ASTAM DIAGNOSTICS

PRODUCT INSERT

REF HCGD

PRATHAM® One Step Urine hCG Pregnancy Test

For the qualitative detection of hCG (human Chorionic Gonadotropin) in human urine.

INTENDED USE

PRATHAM® One Step Urine hCG Pregnancy Test Device is a rapid immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in human urine to an aid in the diagnosis of pregnancy in female. For professional and in-vitro diagnostic use only.

INTRODUCTION

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by placental trophoblastic cells shortly after fertilization. After pregnancy, human body produces a special pregnancy hormone known as hCG. The appearance of hCG in urine soon after conception and its rapid rise in concentration makes it an ideal marker for early detection and confirmation of pregnancy. However elevated hCG levels are frequently associated with trophoblastic and nontrophoblastic neoplasm and hence these conditions should be considered before diagnosis of pregnancy can be made.

TEST PRINCIPAL

Pratham® One Step Pregnancy Test Device contains a membrane strip, which is pre-coated with the anti hCG capture antibody on test band region. The anti-hCG antibody colloid gold conjugate and sample move along the membrane chromatographically to the test region "T" and forms a visible line as antibody-antigen antibody gold particle complex. The Pratham Pregnancy Test Device has letter of "T" and "C" as "test line" and "control line" on the window of test device. The Test line "T" is indicating the specimen is positive and The Control Line "C" is indicating the proper functioning of device and adequate sample volume used for the test performed.

KIT COMPONENTS

1. Pouch contents: Test Cassette, Sample Dropper, Desiccant
2. Instruction for use

MATERIAL REQUIRED BUT NOT PROVIDED

Timer and Urine collection container etc.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30ºC till the duration of self life as indicated on the pouch. Do not freeze. Once the pouch is opened, test card must be used immediately.

PRECAUTIONS

1. For professional use only.
2. Bring all reagents and specimen to room temperature before use.
3. Do not pipette any material by mouth. Do not use kit after
5. Use protective clothing and wear gloves when handling samples. Do not mix components of one kit with another
6. Use absorbent sheet to cover the working area.
7. Immediately clean up any spills with sodium hypochlorite.
8. Dispose of all the reagents and material used as if they contain infectious agent.
9. Neutralize acid containing waste before adding hypochlorite.

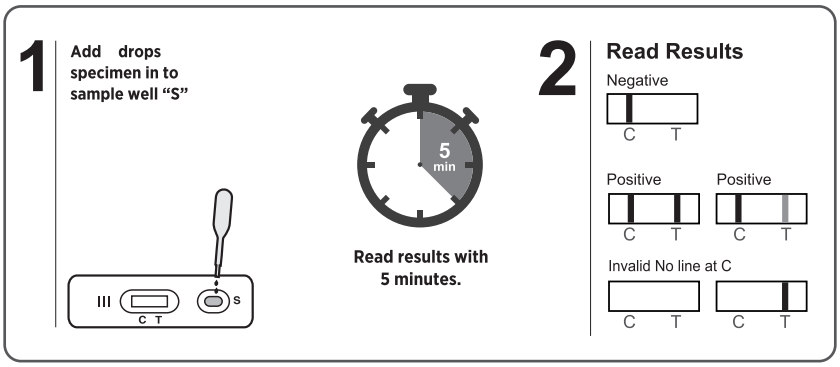
SPECIMEN COLLECTION AND STORAGE

Collect the specimen human urine in a glass or plastic container, test can be used any time of day, but the first morning urine is preferred for testing, usually contains the highest concentration of hCG. If samples are not immediately tested, they should be stored at 2-8°C for not more than 72 hours, otherwise false / incorrect results may be obtained. If specimen stored at 2-8°C brought back to room temperature prior to use. Dispose off after use.

TEST PROCEDURE

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Check the packaging is not damaged. If damaged, discard the test and use another test.
3. Open the pouch & check the desiccant. If color of desiccant does not show any change (Remains blue) you can use the test. If color changes then discard the test and use another test.
4. Add 2 drops of urine specimen into the sample well (S) using the disposable sample dropper provided in kit.
5. Wait for 5 minute and read result. Do not interpret result after 10 minutes.
6. Discard used card in a biomedical waste container after interpreting the results.

TEST PROCEDURE & INTERPRETATION OF RESULTS



Negative:

Appearance of only only one colored band at control line region 'C'. The result should be considered negative.

Positive:

Appearance of two colored bands, one at test region 'T' and other at control line region 'C'. The result should be considered positive.

Invalid:

Appearance of no colored band at the control region C, the result should be considered as invalid. Repeat the test with a new test card.

INTERNAL QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls are not supplied with this kit. It is recommended that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Handle the negative and positive controls in the same manner as patient specimens.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity:** One Step hCG Pregnancy test device detects hCG at a concentration of 25 mIU/ml or greater.
2. **Specificity:** Normal, healthy men and non-pregnant women do not have detectable levels of hCG by the One step hCG Pregnancy Test Device. Physiological levels of LH, FSH and TSH do not interfere with the test.
3. **Accuracy:** A multi-centeric clinical evaluation was conducted. The results of One Step hCG Pregnancy Test device was compared with other commercially available hCG tests (urine). The study showed identical results with100 urine specimens tested.
4. **Precision:** Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive samples. No variations were found in the outcome of the different tests.

LIMITATIONS

1. A number of conditions other than pregnancy including trophoblastic and non-trophoblastic neoplasms such as hydatid form mole, choriocarcinoma etc. cause elevated levels of hCG. Such clinical conditions must be ruled out before 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 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.

DISPOSAL

Consider all test devices run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Every precaution has been taken to ensure diagnostic ability and accuracy of this product. This product is used outside the control of manufacturer and distributors. Various factors including storage temperature, environment conditions, and procedural errors may affect the result. A person who is subject of the diagnosis should consult a doctor for further confirmation.

WARNING

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

REFERENCES

1. Braun stein GD, J Rasor, H. Danzer, D Adler, ME Wade. "Serum human chorionic gonadotropin levels throughout normal pregnancy." Am J. Obstet Gynecol. 1976; 126(6): 678-681.
2. Lenton EA, LM Neal, R Sulalman. "Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy". Fertill. Steril. 1982; 37(6): 773-778.
3. Steier JA, P Bergsjo, OL Myking. "Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy". Obstet, Gynecol. 1984;64(3): 391-394.
4. Dawood MY, BB Saxena, R Landesman. "Human chorionic gonadotropin and its subunits In hydatid from mole and choriocarcinome". Obstet Gynecol. 1977: 50(2): 172-181.

SYMBOLS USED ON LABELS

Read instructions for use	Name of Manufacturer	For single use only
No. of test	Expiry Date of Kit.	Date of manufacturing of IVD Kit
IVD In-vitro diagnostic use	Keep away from Sunlight	REF Reference Catalogue Number
Storage Condition		

ASTAM DIAGNOSTICS

Manufactured By:

ASTAM DIAGNOSTICS PVT. LTD.

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