

hCG-Strip

(Strip for test of Pregnancy)

This strip test is for detection of β hCG in urine which is an indicator for pregnancy.

INTRODUCTION:

Human chorionic gonadotropin, hCG belongs to the family of glycoprotein hormone. It consists of two non-identical subunits the alpha and the beta subunits. The beta subunits of hCG due to the unique amino acid sequence is structurally different from that of other hormones like LH, FSH and TSH. This renders the beta subunits its biological and immunological specificity.

The hCG is produced by the developing placental tissue after implantation of the fertilized ovum in the uterine wall. Hence its level begins to rise and becomes detectable in urine as early as 5 to 10 days after conception and reaches up to 100 IU/ml during the first trimester.

Thus the detection of hCG in urine acts as an excellent tool for the confirmation of pregnancy in normal females.

However, the urine hCG level is also found to rise in case of trophoblastic or non-trophoblastic neoplasm like hydatiform mole and choriocarcinoma conditions.

PRINCIPLE:

The Estrom hCG strip is based on the principle of immunochromatography. Monoclonal antibodies against hCG are conjugated with the colloidal gold reagent and impregnated on the absorbent pad. The reaction zone constituting the nitrocellulose membrane is coated with polyclonal antibodies against hCG and anti-hCG antibody in the test zone and control zone respectively. The Estrom hCG strip when dipped into the specimen sample, flows through the sample pad to the conjugate pad. The hCG if present in the sample binds to the conjugate and this complex moves further by capillary action and binds to the anti hCG antibody forming a purple test line. The excess of the complex moves further when it binds with the polyclonal anti-hCG antibodies to form a control line. In absence of hCG in the sample the hCG conjugate complex is not formed. However the conjugate reagent moves further towards the control zone and binds with the anti hCG antibody to form a control line.

SPECIMEN COLLECTION AND STORAGE:

1. Use a clean container for collection of specimen.
2. It is recommended to use first urine sample of the day for optimal results.
3. Randomly collected sample may also be used.

PRECAUTION:

- Estrom hCG strips is for Invitro diagnostic use only.
- Do not expose the strip to air for a long period. If the specimen is turbid or has precipitates the sample should be centrifuged before testing.

PRESENTATION:

Disposable hCG strips 100 Test
No of pouches 100

STORAGE STABILITY & SENSITIVITY:

The Estrom hCG test strips are stable upto the expiry date printed on label.

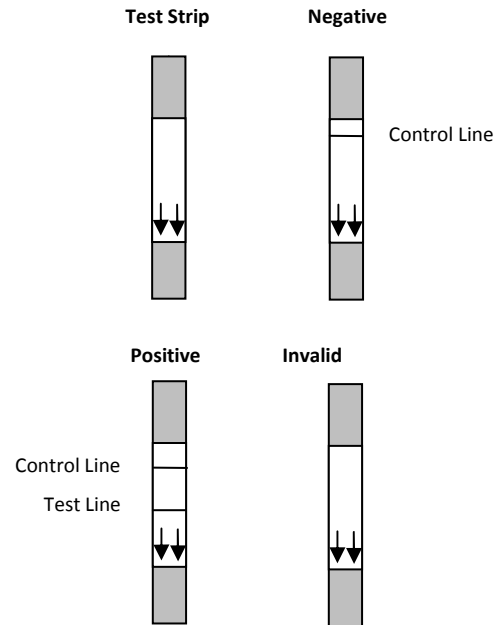
- The Estrom hCG test strips must be stored at 4 - 30^o C. Do not freeze.
- The Estrom hCG test strips has a sensitivity of 25 mIU/ml.

PROCEDURE:

- Allow the hCG test pouch to attain room temperature.
- Transfer the required amount of specimen to a test tube. Carefully remove the strip from the pouch & immerse it into the sample in the test tube
- The level of urine should be below the mark indicated on the strip for 20 seconds.
- Remove the strip from the tube as soon as the control line appears, and place it as a flat surface.

Read results within 5 minutes.

Do not read after 5 minutes



- Negative result: Single band in control zone
Positive result: Two bands one in control zone and one in test zone
Invalid result: No bands even after completion of test

LIMITATIONS:

- Since hCG is found to be elevated in certain conditions other than pregnancy like Trophoblastic diseases and non trophoblastic neoplasm including choriocarcinoma and hydatiform mole. These conditions should be ruled out before confirming diagnosis of pregnancy.
- The hCG levels are elevated in case of ectopic pregnancy, hence the strip may show positive at this time. Later on a spontaneous miscarriage may deplete the level of hCG resulting in a negative test.
- In case of very early pregnancy the test result may show negative or a very faint line due to very low hCG concentration. The test can be repeated after 3-4 days using fresh urine sample.
- A false positive result may be observed in case of some drug addicts.
- As with all diagnostic test procedure, the physician should confirm the test based on all other clinical symptoms and datas of the patient.
- For accurate and reliable results, the test procedure must be followed as per instruction provided in the product insert.

BIBLIOGRAPHY:

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	Attention, see instructions for use		Consult Instructions For Use
	For in vitro diagnostic use only		Catalog #
	Store between 4-30°C		Lot Number
	Do not use if package is damaged		Date of Manufacturing
	Manufacturer		Use by