HCG Pregnancy Test (Strip)

CE 0197

Coretests®

For self-testing and in vitro diagnostic use only

INTENDED USE

HCG Pregnancy Test is a self-testing immunoassay made for the rapid, visual and qualitative determination of human chorionic gonadotropin (HCG) in urine specimen to aid in the early detection of pregnancy.

SUMMARY

Human chorionic gonadotropin (HCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. In normal pregnancy, HCG can be detected in serum as early as 7 days following conception. The concentration of HCG continues to rise rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period and peaking in the 100,000-200,000 mIU/mL range by 10-12 weeks into pregnancy. The appearance of HCG soon after conception and its subsequent rise in concentration during early gestational growth make it an excellent marker for the early detection of pregnancy.

PRINCIPLE

The HCG Pregnancy Test is a chromatographic immunoassay (CIA) for the rapid qualitative determination of HCG in urine. The membrane is pre-coated with anti-α HCG capture antibody on the test line region and goat anti-mouse on the control line region. During testing, the urine specimen is allowed to react with the colored conjugate (mouse anti-β HCG monoclonal antibody-colloidal gold conjugate), which has been pre-dried on the test strip. The mixture then moves upward on the membrane chromatographically by capillary action. For a positive result, a pink-colored line with the specific antibody-HCG-colored conjugate complex will form in the test line region of the membrane. Absence of this pink-colored line in the test line region indicates a negative result. Regardless of the presence of HCG, as the mixture continues to move across the membrane to the immobilized goat anti-mouse, a pink-colored line at the control line region will always appear. The presence of this pink-colored line serves as: 1) verification that sufficient volume is added, 2) that proper flow is obtained, and 3) as a control for the reagents.

COMPOSITION

The test strip contains anti-β HCG on colloidal gold particles and a combination of anti-α HCG coated on the membrane.

WARNINGS AND PRECAUTIONS

1. Read the instruction carefully before performing this test.
2. Do not use beyond the labeled expiration date.
3. The test strip should remain in the sealed pouch until use. Do not use if the pouch is damaged or opened.
4. Do not reuse the test strip. Discard it in the dustbin after single use.
5. Do not touch the membrane located within the windows.
6. Do not swallow the desiccant.

STORAGE

The test strip should be stored at 2-30℃ in the sealed pouch for the duration of the shelf life. Do the test in 1 hour when you open the pouch. DO NOT FREEZE.

SAMPLE COLLECTION

1. Collect fresh urine specimen by using a disposable container which is clean and dry.
2. First morning specimens generally contain the highest concentration of HCG for early detection of pregnancy. However, any urine specimen is suitable for testing.
3. Specimens may be kept at room temperature for 8 hours. If the specimen cannot be tested immediately, store the specimen at 2-8℃ for 48 hours or at -20℃ for a long time. Do not freeze and thaw the specimens repeatedly.
4. Bring the urine specimen to room temperature before testing.

TEST PROCEDURE

Allow the test strip, urine specimens and/or controls to equilibrate to room temperature (15-30℃) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test strip from the sealed pouch and use it as soon as possible.
2. Immerse the test strip in the urine specimen for at least 5 seconds with the arrow end pointing toward the urine.Do not immerse the strip above the printed MAX line.
3. Take the strip out and lay the strip flat. Or leave the test strip in the urine specimen as long as the strip is not immersed above the MAX line.
4. Wait for pink-colored lines to appear. Read result within 5 minutes. Do not read result after 5 minutes.

INTERPRETATION OF RESULTS

PREGNANT: Two distinct pink-colored lines appear, one in the test region (T) and the other one in the control region (C).

NOTE: The intensity of the pink color in the test region (T) may vary depending on the concentration of HCG present in the specimen. Therefore, any shade of pink color in the test region (T) should be considered positive.

NOT PREGNANT: Only one pink-colored line appears in the control region (C). No apparent pink line appears in the test region (T).

INVALID: Control line fails to appear.

NOTE: 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 strip. If the problem persists, please contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing on the control region (C) is considered an internal positive procedural control, indicating proper performance and reactive reagents. A clear background in the membrane is considered an internal negative procedural control. If the test has been performed correctly and reagents are working properly, the background will be clear to give a discernible result.

