Angcard hCG

One Step Pregnancy Test Device(Urine)

ANGSTROM BIOTECH PVT. LTD

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

Human chorionic gonadotropin, hCG belongs to the family of glycoprotein hormone. It consists of two non-identical subunits the alpha and beta subunits. The beta subunit 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 being 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 condition.

PRINCIPLES:
The hCG card is based on the principle of immuno-chromatography. 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 ant-hCG antibody in the test zone and control zone respectively. The hCG card 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 where it binds with the polyclonal anti hCG antibodies to form a control line.

In absence of the 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.

REAGENTS:
The test contains anti-hCG particles coated on the membrane.

SPECIMEN COLLECTION AND STORAGE:
Use a clean container for collection of specimen.
It is recommended to use first urine sample of the day for optimal results.
Randomly collected sample may also be used.

PRECAUTION:
hCG cards is for *in-vitro* diagnostic use only.
Do not expose the card to air for a long time period.
If the specimen is turbid or has precipitates the sample should be centrifuged before testing.

PRESENTATION:

Disposable hCG test Cards	50 Tests
No. of Pouches	50

The hCG test cards are stable up to the expiry date printed on the label.
The hCG test cards must be stored at 4-30°C. Do not freeze.
The hCG card has a sensitivity of 25 mIU/mL.

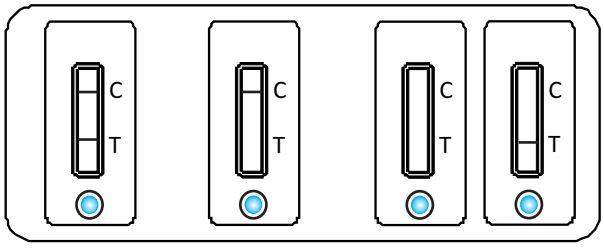
MATERIALS:
Test Devices.
Droppers.
Package Insert.

MATERIALS REQUIRED BUT NOT PROVIDED:
Specimen collection container.
Timer or stop watch.

PROCEDURE:
Allow the hCG test pouch to attain room temperature. Carefully remove the card from the pouch and place it on clean & flat surface. Add 2-3 drops of urine sample into the sample well using the dropper provided. Read results within 5 minutes.

One Step Pregnancy Test Device

1. Add 2-3 drops of urine sample in to the sample well.
2. Read results within 5 minutes..



Positive **Negative** **Invalid**

RESULTS INTERPRETATION:

Positive: Two distinct colored lines appear. One line should be in the control line region 'C' and another line should be in test line region 'T'. ***Note:*** *The intensity of the color in the test line region 'T' may vary depending on the concentration of hCG present in the specimen. Therefore any shade of color in the test line region 'T' should be considered positive.*

Negative: One colored line appears in the control line region 'C'. No apparent colored line appears in the test line region 'T'.

Invalid: Colored line fails to appear. In sufficient specimen volume or incorrect procedural techniques are the most likely reason for the control line failure. Review the procedure and repeat the test kit immediately or contact your local distributor.

LIMITATIONS:
Since hCG found to be elevated in certain conditions other then pregnancy like Trophoblastic disease and non-Trophoblastic neoplasm including Choriocracinoma and hydatiform mole. These conditions should be ruled out before confirming diagnosis of pregnancy.

The hCG levels are elevated even in case of ectopic pregnancy. Hence the card may show positive at this time. Later on a spontaneous miscarriage may deplete the label of hCG resulting in a negative test.

In case of a very early pregnancy the test 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.

As with all diagnostic test procedure, the physician should confirm the test based on all other clinical symptoms and data of patients.

For accurate and reliable results, the test procedure must be followed as per instruction provided in the product pack insert.

Negative results are expected in healthy nonpregnant women and healthy men. 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 One Step Pregnancy Test Device (Urine) has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

BIBILIOGRAPHY:

Catt., KJ, Duffau, J.L., and Varitukaitis, JL, JClin, Endocrinol Metab.

Lenton, EA, Neel, L.M. Sulalman, R., Fertility & Sterility Vol. 37,773

ANGSTROM BIOTECH PVT. LTD
G1 - 1035, Phase - III,
RIICO Industrial Area,
Bhiwadi, Alwar, Rajasthan.
Pin Code - 301019
Email: info@angstrombiotech.in
Website: www.angstrombiotech.in
Customer Care Number - 9599194831

	Attention,see instructions for use		Consult Instructions For Use
IVD	For in vitro diagnostic use only	REF	Catalog #
4°C 30°C	Store between 4-30°C	2	Do not reuse
	Do not use if package is damaged	LOT	Lot Number
Σ	Tests per kit		Date of Manufacturing
	Manufacturer		Use by