One Step
HCG Pregnancy Rapid Test Kit
(Urine)

Package Insert

A rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in human urine.

For in vitro diagnostic use only.

PRODUCT NAME

One Step HCG Pregnancy Rapid Test Kit (Urine)

INTENDED USE

The reagent is used to detect the HCG in urine qualitatively according to the principle of double antibody sandwich method.

Human chorionic gonadotropin (HCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization, including protein subunits of α and β. Its function is to stimulate the corpus luteum to continue producing progesterone, to maintain the endometrium suitable for embryo attachment and embryo implantation. In normal pregnancy, HCG can be produced as early as 4 to 5 days after conception, HCG levels continue to rise very rapidly until delivery, peaking in about 8-10 weeks into pregnancy, and fall to normal level 2 weeks after the delivery.

PRINCIPLE

The One Step HCG Pregnancy Rapid Test Kit 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-β antibody and goat anti-mouse IgG on the nitrocellulose membrane with colloidal gold marked anti-HCG-α 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

There is a control line (C) controlling the reaction process shown on the coated film. Based on test line's (T) appearance to determine whether the tested sample contains HCG (Human Chorionic Gonadotrophin) or not.

MAIN COMPONENTS

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

STORAGE AND EXPIRY

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

SAMPLE REQUIREMENTS

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of HCG, however, urine specimens collected at any time of the day may be used. Urine specimens may be stored at 2-8℃ for up to 48 hours prior to assay. For long-term storage, specimens may be frozen and stored below -20℃, the frozen specimens should be fully melted and restore to room temperature and shake before testing .Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

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℃-30℃) before use. Do not open the inner packaging (pouch) until ready, it must be used in one hour once opened (Humidity:20%~90%, Temp:10℃-50℃)

2. Test Procedure

Strip: Remove the test strip from the sealed pouch, put the end of the test strip which printed with arrows into the urine, the interface of urine should not exceed the max line, take it out after 3 to 5 seconds and place the test strip on a clean and level surface and then start the timer.

Cassette: 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.

Midstream: Remove the test midstream from the sealed pouch, and remove the cap. Then pour the urine in the absorb stick of test midstream directly for 3 to 5 seconds (300 ~400µL). Do not exceed the arrow. Cover the cap, place the test midstream on a clean and level surface and then start the timer.

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

INTERPRETATION OF RESULTS

POSITIVE: Two distinct red lines appear. A red line in the control region (C), and another red line in the test region (T).

A pink to red line (T), even if it is very thin, indicates a positive result.

NEGATIVE: A red line appears in the control region(C). No line appears in the test region (T). (NOT PREGNANT)

INVALID: No red lines appear or control line fails to appear.

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons.

Review the procedure and repeat the test with a new test device.

If the problem persists, discontinue using the kit and contact your local distributor.

POSITIVE (Pregnant) NEGATIVE (Not Pregnant) INVALID

Note: If the result is still suspected, a first morning urine specimen should be collected 24 to 72 hours later and test again.

REFERENCE VALUE

The One Step HCG Pregnancy Rapid Test Kit (Urine) has a sensitivity of 25mIU/mL.

LIMITATIONS

1. The reagent only can be used for screening tests, just like all qualitative detection reagents.

3. Concentration of HCG cannot be determined by this qualitative test.

3. This reagent is designed for the qualitative screening test. A confirmed pregnancy diagnosis should be made only by a physician after all clinical and laboratory findings have been evaluated.

4. False negative results may occur when the HCG levels of the ectopic pregnancy are below the sensitivity level of the test. When pregnancy is still suspected, a b-mode ultrasonograph diagnosis is suggested.

PERFORMANCE CHARACTERISTICS

1. Limit of detection: The limit of detection concentration of HCG test is not higher than 25mIU/ml.

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. Diagnostic specificity and sensitivity

A clinical evaluation was conducted on 245 specimens (including 75 positive specimens and 170 negative specimens) comparing the results obtained using HCG test kits of MR and other commercially available HCG tests. The results are as follows:

Positive specimens	75	HCG test kits of MR	HCG test kits of control group
		75/75(100%)	75/75(100%)
Negative specimens	170	HCG test kits of MR	HCG test kits of control group
		170/170(100%)	170/170(100%)

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

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

6. 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.

7. 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.

BIBLIOGRAPHY

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INSTRUCTIONS OF SYMBOL

CE 0123	CE Mark, certified by TÜV SÜD		Keep dry
	Consult instruction for use	LOT	Batch number
	For single use	IVD	IVD product
	Store between		Date of manufacture
	Manufacturer	Σ	Contains sufficient for <n> tests
EC REP	European union representative		Expire date