EasyCheck® Pregnancy Test

Sensitivity of 25mIU/mL

For professional in vitro diagnostic use only.

INTENDED USE

The hCG Pregnancy Test Cassette is a rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid for the early detection of pregnancy. The test is intended for in vitro diagnostic testing.

SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. Healthy men and healthy non-pregnant woman do not have detectable hCG by the hCG Pregnancy Test Cassette. However, healthy pregnant woman have hCG in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals. In normal pregnancy, hCG can be detected in serum as early as 7 days following conception. The concentration of hCG continues to rise rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period and peaking in the 100,000 – 200,000 mIU/mL range by 10 – 12 weeks into pregnancy. The appearance of hCG soon after conception and its subsequent rise in concentration during early gestational growth make it an excellent marker for the early detection of pregnancy. The hCG Pregnancy Test Cassette has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed period.

PRINCIPLE

The hCG Pregnancy Test Cassette adopts the principles of double antibody sandwich method and immunochromatography to test the human chorionic gonadotropin (hCG) in urine. The membrane is pre-coated with anti-hCG antibodies in the test region (T) and anti-mouse antibodies in the control region (C). During testing, the urine sample reacts with the coloured conjugate (mouse anti-hCG antibody colloidal gold conjugate), which has been pre-coated on the test strip. The mixture then migrates upward on the membrane to react with anti-hCG antibodies in the test region (T) and generate a red line. Presence of a red line indicates a positive result, while its absence indicates a negative result. Regardless of the presence of hCG, as the mixture continues to migrate across the control region (C), a red line at the control region (C) will always appear. The presence of this red line serves as a verification for sufficient sample volume and proper flow as a control for the reagents.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Read all the information in this leaflet before performing the test.
3. Do not use the kit beyond the expiration date.
4. The test cassette should remain in the sealed foil pouch until use. Do not use if pouch is damaged or opened.
5. Do not touch the membrane located within the result window.
6. As with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a doctor after all clinical and laboratory findings have been evaluated.
7. Do not reuse the test cassette. Discard it in the dustbin after single use.
8. All urine specimens and used cassette should be considered potentially infectious. Avoid contact with skin.

COMPOSITION

The test cassette consists of a polyester membrane pre-treated with mouse anti- αhCG monoclonal antibody colloidal gold conjugate and a nitrocellulose membrane pre-coated with mouse anti-αhCG monoclonal antibody on the test line (T) and goat-anti-mouse IgG polyclonal antibody on the control line (C).

Each pouch contains one test cassette, one dropper and one desiccant. Each box contains 40 pouches and one instruction for use.

STORAGE AND STABILITY

1. Store as packaged in the sealed pouch at room temperature (4-30˚C or 40-86˚F). The kit is stable within the expiry date printed on the labelling.
2. Once the sealed pouch is opened, the test cassette should be used within one hour. Prolonged exposure to ambient humidity will cause product deterioration.
3. DO NOT FREEZE.

ADDITIONAL EQUIPMENT REQUIRED

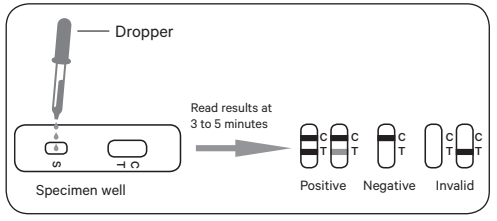
1. Specimen collection container (clean and dry).
2. Timing Mechanism (such as a watch or clock).

SPECIMEN COLLECTION

The urine specimen must be collected in a clean, dry plastic or glass container. The first morning urine is preferred since it generally contains the highest concentration of hCG. However, urine at any time of the day may be used. Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay.

TEST PROCEDURE

Read the entire procedure carefully before performing any tests. **The cassette test and urine samples should be brought to room temperature (15-30˚C) prior to testing.** Do not open the pouches until ready to perform the test.



1. Remove the test cassette from its foil pouch by tearing at the notch. Use cassette as soon as possible but within one hour after removal from pouch, particularly if the room temperature is more than 30°C and in a high humidity environment.
2. To perform the test, draw the urine specimen using the dropper provided, and dispense three drops (approx. 0.1 mL) onto the sample well (S) of the cassette (see diagram).
3. Wait for red-colored lines to appear. The test should be read in approximately 3-5 minutes. Do not interpret results after 5 minutes. Do not interpret the results before 3 minutes.