EXPECTED VALUES

Negative result will be found in the urine of healthy men and healthy non-pregnant women. However, 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 Test Strip has an analytical sensitivity of 25mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity: No less than 25mIU/ml

Analytical Specificity: The test results show negative for the 500mIU/ml hLH, 1000mIU/ml hFSH and 1000μIU/ml hTSH specimens.

Diagnostic Sensitivity and Diagnostic Specificy: This HCG Pregnancy Test detects HCG at a concentration of 25mIU/ml or greater. 900 known negative urine specimens were equally divided into 6 groups. Each group of specimens (150) were spiked with HCG to the concentration of 0mIU/ml, 5mIU/ml, 15mIU/ml, 25mIU/ml, 50mIU/ml and 5IU/ml separately, calibrated against WHO 4th international standard. Each group of specimen was tested with HCG Pregnancy Test. The results from this study gave >99% agreement with the expected results.

Result	0mIU/ml	5mIU/ml	15mIU/ml	25mIU/ml	50mIU/ml	5IU/ml	Total
Positive	0	0	0	150	150	150	450
Negative	150	150	150	0	0	0	450
Total	150	150	150	150	150	150	900

Diagnostic sensitivity=100% (450/450)
Diagnostic specificity=100% (450/450)

Interference Testing: The following substances were added in HCG free and HCG spiked urine specimens. None of the substances at concentration tested interfered in the assay. For example:

Acetaminophen	0.2mg/ml	Acetylsalicylic Acid	0.2mg/ml
Ascorbic Acid	0.2mg/ml	Atropine	0.2mg/ml
Caffeine	0.2mg/ml	Gentesic Acid	0.2mg/ml
Glucose	20mg/ml	Hemoglobin	10mg/ml
Tetracycline	0.2mg/ml		

LIMITATION

1. Although it is not necessary to test with an early morning urine specimen, excessive fluid intake should be avoided before testing. A "Not Pregnant" result may be obtained if the urine specimen is too dilute.
2. The contents of this strip are for use in the qualitative detection of HCG in urine only.
3. A specimen with a low level of HCG may show color development over time. If a negative result is obtained but pregnancy is suspected, another specimen should be collected after 48-72 hours and tested.
4. Fertility drugs containing HCG can give misleading results (these fertility drugs are usually given by injection and testing too soon after administration may give a false pregnancy result).
5. Other fertility therapies (such as clomiphene citrate), painkillers and hormonal contraceptives (e.g. contraceptive pill) should not affect the result.
6. HCG may remain detectable for a few days to several weeks after delivery, spontaneous abortion, or HCG injections.
7. Ectopic pregnancy, ovarian cysts, menopause, and some very rare medical conditions can give misleading results.
8. While pregnancy is the most likely reason for the presence of HCG in serum and urine, elevated HCG concentrations unrelated to pregnancy have been reported in some patients, for example, trophoblastic disease and certain nontrophoblastic neoplasms.
9. Alcohol may interfere the test result. It is not recommended using the test after drinking.
10. 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.

QUESTIONS & ANSWERS

1. Q: How soon after I suspect that I am pregnant can I take the test?
   A: You can test your urine as early as the first day you miss your period.
2. Q: Do I have to test with first morning urine?
   A: You can perform the test at any time of the day. However, your first morning urine is usually the most concentrated of the day and would have the most HCG in it.
3. Q: How do I know that the test was run properly?
   A: The appearance of a colored line in the control region (C) tells you that you followed the test procedure properly and proper amount of urine was absorbed.
4. Q: Can test results be interpreted after more than five minutes?
   A: No. Test results must be read within 5 minutes. Though a positive result should not change for several days, a negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading.

REFERENCES

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5. Chard T. Pregnancy tests-a review. Hun. Reprod.1992;7 (5):701-10.

Index of Symbols

	Do not reuse		Use by	LOT	Lot Number
	Manufacturer		Temperature Limitation	CE 0197	CE Mark
IVD	For Invitro Diagnostic Use		Consult instructions for use		
n	Contains sufficient for <n> tests	EC REP	Authorized Representative		

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