

## Pregnancy (HCG) Rapid Test Cassette (Colloidal Gold)

Cassette

### Instruction for Use

A lateral flow immunochromatographic assay for the qualitative detection of human chorionic gonadotropin (HCG) in urine specimen at sensitivity of 25mIU/ml.



In Vitro Diagnosis  
For Professional Use

### PACKAGING SPECIFICATION

1T/box, 10T/box, 20T/box, 25T/box, 40T/box, 50T/box

### INTENDED USE

The Pregnancy (HCG) Rapid Test Cassette (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (HCG) in urine samples to aid in the early detection of pregnancy by both professional and home users.

### SUMMARY

The Pregnancy (HCG) Rapid Test Cassette (Colloidal Gold) measures the presence of the hormone Human Chorionic Gonadotrophin (HCG) in human urine at 25mIU/ml for the early detection of pregnancy. During pregnancy, the placenta produces HCG after the embryo attaches to the uterine lining. This test is capable of detecting pregnancy the first day after a missed period. As pregnancy progresses, urine contains higher the levels of HCG at concentrations of 25mIU/ml (Milli-International Units) or greater. The concentration of HCG in non-pregnant women is normally 5.0mIU/ml. At the time of the last missed menstrual period, urine HCG levels are about 100mIU/ml with peak levels of 100,000 to 200,000mIU/ml.

The Pregnancy (HCG) Rapid Test Cassette (Colloidal Gold) is a rapid one-step test based on immunochromatographic technology. A membrane with an absorbent pad over a strip of fiber glass paper is impregnated with a colloidal conjugate of gold particles and monoclonal antibodies to HCG. Other absorbent pads at the end of the strip absorb excess sample fluid. The urine sample is introduced into a chromatographic membrane. As it contacts the membrane, the sample dissolves the lyophilized conjugate. In a reactive sample, the HCG antigen will attach to the antibodies in the colloidal solution. As the conjugate moves forward on the membrane, anti-HCG monoclonal antibodies affixed on the test zone ("T") will bind the HCG-gold conjugate complex, forming a pink line ("T"). Any sample will cause a pink colored line to appear in the control zone ("C"). This line is formed by the binding of polyclonal antibodies (Anti-mouse IgG) affixed onto the control zone to the sample-colloidal gold conjugate. Presence of this line indicates that the test has been carried out correctly.

### PRECAUTIONS

1. For in vitro diagnostic use only.
2. Please read the instruction inserts carefully before performing the test.
3. Do not reuse the test device.
4. Do not use expired devices.
5. Keep out of the reach of children.
6. Do not open the pouch until ready to perform the assay.
7. Do not use if the pouch is opened or damaged before testing.
8. Discard each test devices after use. Treat urine samples and used test devices as if they were potentially infectious. Avoid contact with skin.
9. Please wash hand thoroughly after performing the assay.

### MATERIAL

#### Material provided:

- 1) Test devices. The test Cassette is sealed in a foil pouch with a package of desiccant;
- 2) One package insert (Instruction for use).

#### Material needed but not provided:

Timer (It can be a clock or watch)

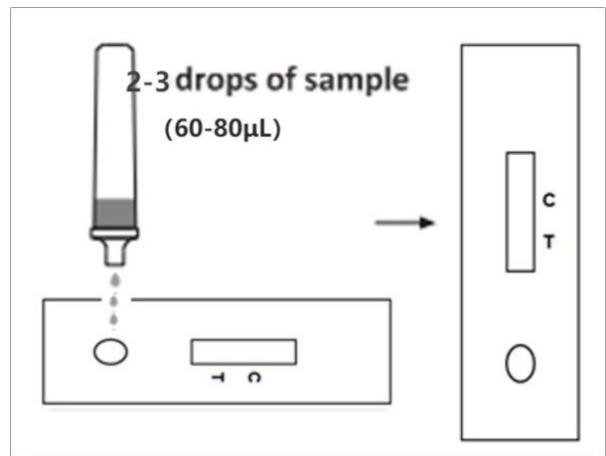
### STORAGE AND STABILITY

1. The test kit can be stored at room temperature (4°C-30°C) in the sealed pouch to the date of expiration. The shelf-life of the kit under these storage conditions is 24 months.
2. The test kits should be kept away from direct sunlight, moisture and heat.
3. **Do not freeze.**

### SPECIMEN PREPARATION

- 1) Collect urine specimen in a disposable urine cup provided. Urine samples collected first in the morning are ideal because they generally contain higher concentration of HCG. However, urine samples collected at any time of the day may also be used.
- 2) If testing is not to be performed immediately after specimen collected. The specimen can be stored at room temperature for up to 8 hours or in the refrigerator for up to 24 hours. Do not freeze.
- 3) If specimen is refrigerated, it must be equilibrated to room temperature (15-30°C) before testing.

