B-hCG cassette CE

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REF	4130040	B-hCG	40 tests
For professional *in vitro* diagnostic use only			

B-hCG

A rapid test for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum.

ONE STEP

PRINCIPLE

The LINEAR B-hCG cassette is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum 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 adding urine or serum specimen to the specimen well of the test cassette 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 and 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.

REAGENT COMPOSITION

Pregnancy test device, contains anti-hCG particles and anti-hCG coated on the membrane.

PACKAGING CONTENTS

REF 4130040 40 Pregnancy test device
40 Disposable specimen droppers.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

A urine specimen must be collected in a clean and dry container. A 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 may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.
Blood should be collected aseptically into a clean tube without anticoagulants. Separate the serum from blood as soon as possible to avoid hemolysis. Use clear non-hemolyzed specimens when possible.
Urine or serum specimen 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.

MATERIALS REQUIRED

- Timer.
- Specimen collection container.

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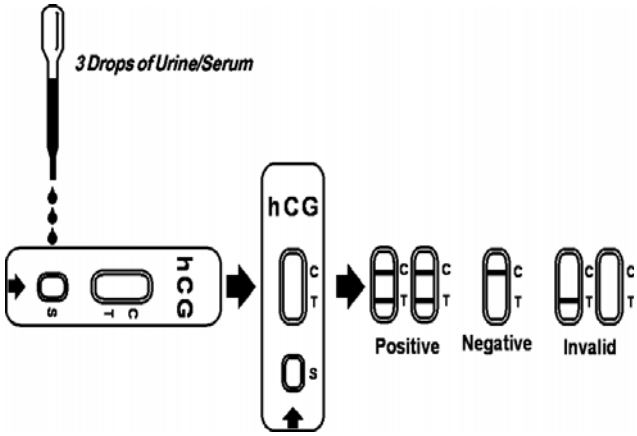
PROCEDURE

Allow the test cassette, urine or serum specimen and/or controls to equilibrate to room temperature (20-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer **3 full drops** of urine or serum (approx. 120μL) without air bubbles into the sample well of the test device.to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the red line(s) to appear. Read the result within **3-5 minutes.**

Note: After 15 minutes the sensitivity increases to 10 mIU/mL. This increase risks to get apparently false positive results due to natural abortions, elevated physiological hCG levels of non-pregnant women and drugs comprising hCG. Thus, we recommend to interpret the test after 5 minutes reaction time for routine purposes.



POSITIVE: Pregnant. Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

NOTE: The shade of red color in the test line region (T) will vary depending on the concentration of hCG present. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

NEGATIVE: Non-pregnant. One red line appears in the control region (C). No apparent red or pink line appears in the test region.

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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 cassette. If the problem persists, discontinue using the test kit immediately and contact your distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

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 test devices are received.

CLINICAL SIGNIFICANCE

Human chorionic gonadotropin 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]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 LINEAR B-hCG cassette is a rapid test that qualitatively detects the presence of hCG in urine or serum specimens at the sensitivity of 20 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine or serum. At the level of claimed sensitivity, the LINEAR B-hCG cassette shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

ANALYTICAL PERFORMANCE

The test device can be evaluated 3 to 5 minutes after the addition of specimen to the test device.

Sensitivity

The analytical sensitivity of LINEAR hCG Pregnancy Test is 20 mIU/mL (based on the 4th IRP of HCG). The sensitivity was established by repetitive testing of samples containing 20 mIU/mL hCG during a period of several weeks.

The LINEAR hCG Pregnancy Tests do not show a “high dose Hook” or “Prozone Effect” up to the maximal observed physiological concentration (600 IU/mL). Thus, the working range is 20 mIU/mL up to 600 IU/mL.

Specificity

The specificity of the hCG Pregnancy Test 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 300 mIU/mL hLH, 1000 mIU/mL hFSH and 1000 μIU/mL hTSH.

Precision/Urine Assay

Studies were performed which consisted of testing 130 positive and 178 negative urine specimens using the hCG one step versus a reference hCG immunoassay. Both of these studies demonstrate 100% (relative) correlation.

Precision/Serum Assay

Another studies were performed which consisted of testing 169 positive and 250 negative serum specimens using the hCG one step versus a reference hCG immunoassay. Both of these studies demonstrate 100% (relative) correlation.

NOTES

1. 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.
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 or serum specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine or serum specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons,[5] a test result that is weakly positive should be confirmed by retesting with a first morning urine or serum specimen collected 48 hours later.
4. 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.6,7 Therefore, the presence of hCG in urine or serum specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. Do not use test if pouch is damaged.
6. Do not use more than the required amount of liquid
7. Do not touch the reaction zone of the device to avoid contamination
8. Avoid cross-contamination of samples by using a new specimen collection container and specimen pipette for each sample.
9. 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.

REFERENCES

1. Batzer FR. Fertility and Sterility 1980; 34:1.
2. Catt KJ, Dufan ML, Vaitukaitis JL. J. Clin. Endocrinol. Metab. 1975; 40:537.
3. Baunstein GD, Rasor J, Adler D, Danzer H, Wade ME. Am. J. Obstet. Gynecol. 1976; 126:678.
4. Lenton EA, Neal LM, Sulaiman R. Fertility and Sterility 1982; 37:773.
5. Engvall E. Methods in Enzymology 1980; 70:419.
6. Uotila M, Ruoslahti E, Engvall EJ. E. J. Immunol. Methods 1981; 42:11.
7. Steier JA, Bergsjo P, Myking OL. Am. J. Obstet. Gynecol. 1984; 64:391.
8. Dawood MY, Saxena BB, Landesman R. Am. J. Obstet. Gynecol. 1977; 50:172.
9. Braunstein GD, Vaitukaitis JL, Carbone PP. Ann. Inter. Med. 1973; 78:39.

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