Eva™ hCG STRIP

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INTENDED USE

Strip test for detection of hCG in Urine.

Easy to use
- High Specificity
- Sensitivity better than 20 mIU/ml
- 5 minutes test.

INTRODUCTION

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by trophoblastic cells and later by the placenta. Hence in a normal pregnancy hCG appears in urine soon after conception. Concentration of the hormone increases rapidly and therefore it serves as an indicator of pregnancy. The level of urinary hCG is about 100 mIU/ml at the time of the first missed menstrual period. The highest values (1,00,000-2,00,000 mIU/ml) can be demonstrated towards the end of the first trimester.

Elevated serum hCG levels are also associated with trophoblastic or nontrophoblastic neoplasms like hyadatidiform mole, choriocarcinoma, therefore such diseases should be ruled out before a positive hCG result is considered diagnostic for pregnancy.

PRINCIPLE

The Eva hCG strip includes a sample (filter) pad, a conjugate pad, conjugate consisting of anti β hCG (monoclonal) antibody, a test line (zone) on the chromatographic membrane with coating of anti α hCG (monoclonal) antibody and a control line (zone) consisting of Goat anti-mouse IgG and finally attached to another filter pad acting as sink for excess flow.

Testing is started by placing the test strip in a test tube with sample. The sample flows through a filter into the chromatographic membrane where it comes into contact with different reagent zones. At first the sample rehydrates the pink-purple conjugate reactive with anti β hCG. The hormone in the sample attaches on to the conjugate and the complex migrates further in the membrane towards the stationary antibody zone where the antibody conjugate hCG complex is captured by anti α hCG antibody leading to the formation of a pink-purple line in the test reaction Zone (test line).

The test includes excess of the conjugate complex which migrates further in the membrane where it will be captured by the second stationary antibody reactive to the antibody conjugate leading to the formation of a second pink-purple line in the reaction zone (control line), indicating the proper performance of the test. If the specimen does not contain hCG hormone or if the hormone level is very low, the antibody conjugate hCG complex will not be formed, the antibody conjugate reagent will freely pass over the first stationary antibody zone, will be captured by the second antibody in the membrane and leading to the formation of only one pink-purple line (control line). The sensitivity of Eva hCG Strip has been adjusted so that it will detect the urinary hCG level equal or higher than 20 mIU/ml. (The World Health Organisation, Third International Standard.) This level is normally reached in approximately 10 days after conception.

PRESENTATION

	50 Test	100 Test	250 Test
Eva (hCG) Test Strip	50 Strips	100 Strips	250 Strips

Each Strip is sealed in an individual aluminum pouch along with the silica gel (desiccant).

CE

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PRECAUTION

- Do not cut the pouch and leave the strip exposed to air. Cut as many pouches as required and use immediately.
- Handle the strip with care and do not bend them.

STORAGE AND STABILITY

Eva hCG test strip should be stored at 4-40°C. The strip may be stored at room temperature but not exceeding 40°C in the original sealed pouch. The shelf life or expiry of the strip is printed on the pouch as well as on the carton label. The test kit should be kept away from direct sunlight, moisture and heat.

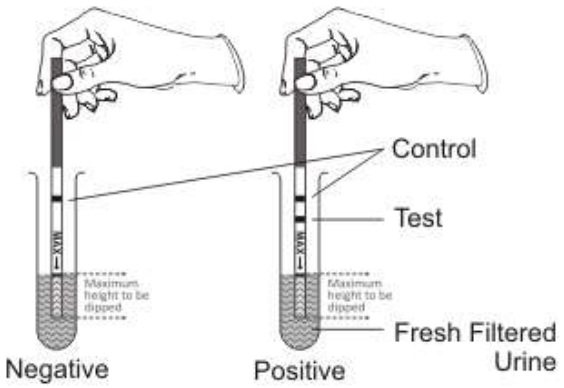
SPECIMEN COLLECTION AND STORAGE

The concentration of hCG is highest in the first urine of the morning. Therefore, it is recommended to perform the test using this specimen. However, if it is not possible any other urine sample can be used. The urine sample can be stored at room temperature (25 ± 5°C) for upto 8 hours and at 2-8°C for upto 4 days.

TEST PROCEDURE

1. Open the pouch and remove the strip.
2. Bring the specimen to room temperature. Place a 12 x 50 mm test tube in a test tube stand. Pipette approximately 200µl of sample directly to the bottom of the test tube. Avoid wetting of the inside walls of the test tube as drops on the walls of the test tube may risk the test by wetting the test strip above the filter area.
3. Take one test strip from the pouch and place it in the test tube till the mark (⇓⇓) on the strip with sample pad end downwards.
4. Let the strip remain standing in the urine until you see that the control line (the upper line in the reaction zone) has fully formed.
5. Read the result within 3 to 5 minutes after having placed the test strip into the tube.
6. Faint line or doubtful results are confirmed by simply keeping the strip on a flat surface for further 5 to 10 minutes. But always read the result before complete drying of the strip.

INTERPRETATION OF RESULTS



1. If a distinct pink-purple line is formed only at the upper end (control line) of the reaction zone, the test result is negative.
2. If a distinct pink-purple line is formed at the lower end (test line) and at the upper end (control line) of the reaction zone, the test result is positive.

NOTE

1. Filtered urine always gives a better test result.
2. Read the results within 5 to 10 minutes. Appearance of two lines is indicative of presence of hCG.
3. Observe the strip within 5 to10 minutes. In many cases a faint test band may appear, for the following reasons.
   (a) A very early pregnancy. The strip test is very very sensitive and reads well below the claimed (20 mIU/ml) value.
   (b) Improper storage of urine resulting in partial loss of hCG.
   (c) A nonspecific binding due to urine contaminated with bacteria, and/or presence of protein (albumin) etc.
   (d) Patients on drugs and drug addicts.
4. If a faint test band appears after 5 minutes, it is always advisable to repeat the test after 2-3 days before final interpretation.

SPECIFICITY

No interference or false positive results observed due to structurally related hormones such as Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH) and Thyroid Stimulating Hormone (TSH) at physiologically possible levels.

LIMITATIONS

1. Signs and symptoms of the patient must be clinically correlated for the interpretation of pregnancy test.
2. During certain conditions like trophoblastic diseases and nontrophoblastic neoplasms, hCG levels are elevated, comparable to normal pregnancy. The diagnosis should be based on appropriate clinical evidences.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. A false positive result may be seen in case of drug addicts.
5. A positive strip result which shows negative on subsequent testing (after 1 to 2 days) indicates an early abortion due to uterine pathology.
6. The strip may show positive for hCG due to the tumors of ovaries Dysgerminoma, Embryonal carcinoma with STGC, yolk sac tumer with STGC, Seminoma, Seminoma with STGC, Primary epithelioma of ovaries etc. (STGC = Syncytiotrophoblastic Giant Cells)

HIGH DOSE EFFECT

Normal Urine that were spiked with hCG concentration of 62,500,1,25,000, 2,50,000 1,000,000 and 2,000,000 mIU/ml were used to study the high dose hook effect on one step hCG Pregnancy Test. It was noticed that both color bands at the test band region and the control region were visible. However, when hCG levels were over 500,000 mIU/ml, the higher the hCG concentration became, the lighter the band at the test region became.

REFERENCES

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