Directions for Use

1. Use the test card with early morning urine.
2. Put 3 drops of urine on the sample well.
3. Two pink lines indicate that you are pregnant.
4. One pink line indicates that you are not pregnant.
5. If you get a light pink line, then you have to retest using the required amount of urine.

Manufactured by:
CHIMERA BIOTECH PVT. LTD.
199, DSIIDC Sheds,IInd Floor
Okhla Industrial Area, Phase-1, New
Delhi-110020. INDIA
Email Address: info@chimerabiotec.com

PREGNCY TEST

Description

Get pregnancy results in just 5 minutes with Pregayan Pregnancy Test Card. It is specially designed for assessing pregnancy results at the comfort of your home with 3 drops of the urine sample. It comes with a sample well and result window that makes it easy for using and reading the results so you can detect whether or not you are pregnant super quick.

Key Benefits

- Simple to use and read pregnancy results.
- Works with just 3 drops of urine sample.
- Shows results as quick as in 5 minutes.

Safety Information

- Read the label carefully before use.
- Store in a cool and dry place.

CHIMERA®

Pregyan

One step urine pregnancy test

Agglutinating sera reagent for detection of hCG for in-vitro diagnostic use only.

Pregyan Pregnancy Test

Lateral flow chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin(hCG) hormone in human urine/serum

Introduction

Human chorionic gonadotropin (hCG) is a hormone that is useful as an early pregnancy marker in humans. It is a glyco-protein secreted by the placenta in pregnant women. Its levels can be detected qualitatively about 2 weeks after fertilization in urine. The concentration of the hormone rises very rapidly,and is present in enough concentration to be detected in urine by the first missed menstrual cycle. Its concentration peaks during the second trimester (8-11 weeks), reaching upto 200,00mIU/mL.The main function of hCG is to maintain the corpus luteum during early pregnancy, thereby placing an important role in progesterone production and hence thickening of the uterus lining to support the growing fetus.

Intended Use

The Chimera Pregyan Pregnancy Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin hormone in human urine/serum. The kit is intended for professional use as well as home use. All positive samples should be confirmed by a supplemental assay such as a quantitative beta-hCG blood test.

Test Principle

The Chimera Pregyan Pregnancy Rapid Test is based on the principle of immune complex formation.It is a sandwich immunoassay.Colloidal gold is conjugated to anti-hCG antibodies and coated on the conjugate release pad. The test line is coated with anti-hCG antibody and the control line is coated with anti-chicken IgY hCG hormone, if present in the sample, binds to conjugate and forms a complex. The immunocomplex moves across the pad through capillary action and is then captured on the membrane by the pre-coated antibodies leading to the formation of a sandwich immune complex.This sandwich complex can be seen as coloured test line. In absence of hCG hormone in the sample, no complex is formed and hence no visible precipitation is seen at the test line.

ACTIVE INGREDIENTS OFMAIN COMPONENT Materials Provided

Components	25 Tests
Test Device (individually in a foil pouch with desiccant)	25 Tests
Specimen transfer droppers	25 Tests
Instructions for use	1

For serum: Collect blood specimen by venipunctures in a tube without anti-coagulant. Allow the specimen to clot at room temperature and then separate the serum by centrifugation

Kit Storage and Stability

The kit should be stored at 2-30℃ in a clean and dry area, away from moisture and directsunlight.DO NOTFREEZE.
The test kit is stable through the expiration date printed on the sealed pouch.The test kit should
not be opened before use.Use beyond expiration date is not recommended.

Specimen Collection and Preparation

For urine:Collect urine in a clean and dry specimen container.It is preferable to collect the first urine of the morning as it contains the highest concentration of the hCG hormone.
Centrifuge/filter/allow the sample to settle in case the urine sample contains visible precipitate

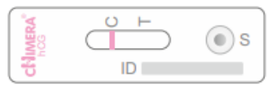
TEST PROCEDURE

1. Allow specimens and test components to reach temperature.The specimen must be mixed thoroughly before proceeding with the test.
2. Take the device out of the pouch and place it on a clean flat surface. Label the device properly with the patient ID.
3. Add 2 drops (approximately 20-25µL) of the specimen (urine) into the center of the sample well (S) using the provided dropper or a precise micropipette.
4. Take a reading after
5 minutes.DO NOTTAKE AREADING AFTER 20 MINUTES.

INTERPRETATION OFTESTRESULTS

Negative result:

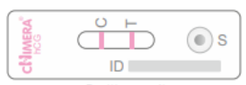
Only Control line ("C") within the result window indicates a negative result for pregnancy.



Negative result

Positive result:

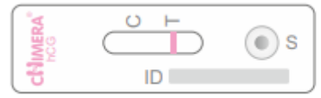
Two coloured bands (Control line "C" and Test line "T") within the result window indicate a positive result for pregnancy.



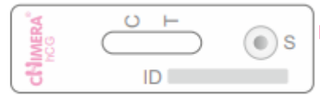
Positive result

Invalid result:

If the control band (Control line "C") is not visible within the result window, the test result is considered invalid.
The directions may not have been followed correctly or the test may have deteriorated.Re-test with a new device



Invalid result



Invalid result

QUALITYCONTROL [Internal QualityControl]

Internal procedural controls are included in the test.Acolor line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

WARNINGS & PRECAUTIONS

1. Do not re-use the kit.
2. Do not use the device if the device package is damaged or seal is broken.
3. Do not smoke,drink or eat while handling specimen.
4. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local,state and national regulations.
5.Silica gel in device package is to absorb moisture and keep humidity from affecting products
6. Do not use any body fluid other than urine/serum.
7. For in vitro diagnostic use only.
8. Do not use the kit contents beyond the expiration date printed on the outside the box.
9. Immediately perform the test after removing the test device from the device package.
10. Discard the device immediately after reading result.

LIMITATION OFTHE TEST

1. The kit only provides qualitative detection of hCG hormone.It is not for quantitative use.
2. The kit provides presumptive detection of pregnancy. Confirmatory testing by quantitative beta-hCG detection must be done for all positive tests.
3. A negative result may be obtained for samples containing very low concentrations of hCG hormone. Hence, a negative test result does not completely rule out the possibility of pregnancy

Product Disclaimer

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside the control of Chimera and distributor. The result may accordingly be affected by environmental factors and/or use error.A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result. Chimera and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.