B-hCG cassette CE

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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 4130020 20 Pregnancy test device
20 Disposable specimen droppers.

REF 4130050 50 Pregnancy test device
50 Disposable specimen droppers.

STORAGE AND STABILITY

Store at 4-30ºC.
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.

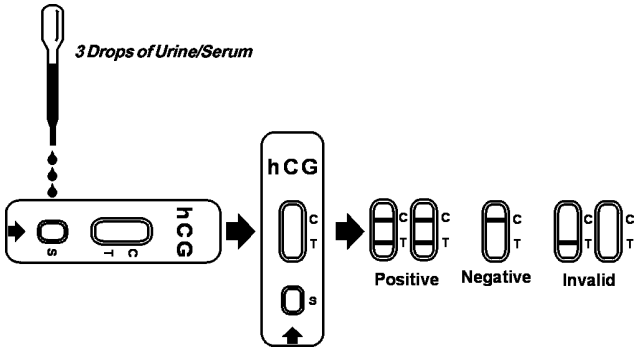
MATERIALS REQUIRED

- Timer.
- Specimen collection container.

PROCEDURE

Allow the test cassette, urine or serum specimen and/or controls to equilibrate to room temperature (15-30°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. 100µl) 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 at 3 minutes when testing a urine specimen, or at 5 minutes when testing a serum specimen.
   Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.



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

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

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

Joaquim Costa, 18, 2ª planta. 08390 Montgat – Barcelona (Spain). Tel. (+34) 93 4694990 Fax (+34) 93 4693435
Almacén: Sant Antoni Mª Claret, 8 bis. 08390 Montgat – Barcelona (Spain) www.linear.es e-mail: info@linear.es

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.[1,2,3,4] hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period,[2,3,4] 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 LINEAR B-hCG cassette is a rapid test that qualitatively detects the presence of hCG in urine or serum specimens 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 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

A multi-center clinical evaluation was conducted comparing the results obtained using the LINEAR B-hCG cassette to another commercially available urine/serum membrane hCG test. The urine study included 159 specimens and both assay identified 88 negative and 71 positive results. The serum study included 72 specimens and both assays identified 51 negative and 21 positive results. The results demonstrated a 100% overall accuracy of the LINEAR B-hCG cassette when compared to the other urine/serum membrane hCG test.

hCG Reference Method (Urine)

Method		*Other hCG Rapid Test*		**Total Results**
LINEAR B-hCG cassette	Results	Positive	Negative	
	Positive	71	0	71
	Negative	0	88	88
Total Results		79	76	159

Relative Sensitivity: 100%
Relative Specificity: 100%
Accuracy: 100%

hCG Reference Method (Serum)

Method		*Other hCG Rapid Test*		**Total Results**
LINEAR B-hCG cassette	Results	Positive	Negative	
	Positive	21	0	21
	Negative	0	51	51
Total Results		21	51	72

Relative Sensitivity: 100%
Relative Specificity: 100%
Accuracy: 100%

Sensitivity and specificity

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

Interfering Substances

The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen	20 mg/mL	Caffeine	20 mg/mL
Acetylsalicylic Acid	20 mg/mL	Gentisic Acid	20 mg/mL
Ascorbic Acid	20 mg/mL	Glucose	2 g/dL
Atropine	20 mg/mL	Hemoglobin	1 mg/dL
Bilirubin (serum)	40 mg/dL	Bilirubin (urine)	2 g/dL
Thiglycerides (serum)	1200 mg/dL		

None of the substances at the concentration tested interfered in the assay.

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. 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.

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Joaquim Costa, 18, 2ª planta. 08390 Montgat – Barcelona (Spain). Tel. (+34) 93 4694990 Fax (+34) 93 4693435
Almacén: Sant Antoni Mª Claret, 8 bis. 08390 Montgat – Barcelona (Spain) www.linear.es e-mail: info@linear.es