INTERPRETATION OF RESULTS

PREGNANT: Two distinct red-coloured lines will appear, one in the test region (T) and one in the control region (C). Positive test results are possible but not definitive for the diagnosis of pregnancy. It is strongly recommended that an additional urine specimen should be obtained after 48-72 hours and tested again, or consulting a Medical Doctor.

NOTE: The intensity of the red-coloured line in the test-region (T) may vary depending on the concentration of hCG present in the specimen. Therefore, any shade of red colour in the test region (T) should be considered positive.

NOT PREGNANT: Only one red-coloured line appears in the control region (C). No apparent red or pink line appears in the test region (T). Negative test results mean that you may not be pregnant. However, you should re-test with a first morning specimen obtained 48-72 hours later.

INVALID: Control band fails to appear, which means improper testing procedures or deterioration of reagents probably occurred. Review the procedure and repeat the test with a new cassette test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

NOTE: The result is invalid if no red-coloured line appears in the control region (C), even if a line appears in the test region (T).

QUALITY CONTROL

1. A procedural control is included in the test. A coloured line appearing in the control region (C) is considered an internal positive procedural control, indicating proper performance and reactive agents. A clear background in the Result Window can be seen as a basis for effective testing, and is considered an internal negative procedural control. If the test has been performed correctly and reagents are working properly, the background will be clear to give a discernable result. If the test line is weak, it is recommended that the test be repeated with the first morning specimen obtained 48-72 hours later.
2. It is recommended that a positive hCG control (containing 25-100 mIU/ml hCG) and a negative hCG control (containing "0" mIU/ml hCG) be included in each days testing to verify proper test performance.

LIMITATION

1. Drinking too much fluid before taking the test may cause a false-negative result. For the most accurate results, take the test first thing in the morning when your urine is the most concentrated.
2. Very low levels of hCG (less than 50mIU/mL) are present in urine specimens shortly after conception. A test result that is weakly positive should be confirmed by re-testing with a first morning urine specimen collected 48 hours later.
3. Certain fertility medications which contain hCG (such as Pregnyl, Profasi, Novarel) can give a false-positive result. Alcohol, oral contraceptives, birth control pills, analgesics (pain killers), antibiotics or hormone therapies that do not contain hCG should not affect the test result.
4. A number of medical conditions other than pregnancy, including ovarian cyst, choriocarcinoma or ectopic pregnancy (pregnancy outside the uterus) can cause elevated levels of hCG.
5. Using the test cassette within 8 weeks of giving birth or having a miscarriage may also cause a positive result. You should ask your doctor for help in interpreting your test result if you have had the experience of pregnancy as described above recently.

PERFORMANCE CHARACTERISTICS

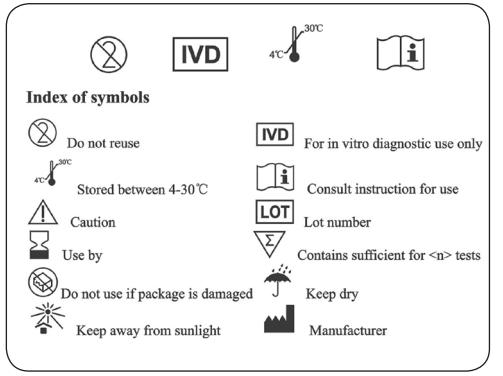
Sensitivity: The analytical sensitivity of the hCG Pregnancy Test Cassette is 25mIU/ml. The sensitivity was established by repetitive testing of samples containing 25mIU/ml hCG during a period of several weeks.

Specificity: The specificity of the hCG Pregnancy Test Cassette was determined from cross-reactivity studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH). Negative results were obtained from all tests conducted with 500mIU/ml hLH, 1000mIU/ml hFSH, 1000μIU/ml hTSH and negative hCG Specimen.

Precision: A study was conducted which consisted of performing a series of replicate assays using 25mIU/ml and 100mIU/ml hCG in urine. All the test results were consistent.

Diagnostic sensitivity and specificity: Studies were performed which consisted of testing 126 positive and 177 negative specimens using the hCG Pregnancy Test Cassette versus a reference hCG immunoassay. Both of these studies demonstrate 100% (relative) correlation.

INDEX OF SYMBOLS



Distributed by: Phoenix MedCare Ltd,
AUCKLAND, New Zealand
Email: enquiries@phoenixmedcare.co.nz
www.phoenixmedcare.co.nz
NZ Freecall 0800 338 019
AU Freecall 1800 830 125

Manufactured by: Hangzhou Clongene Biotech Co., Ltd.
No.1 Yichuang Road, Yuhang Sub-district, Yuhang District,
Hangzhou 311121, China

Effective Date: 14 March 2017