

Rapid Urine hCG Pregnancy Test

Ref. No. 2714

A rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine.

INTENDED USE

The hCG Pregnancy Test is a colloidal gold/antibody complex based rapid chromatographic immunoassay for the detection of hCG in urine to assist in the early detection of pregnancy and its progression.

SUMMARY AND EXPLANATION

hCG is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in urine as early as 7 days after conception. hCG levels double every two days in the first few weeks of pregnancy, frequently exceeding 100 mIU/ml by the first missed menstrual period. hCG concentrations peak at about 9-12 weeks into pregnancy. The amount of hCG will vary greatly with gestational age and between individuals.

The appearance of hCG in both the urine and serum soon after conception and its subsequent rapid rise in concentration during early normal gestational growth make it an excellent marker for the early detection of pregnancy. The Rapid Urine hCG Pregnancy Cassette Test qualitatively detects the presences of hCG in urine specimen at the sensitivity of 25 mIU/ml. Table I is provided to indicate the relationship between urine hCG level and the time from gestation.

TABLE I: NORMAL, SINGLE FETUS PREGNANCY STATUS & SUBSEQUENT hCG LEVELS:

Days Past Ovulation	Average hCG mIU/ml	High hCG mIU/ml	Low hCG mIU/ml
14 days	48	119	5
15 days	59	147	17
16 days	95	223	33
17 days	132	429	55
18 days	292	758	70
19 days	303	514	111
20 days	522	1690	135
21 days	1061	4130	324
22 days	1287	3279	185
23 days	2034	4660	506
24 days	2637	10000	540

Test Principle

The HCG Urine Test consists of a plastic cassette device comprising a chromatographic absorbent test strip and an unique combination of monoclonal antibodies that selectively detect HCG in test samples with a high degree of sensitivity. In five minutes, levels of HCG as low as 25 mIU/ml are detected.

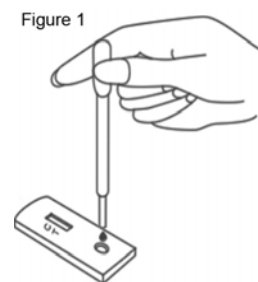
Urine applied to the sample (S) well of the cassette migrates through the absorbent area and along the test membrane. HCG present in the specimen is bound by antibody-gold conjugate forming an antibody-antigen complex. The complex is captured by anti-HCG antibody immobilized in the test zone (T) of the membrane forming a pink-rose band (in the absence of HCG, no line will form in the test zone). While the test line indicates the level of HCG present in the sample, another gold conjugate is captured by the antibody immobilized in the control zone (C) of the membrane producing pink-rose color band, regardless of the presence or absence of HCG in the sample.

Storage and Stability

Store the test device at 2 - 30°C. Prior to use bring test device and components to room temperature.

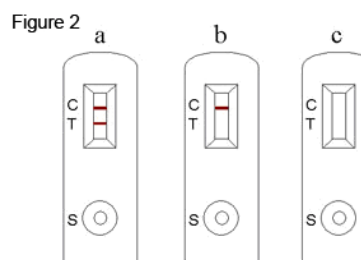
Assay Procedure

1. Bring test components including urine to room temperature.
2. Remove test device and the pipette from the pouch.
3. Transfer 2 full drops (about 80ul) of urine into the sample (S) well of the cassette device by holding the pipette vertically above the cassette.
4. Read test results at 5-10 minutes; do not interpret results after 30 minutes. (see Figure1).



Interpretation of Results

Figure 1. Cassette Test Results.



- a. POSITIVE:** A positive result is observed when there is a control line and a test line and indicates a **minimum HCG** concentration of 25 mIU/ml. At concentrations less than 25 mIU/ml, there may be weak signal appearing at the test line area. A second test may be performed 2 to 3 days after the first test to confirm the positive result.
- b. NEGATIVE:** If HCG concentration in the urine sample is below 25mIU/ml, there will be a weak rose-color band at the test line area or there is no visible test line appearing at the test section.

INVALID: If there is no rose-color band visible in the control window, then the test result is invalid. It is recommended that the urine be re-tested.

