100 ug/ml | 1-Phenylephrine | 100 ug/ml |
| Dexbrompheniramine | 100 ug/ml | β-Phenylethylamine | 100 ug/ml |
| Dextromethorphan | 100 ug/ml | Procaine | 100 ug/ml |
| Diphenhydramine | 100 ug/ml | Quinidine | 100 ug/ml |
| Dopamine | 100 ug/ml | Ranitidine | 100 ug/ml |
| (+/-)-Epinephrine | 100 ug/ml | Riboflavin | 100 ug/ml |
| Erythromycin | 100 ug/ml | Sodium Chloride | 100 ug/ml |
| Ethanol | 100 ug/ml | Sulindac | 100 ug/ml |
| Furosemide | 100 ug/ml | Theophylline | 100 ug/ml |
| Glucose | 100 ug/ml | Tyramine | 100 ug/ml |
| Guaiacol Glyceryl Ether | 100 ug/ml | 4-Dimethylaminoanti pyrine | 100 ug/ml |
| (1R,2S)-(-)-N-Methyl-Ephedrine | 100 ug/ml | | |

## BIBLIOGRAPHY


1. Batzer F R “Hormonal evaluation of early pregnancy”, Fertil. Steril. 1980; 34(10:1-13.
2. Catt K J,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, D Adler, ME Wade “Serum human chorionic gonadotropin levels throughout normal pregnancy’,Am.J.Obstet. Gynecol.1976;126(6): 678-681.
4. Lento EA,LM Neal,R Sulaiman “Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy”, Fertil.Steril.1982;37(6): 773-778.


## SYMBOLS

| Symbol | Meaning | Symbol | Meaning |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | | Storage temperature limit |
| | Manufacturer | EC REP | Authorized representative in the European Community /European Union |
| | Date of Manufacture | | Use-by date |
| | Do not re-use | | Consult instructions for use or consult electronic instructions for use |
| LOT | Batch code | | Do not use if package is damaged and consult instructions for use |
| REF | Catalogue number | Σ | Contains sufficient for <n> tests |

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