Gravi Check®

ONE STEP PREGNANCY TEST
Device

INTRODUCTION
Gravi Check®, One Step Pregnancy Test is a rapid, self-performing, qualitative, two site sandwich immunoassay for the determination of human Chorionic Gonadotropin (hCG), a marker for pregnancy, in urine/serum specimens.

SUMMARY
Human chorionic gonadotropin (hCG), is a glycoprotein hormone secreted by viable placental tissue during pregnancy. The appearance of hCG in urine/serum soon after conception and its rapid rise in concentration makes it an ideal marker for the early detection and confirmation of pregnancy. However elevated hCG levels are frequently associated with trophoblastic and non-trophoblastic neoplasms and hence these conditions should be considered before a diagnosis of pregnancy can be made. ***Gravi Check***®, One Step Pregnancy Test detects the presence of hCG in urine/serum specimens, qualitatively, at concentrations as low as 10 mIU/ml.

PRINCIPLE
Gravi Check®, One Step Pregnancy Test utilizes the principle of **Immunochromatography**, a unique two site immunoassay on a membrane. As the test sample flows through the membrane assembly of the device, the colored anti-hCG-colloidal gold conjugate complexes with the hCG in the sample. This complex moves further on the membrane to the test region where it is immobilized by the anti-hCG coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the anti-rabbit antibodies coated on the membrane at the control region, forming a colored band. This control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED
Each kit contains:
A. Individual pouches each containing a :
1. Test device: Comprising of membrane assembly predispensed with anti-hCG antisera-colloidal gold conjugate, rabbit IgG colloidal gold conjugate and anti-hCG antiserum and anti-rabbit antiserum at the respective regions.
2. Disposable plastic dropper.
3. Desiccant pouch.

B. Package insert.

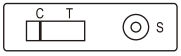
STORAGE AND STABILITY
The sealed pouches in the test kit may be stored between 4-30°C till the duration of the shelf life as indicated on the pouch. DO NOT FREEZE.

NOTE
1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.

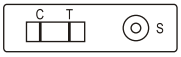
SPECIMEN COLLECTION AND PREPARATION
Urine as sample:
Though random urine specimens can be used, first morning urine specimen is preferable as it contains the highest concentration of hCG. Specimens should be collected in clean glass or plastic containers. If testing is not immediate, the urine specimens may be stored at 2-8°C for upto 72 hours. Turbid specimens should be centrifuged or allowed to settle and only the clear supernatant should be used for testing.
Serum as sample:
No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum is preferable, serum specimens may be stored at 2-8°C for upto 24 hours, in case of delay in testing. Do not use hemolysed or contaminated specimens. Turbid specimens should be centrifuged or allowed to settle and only the clear supernatant should be used for testing.

TEST PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the sealed pouch to room temperature, open the pouch and remove the device. Once opened, the device must be used immediately.
2. Dispense two drops of urine/serum specimen into the sample well `S' using the dropper provided. Refrigerated specimens must be brought to room temperature prior to testing.
3. Read the results **at the end of five minutes,** for urine samples and **at the end of fifteen minutes** for serum samples as follows:



Negative: Only one colored band appears on the control region`C.



Positive: In addition to the control band, a distinct colored band also appears on the test region`T'.

4. The test should be considered invalid if no band appears. Repeat the test with a new device.
5. Although, depending on the concentration of hCG in the specimen, positive results may start appearing as early as 30 to 60 seconds, negative results must be confirmed only at the end of the stipulated time.

LIMITATIONS OF THE TEST

1. A number of conditions other than pregnancy including trophoblastic and non-trophoblastic neoplasms such as hydatidiform mole, choriocarcinoma etc. cause elevated levels of hCG. Such clinical conditions must be ruled out before a diagnosis of pregnancy can be made.
2. Highly dilute urine specimens and specimens from very early pregnancy may not contain representative levels of hCG. If pregnancy is still suspected, repeat the test with first morning urine after 48-72 hours after the initial test.
3. As with any assay employing animal antibodies, presence of cross-reacting heterophilic antibodies may yield discrepant results.
4. As with all diagnostic tests, the results must be correlated with clinical findings.

PERFORMANCE CHARACTERSTICS

1. Sensitivity: ***Gravi Check***®, One Step Pregnancy Test detects the presence of hCG in urine/ serum specimens, qualitatively, at concentrations as low as 10 mIU/ml. Concentrations of about 100 mIU/ml of hCG are reached by the first missed menstrual period in normal pregnancy. Thus ***Gravi Check***®, One Step Pregnancy Test is able to detect pregnancy at very early stages.
2. Specificity: Normally, healthy men and healthy non-pregnant women do not have detectable levels of hCG by the ***Gravi Check***®, One Step Pregnancy Test. Homologous hormones and other potentially interfering substances spiked beyond peak physiological concentrations do not cross react with ***Gravi Check***®, One Step Pregnancy Test.
3. Accuracy: The results obtained by ***Gravi Check***®, One Step Pregnancy Test correlated very well when run in parallel with other commercially available tests for pregnancy, using known positive and negative specimens.

WARRANTY

This product is designed to perform as described on the label and the package insert, the manufacturer disclaims any implied warranty of use and sale for any other purpose.

REFERENCES

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