### TEST PROCEDURE



Test device and specimen should be brought to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.

1. Bring the sealed pouch to room temperature. Remove the cassette from the foil pouch.
2. Add 2-3 full drops (60-80µL) of urine by the disposable plastic straws vertically to the sample well (S) of the cassette. Avoid the formation of bubbles and then start the timer. As the test begins to work, you may notice a light burgundy flow moving across the Test and Control windows.
3. Start to calculate the time, and read the result in 5 minutes. **Do not read after 5 minutes.**

**Note:** Depending on the concentration of HCG in the urine sample, positive results may appear within 1 minute. Wait for the full five minutes to confirm the result. Do not read result after 5 minutes as this may give an incorrect test result.

This is a single use test. Please safely dispose the cassette, regard it as infectious material and dispose appropriately after use.

### INTERPRETATION OF RESULTS

(Please refer to the illustration)



**Positive:** If two pink/purple colored lines appear on the test strip, one in the control area (C) and one in the test area (T), it means HCG has been detected in the urine and there is a strong possibility of pregnancy.

The lines seen may be faint and one line may be lighter than the other; however this is still a positive result. The lines do not have to match in strength or color.

**Negative:** If one colored pink/purple line appears in the control area (C) on the test strip and there is no line in the test area (T), it means a negative result and no HCG has been detected in the urine, which indicates you are either not pregnant or you have tested too early. If you are not sure, repeat the test in 48 hours.

**Invalid:** If no lines appear anywhere on the control zone, the test is invalid. Invalid Test Results can be caused by:

- The absorbent tip not being wetted thoroughly.
- Reading the test result too early or too late. A 5 minutes reaction time is required.

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

If the case happens again, please take below **follow-up action:**

If the obtained result has taken into account the possibility of false results, please do not make any decision of medical relevance without first consulting his or her physician and/or having received appropriate training.

### QUALITY CONTROL

Built in Quality Control Features:

The appearance of a line in the control area indicates that the Pregnancy (HCG) Rapid Test Cassette (Colloidal Gold) is performing properly and serves as a procedural control. It is recommended that a positive hCG control (containing 25-250mIU/mL hCG) and a negative hCG control (containing 0mIU/mL hCG) are evaluated to verify proper test performance when a new shipment of tests is received.

### PERFORMANCE

#### SENSITIVITY

Pregnancy (HCG) Rapid Test Cassette (Colloidal Gold) will display positive results with specimens containing HCG at levels of 25mIU/ml or greater.

#### ACCURACY

Comparison studies on the Pregnancy (HCG) Rapid Test Cassette (Colloidal Gold) with a legally marketed device were performed in-house and in a clinical reference laboratory. Positive and negative results were compared and the correlation was >99%.

#### SPECIFICITY

The following compounds exhibited no interference when dissolved in urine, which has HCG levels of 0 and 25 mIU/ml.

hLH.....	500mIU/ml
hFSH.....	1000mIU/ml
hTSH.....	1000µIU/m

Acetaminophen	20mg/dL	Codeine	6ug/dL
Acetoacetic Acid	2000mg/dL	Ethanol	1.0%
Asorbic Acid	20mg/dL	Methanol	10%
B-hydroxybutyrate	2000mg/dL	Albumin	2000mg/dL
Caffeine	20mg/dL	Glucose	2000mg/dL
Ephedrine	20mg/dL	Bilirubin	2mg/dL
Gentisic Acid	20mg/dL	Atropine	20mg/dL
Phenylpropanolamine	20mg/dL	Estriol-17-beta	1400ug/dL
Salicylic Acid	20mg/dL	Hemoglobin	500mg/dL
Phenothiazine	20mg/dL	Pregnanediol	1500ug/dL
EDTA	80mg/dL	Thiophene	20mg/dL
Acetylsalicylic Acid	20mg/dL	Ampicillin	20mg/dL
Benzoyllecgonine	10mg/dL	Tetracycline	20mg/dL
Cannabinol	10mg/dL	Ketone	20mg/dL

