QUANTON BIOLIFE SCIENCES

YOUR PARTNER IN PRECISION MEDICINE

hCG – Pregnancy Rapid Test Strip

QBL/hCG/RPT_048

A rapid, one step test Strip for the qualitative detection of human chorionic gonadotropin (HCG) in urine

INTENDED USE

The hCG-Pregnancy Rapid 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.

INTRODUCTION

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 100 mIU/mL by the first missed Menstrual period (2-4), 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 monoclonal and polyclonal 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 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 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 at the control line region if the test has been performed properly.

CONTENTS OF KIT

Test Strips in sealed pouch and Product Insert.

STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test strip is stable through the expiration date printed on the pouch. The test strip must remain in the pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

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 ºC for up to 48 hours prior to assay. Urine containing excessive bacterial contamination should not be used as this may cause spurious results.

ASSAY PROCEDURE

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

1. Remove the hCG-Pregnancy Rapid Test Strip from 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.

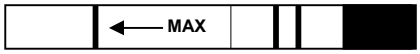
3. Wait for red bands to appear. The test should be read in approximately 3-5 minutes for urine. It is significant that the background is clear before reading the test, especially when samples have low HCG concentration, and only a weak line appears in the test band region (T). Do not interpret results after 10 minutes.

READING TEST RESULTS:

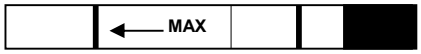
A. Negative: Only one pink colored line appears in the Control area showing that the test has been carried out correctly & no apparent line in the Test region. The test is reported as negative for HCG.

B. Positive: In addition to the colored line in the control region a clearly distinguishable pink – rose colored line also appears in the test region indicating a positive result and that the sample contains HCG. A difference of intensity may occur between the lines in the test region and the test region but this does not affect the interpretation of the result.

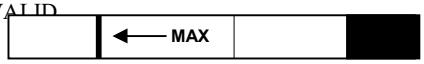
POSITIVE



NEGATIVE



INVALID



C. In conclusive: If no line appears in the control as well as the test region, the test should be repeated with fresh test strip.

SPECIFICITY

The specificity of the hCG-Pregnancy Rapid 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 □IU/ml hTSH.

SENSITIVITY

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

PRECISION

A study was conducted which consisted of performing a series of replicate assays using 4 different concentrations of hCG in urine.

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-Pregnancy Rapid 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.

The HCG-Pregnancy Rapid 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.

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.

BIBLIOGRAPHY

1. Balzer FR. Fertility and Sterility 1980; 34: 1

2. Catt KJ, ML Dufan, JL Vaitukaitis. J. Clin. Endocrinol. Metab. 1975; 40:537

3. Baunstein GD, J Rasor, D Adler, H Danzer, ME Wade. Am. J. Obstet. Gynecol. 1976; 126:678

4. Lenton EA, LM Neal, R Sulaiman. Fertility and Sterility 1982; 37:773

5. Engvall E. Methods in Enzymology 1980; 70:419

6. Uotila M, E Ruoslahti, EJ Engvall. E. J. Immunol. Methods 1981; 42:11

7. Steier JA, P Bergsjo, OL Myking. Am. J. Obstet. Gynecol. 1984; 64:391

8. Dawood MY, BB Saxena, R Landesman. Am. J. Obstet. Gynecol. 1977; 50:172

9. Braunstein GD, JL Vaitukaitis, PP Carbone. Ann,Inter. Med. 1973; 78:39

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

Quanton Biolife Sciences Private Limited
Anand Mangal Apartment, Behind Axis Bank,
Dak Bunglow Road, Ghatsila, East Singhbhum
Jharkhand – 832303, India
quantoncare@qblsci.com
www.quantonbiolifesciences.com