One Step HCG Pregnancy Rapid Test Kit

Product name

HCG Pregnancy Rapid Test Kit（Colloidal Gold）

INTENDED USE

Human chorionic gonadotropin (HCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, HCG can be detected in both urine and serum as early as 7 to 10 days after conception. which can be tested in the urine of pregnant women after conception.

HCG levels continue to rise very rapidly ,frequently exceeding 100mIU/mL by the first missed menstrual period, and peaking in the 100,000-200,000mIU/mL range about 10-12 weeks into pregnancy. The appearance of HCG in both urine and serum soon after conception, and its subsequent rapid in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

In this product, there are three different HCG minimum detection limits. They are 25, 100, and 500mIU/mL respectively. The HCG level in urine samples is determined semi-quantitatively by the display results of different test lines.

The reagent is used for medical and health institutions and self-tests at home, as an early auxiliary diagnosis of pregnancy.

Test Principle

Human chorionic gonadotropin Test Card is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (HCG) in urine to aid in the early detection of pregnancy. The test utilizes antibodies including a monoclonal HCG-α antibody and goat anti-mouse IgG on the nitrocellulose membrane with colloidal gold marked anti-HCG-β monoclonal antibody as an mark tracer. The reagent is used to detect the HCG in urine according to the principle of double antibody sandwich method and gold immunochromatography assay.

Main Components

Sample pad, colloidal gold marked pad （ coated with HCG- β monoclonal antibody）, nitrocellulose membrane（test line coated with HCG- α monoclonal antibody,control line coated with goat anti-mouse IgG.）, absorbent paper and PVC board.

Other tools required for the test: stopwatch, disposable clean urine cup.

Storage and Expiry

The product shall be stored at 4℃~30℃. avoid light and heat, and store in a dry place without freezing; certain protective measures should be taken in hot summer and cold winter to avoid high temperature or freezing and thawing. The reagent board has a shelf life of 24 months. The product should be used within 1 hour (humidity: 20%~90%, temperature: 10℃~50℃) after opening the package.

Date of manufacture and expiry date: See the packaging label.

Sample requirement

The reagent is applicable to urine samples.

Sample collection: Collect fresh urine in a clean and dry container, fresh morning urine as the best. Visible turbid sample should be centrifuged, filtered and precipitated, and the superannuate is taken for test. For delayed test, the urine sample can be stored for 48h in refrigerator at 2℃~8℃, 12 months in freezer at -20℃, and can be unfrozen for 3 times, without impact on the test results.

Test Procedure

TEST METHODS

1. *Instruction for Use* must be read carefully before taking the test. Allow the required test device to come to room temperature for 30 minutes (20°C -30°C) before use. Do not open the inner packaging (pouch) until ready, it must be used in one hour once opened.

2. Test Procedure

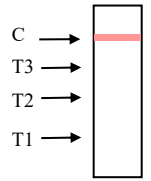
Collect the urine, remove the test cassette from the sealed pouch and place on a clean and level surface. Using the dropper, vertically transfer 2 full drops of urine (approx. 80~100μL) to the specimen well (S) of the test cassette avoiding the formation of bubbles and then start the timer.

3. Observe the test results immediately within 5 minutes, the result is invalid over 5 minutes.

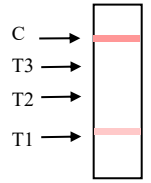
Positive judgment value

Limit of detection：T1：25mIU/mL，T2：100 mIU/mL，T3：500 mIU/mL。

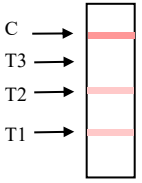
Interpetation of results



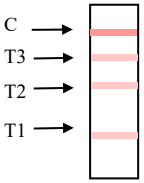
Negative： A red line appears in the control region(C). No line appears in the test region (T). The concentration of HCG is less than 25mIU/mL.