**LIMITATION OF THE PROCEDURE**

1. Performing the test too early can yield a false negative due to low HCG levels. In this case, another urine specimen should be obtained at least 48 hours later and tested.
2. HCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, or spontaneous abortion.
3. If urine sample is too dilute (ie: low specific gravity) it may not contain a representative level of HCG. If pregnancy is still suspected, wait 48 hours. Collect a urine sample first thing in the morning and retest it with another strip test.
4. As is true with any diagnostic procedure, the user should evaluate data obtained by the use of this kit with consideration to other clinical information and consult their doctor for the final diagnosis of pregnancy before making any decision of medical relevance.

**BIBLIOGRAPHY**

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**FREQUENTLY ASKED QUESTIONS (FAQ)**

**1. What is HCG?**

HCG is human chorionic gonadotropin. It is a hormone produced by the placenta during pregnancy.

**2. How does the HCG Pregnancy Rapid Test work?**

The Pregnancy (HCG) Rapid Test Cassette (Colloidal Gold) detects the very beginning of HCG increase in urine at the controlling level of 25mIU/ml. Shortly after fertilization, Human Chorionic Gonadotropin (HCG) is secreted by the developing placenta and the concentration of HCG continues to rise rapidly, frequently exceeding 100mIU/ml by the first missed menstrual period.

**3. How soon after I suspect that I am pregnant can I take the test?**

You can test your urine as early as the first day you miss your period. You can perform the test anytime of the day; however, if you are pregnant, first morning urine contains the most pregnancy hormone.

**4. Why does the HCG level of the test matter?**

Basically the pregnancy tests that detect the lowest number of units should give you the earliest results. The Pregnancy (HCG) Rapid Test Cassette (Colloidal Gold) could detect 25mIU/ml hCG in urine sample.

**5. What if the lines in the windows are different shades of pink?**

As long as 2 parallel lines appear, the result is positive, even if the two lines are different shades of pink.

**6. How accurate is the test?**

In both laboratory and consumer clinical studies, The Pregnancy (HCG) Rapid Test Cassette (Colloidal Gold) has been proved to be greater than 99.6% accurate.

**7. Which factors may affect the test result?**

Drugs which contain HCG can give a false positive result. A number of medical conditions other than pregnancy, including, ovarian cyst or ectopic pregnancy (pregnancy outside the uterus) can cause elevated levels of HCG.

**8. Can I be pregnant and not get a positive result?**

Yes. Most women will register on self-testing pregnancy tests by the time they are a few days late for a period, but not everyone will. If you suspect you are pregnant, you should see your doctor for a quantitative HCG test no matter what result you get from a self-testing pregnancy test. Also a false negative result (negative when pregnancy exist) may occur if the urine is too dilute or with very early stage pregnancy. In this case, if pregnancy is still suspected, retest using a first-morning urine.

**9. What should I do if the result shows that I am pregnant?**

It means that your urine contains HCG and you are probably pregnant. See your doctor to confirm that you are pregnant and to discuss the steps you should take.

**10. What should I do if the result shows that I am not pregnant?**

It means that no HCG has been detected in your urine and probably you are not pregnant. If you do not start your period within a week of its due date, repeat the test with a new test. If you receive the same result after repeating the test and you still do not get your period, you should see your doctor. Encourages you to take the following steps to increase your chances for a healthy pregnancy and your baby.

1. Use the Pregnancy (HCG) Rapid Test Cassette (Colloidal Gold) to detect pregnancy when your period is late. You can begin better prenatal care as soon as you learn of your pregnancy.
2. If you get a positive result, it is advisable to visit your doctor immediately to begin your prenatal care.
3. Maintain a well-balanced diet, stop smoking, and reduce your intake of alcohol.

**Reference:**

The Questions and Answers are based on Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) .

**Code:GKPD026-1 Effective date: May 28, 2024**

**Index of Symbols**

	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
	Temperature scope within which the product is reserved		Batch number
	Catalog #		Tests / box
	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

**Manufacturer:**



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