Performance Characteristics

1. **Sensitivity.** The Acro Rapid Cassette hCG Urine Test detects hCG at concentrations equal to or greater than 25 ng/ml.
2. **Specificity.** Interference of substances that may be present in urine specimens, as well as effect of sample pH and specific gravity was also studied.
 - a. Cross-reactivity of non-hCG related compounds at concentrations much higher than normally found in the urine of people using or abusing them were tested using the assay devices. No cross-reactivity was detected with the substances listed in Table I.
 - b. Table II lists hCG related substances and concentrations that produced results approximately equivalent to the cutoff level for amphetamine.
 - c. Varying sample pH within the range of 4 and 9 has no significant effect on the assay results.
 - d. Varying sample specific gravity within the range of 1.003 and 1.040 has no significant effect on the assay results.

Table-I: Compounds tested and found not to cross-react with the test at the concentration of 10 µg/ml and 100 µg/ml in urine.



<i>Acetaminophen</i>	<i>Hemoglobin</i>
<i>Acetone</i>	<i>Ibuprofen</i>
<i>Albumin</i>	<i>(+/-)-Isoproterenol</i>
<i>Ampicillin</i>	<i>Ketamine</i>
<i>Ascorbic Acid</i>	<i>Levorphanol</i>
<i>Aspartame</i>	<i>Lidocaine</i>
<i>Aspirin</i>	<i>(+)-Naproxen</i>
<i>AtrPPXne</i>	<i>Niacinamide</i>
<i>Benzocaine</i>	<i>Nicotine</i>
<i>Bilirubin</i>	<i>(+/-)-Norephedrine</i>
<i>Caffeine</i>	<i>Oxalic Acid</i>
<i>Chloroquine</i>	<i>Penicillin-G</i>
<i>(+)-Chlorpheniramine</i>	<i>Pheniramine</i>
<i>(+/-)-Chlorpheniramine</i>	<i>Phenothiazine</i>
<i>Creatine</i>	<i>1-Phenylephrine</i>
<i>Dexbrompheniramine</i>	<i>β-Phenylethylamine</i>
<i>Dextromethrophan</i>	<i>Procaine</i>
<i>Diphenhydramine</i>	<i>Quinidine</i>
<i>Dopamine</i>	<i>Ranitidine</i>
<i>(+/-)-Epinephrine</i>	<i>Riboflavin</i>
<i>Erythromycin</i>	<i>Sodium Chloride</i>
<i>Ethanol</i>	<i>Sulindac</i>
<i>Furosemide</i>	<i>Theophylline</i>
<i>Glucose</i>	<i>Tyramine</i>
<i>Guaiacol Glyceryl Ether</i>	<i>4-Dimethylaminoantipyrine</i>
	<i>(1R, 2S)-(-)-N-Methyl-Ephedrine</i>

Table-II: Concentration of hCG-related compounds showing a positive response approximately equivalent to the morphine cut-off set for the test.

Compound /
hCG **Concentration in ng/ml**
25ng/ml

3. **Accuracy.** The accuracy study was performed by testing clinical hCG urine samples with the device and comparing the results with device and comparing the results with predicate device results.

Rapid Test	Predicate			
	Negative (<50%)	Near Cutoff Negative (-50% to cutoff)	Near Cutoff Positive (cutoff to +50% cutoff)	Positive (>+50%)
Positive	0	3	8	80
Negative	70	7	2	0

% Agreement of negative samples is 77/80 = 96%

% Agreement of positive samples is 88/90 = 97%.

LIMITATIONS

1. The rapid hCG Pregnancy Urine Test is a preliminary qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. Low levels of hCG (less than 50 mIU/ml) are present in urine specimens shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later or thereafter.
4. This test may produce false positive results. A number of conditions other than pregnancy, including trophoblastic disease and certain non-

trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.

5. This test may produce false negative results. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested. In case pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.

REFERENCES

1. Embree, L. (1985). *Development of a High-Performance Liquid Chromatographic Assay for Human Chorionic Gonadotropin as an Alternative to the Official United States Pharmacopeial Animal Assay*. Vancouver, BC: University of British Columbia.
2. Frye, A. & Wheeler, R. (1990). *Understanding Lab Work in the Childbearing Year: A Guide for Givers and Receivers of Health Care in Childbirth*. New Haven, CT: Labrys Press.
3. Hussa, R.O. (1987). *The Clinical Marker hCG*. New York, NY: Praeger Publishers.