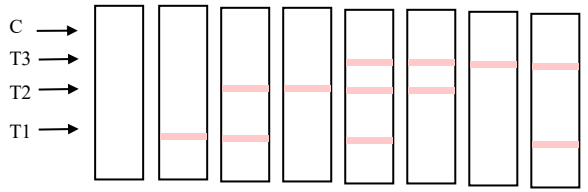
Positive： A red line appears in the control region(C) and the test region(T1). The concentration of HCG is high than 25mIU/mL.



Positive：A red line appears in the control region(C) and the test region(T1,T2). The concentration of HCG is high than 100mIU/mL.



Positive： A red line appears in the control region(C) and the test region(T1,T2,T3). The concentration of HCG is high than 500mIU/mL.



INVALID: Control line fails to appear. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue.

Reference Value (Reference Range)

The hCG reference values of pregnant women are shown in the following table

Pregnancy Weeks	hCG（mIU/ml）
0.2--1	5-50
1-2	50-500
2-3	100-5000
3-4	500-10000

Limitations

1. The reagent is disposable in vitro diagnostic reagent. Please use it within its shelf life. Do not reuse it.

2. The test results of this reagent are only for reference and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered comprehensively in combination with their symptoms/signs, medical history, other laboratory tests and treatment reactions.

3. If the result is negative and the subject is still suspected of becoming pregnant, the morning urine can be collected 24 to 72 hours later for another determination.

4. Patients with uterine tumors, hydatidiform moles or menopause may have a positive result due to high levels of HCG in the urine.

5. The HCG content in patients with ectopic pregnancy is lower than that of normal pregnancy, and false negative results may occur. If the test results are inconsistent with the expected results, it is recommended to go to the hospital to use B ultrasound for diagnosis.

6. If the test result is weakly positive, it is recommended to use other methods to test the blood sample.

7. The color depth of the detection line is related to the level of HCG contained in the urine at different stages of conception. There may be differences in hormone levels in different people. This reagent cannot determine the exact content of HCG.

8. The result of gestational week is the result of comprehensive HCG hormones in pregnant women. The HCG hormone content in multiple pregnancy is significantly higher than that of singletons, and the gestational week results shown may fluctuate slightly.

9. When the concentration of HCG in urine is very high, the color of detection line (T line) may become lighter due to HOOK effect, which is a normal phenomenon.

Performance characteristics

1. Limit of detection: The minimum detection limits are 25, 100, and 500mIU/mL respectively.

2. Specificity

2.1 Negative specificity:

Samples	500mIU/mL hLH, 0mIU/mL HCG	1000mIU/mL hFSH, 0mIU/mL HCG	1000μIU/mL hTSH, 0mIU/mL HCG
Results	Negative	Negative	Negative

2.2 Positive specificity:

Samples	500mIU/mL hLH, 25mIU/mL HCG	1000mIU/mL hFSH, 25mIU/mL HCG	1000μIU/mL hTSH, 25mIU/mL HCG
Results	Positive	Positive	Positive

3. Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the 25,100,500mIU / mL of HCG standards by 10 kits of the same batch.

4. Lot tolerance: Detecting with three different batches HCG test kits, the results should all meet the requirements of repeatability.

5. Analytical sensitivity: Chyluria proteinuria, hematuresis, bilirubinuria and proteinuria has no effect on the detection results, however injection or oral administration of human chorionic gonadotropin may affect the detection results.

6. Hook effect: When the concentration of HCG exceeds 50000mIU/ml, the detection result may be negative due to the hook effect and should be diluted and test again.

Precautions

1. The test line is significant when the concentration of HCG is high, and the control line maybe weak. It is a normal phenomenon.

2. A number of conditions other than pregnancy, including uterine cancer, hydatidiform mole or menopause, cause elevated levels of HCG and positive result.

3. If ectopic or abnormal pregnancy is still suspected, a confirmed pregnancy diagnosis should be made by other methods.

4. If pregnancy is still suspected, a first morning urine specimen should be collected 48 to 72 hours later and tested.

5. Reagents should be used as soon as possible after opened.This reagent cannot be reused for disposable.

6. The test device should remain in the sealed pouches until use. If sealing problem happens, do not test. Don’t use after the expiration date.

7. A small bag of desiccant is in the aluminum foil bag, do not eat.

8. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.