hCG – Pregnancy Rapid Test Kit

The hCG – Pregnancy Rapid Test 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 *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PHGC 01
05 Tests	PHGC 05
10 Tests	PHGC 10
25 Tests	PHGC 25
50 Tests	PHGC 50

CLINICAL SIGNIFICANCE

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 as early as 7 to 10 days after conception.[1] 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.[2,3] The appearance of HCG in both 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.[4,5] The hCG - Pregnancy Rapid Test Kit (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.

The hCG-Pregnancy Rapid Test (Urine) is a qualitative test device to detect HCG in human sample which aids in the prediction of pregnancy.

PRINCIPLE

The hCG - Pregnancy Rapid Test Kit (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 applying urine sample in the sample well 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

Cassette
Test Device (Cassette)
Instruction for Use (IFU)
Desiccant
Disposable Droppers

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION & PREPARATION

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

PROCEDURE

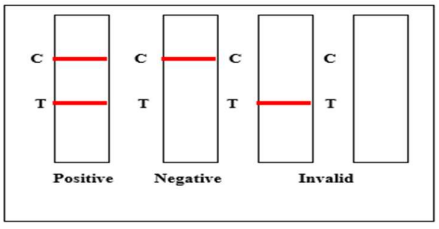
Card Test Procedure

Read the entire procedure carefully prior to performing any tests.

1. Allow test card and urine samples to equilibrate to room temperature (20-30°C) prior to testing.
2. Remove the HCG one step pregnancy card from foil pouch (bring the test to room temperature before opening the pouch). Use card 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.
3. Add 50 µl (2 drops) of specimen to the sample window 'S'
4. 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.

INTERPRETATION OF RESULTS

1. **Negative**: Only one pink colored line appears in the Control area showing negative for HCG.
2. **Positive**: In addition to the coloured line in the control region a clearly distinguishable pink – rose coloured line also appears in the test region indicating a positive result and that the sample contains HCG.
3. **In conclusive / Invalid**: If no line appears in the control as well as the test region, the test should be repeated with fresh card
4.



QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the Reference Line region (R) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. A positive result means your urine contains the level of HCG that would indicate you are pregnant.
A negative result indicates non pregnancy

INTERFERING SUBSTANCES
SENSITIVITY AND CROSS-REACTIVITY

The hCG Pregnancy Rapid Test Kit detects hCG at a concentration of 25mIU/ml or greater. The test has been standardized to the W.H.O. International Standard. The addition of LH (300mIU/ml), FSH (1,000mIU/ml), and TSH (1,000μIU/ml) to negative (0mIU/ml hCG) and positive (25mIU/ml hCG) specimens showed no cross-reactivity.

Interfering Substance

The following potentially interfering substances were added to hCG negative and positive specimens. Acetylsalicylic Acid-20mg/dl, Bilirubin-2mg/dl, Hemoglobin-1mg/dl, Glucose-2g/dl, Gentisic Acid-20mg/dl, Atropine-20mg/dl, Ascorbic Acid-20mg/dl & Caffeine-20mg/dl.
None of the substances at the concentration tested interfered in the assay

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, 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. Therefore, the presence of hCG in urine as determined by using hCG Pregnancy 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 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 Kit (Urine) 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.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the HCG Pregnancy Rapid Test Kit to another commercially available urine membrane hCG test. The study included 543 urine specimens, and both assays identified 280 negative and 163 positive results. The results demonstrated >99% overall accuracy of the hCG Pregnancy Rapid Test Kit when compared to the other hCG Rapid Test.

Method		Other hCG Rapid Test		Total Results
hCG Pregnancy Rapid Test	Results	Positive	Negative	
	Positive	163	0	163
	Negative	0	280	280
Total Results		163	280	543

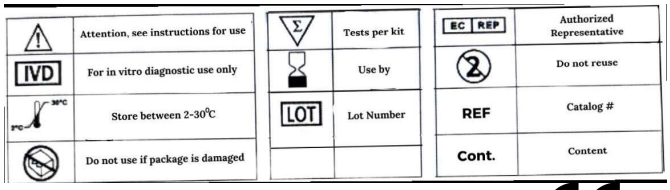
Relative Sensitivity: >99.9% (98.7%~100%)*
Relative Specificity: >99.9% (99.2%~100%)
Overall Accuracy: >99.9% (99.5%~100%)*
* 95% Confidence Intervals

BIBLIOGRAPHY

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

GLOSSARY OF SYMBOL

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



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