

Hoopsy

One Step hCG Pregnancy Test

INTENDED USE

One Step hCG Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine at a concentration level from 20mIU/ml or greater to aid in the early detection of pregnancy. The test is designed for over-the-counter use.

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 to 10 days after conception. hCG levels continues 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 urine soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy(7,8,9,10).

PRINCIPLE OF TEST

One Step hCG Pregnancy Test 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 a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by adding urine specimen to the specimen well of the test device and observing the formation of pink colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific antibody-hCG-colored conjugate and form a pink colored line at the test line region of the membrane. Absence of this pink colored line suggests a negative result. To serve as a procedural control, a pink colored line will always appear at the control line region if the test has been performed properly.

MAIN COMPONENTS

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-rat IgG.

WARNINGS & PRECAUTION

- 1) For in vitro diagnostic use and Self-testing use only.
- 2) Check expiration date on package label before use. Do not use test kit beyond the expiry date.
- 3) Inspect pouch for damage before use. Do not use if pouch is visibly damaged before opening.
- 4) The test kit should not be reused.
- 5) The test kit is moisture sensitive and should be used immediately after taking out of the pouch. When handling, avoid touching the test membrane.
- 6) Used test contains potentially infectious urine residues; dispose per local waste regulations.

MATERIALS PROVIDED

- 1) One Step hCG Pregnancy Test.
- 2) Instructions for use.

MATERIALS NEEDED BUT NOT PROVIDED

- 1) Clean glass or plastic container for urine collection if you want to dip the test in to use it rather than using it midstream.
- 2) Timer

URINE COLLECTION

Fresh urine should be used for the test, no pre-treatment is necessary. Your urine can be tested midstream or collected in a clean glass or plastic container and tested using the midstream test as a dip test. You can refrigerate (2-8°C) your urine and store for up to 2 days before testing. If refrigerated urine should be allowed to come to room temperature and mixed thoroughly before testing.

HOW TO USE YOUR PREGNANCY TEST

Allow the test and the specimen to equilibrate to room temperature (15-30°C) prior to testing



When you're ready to take your pregnancy test, open a pouch by tearing along the notch.



Hold the end with the Hoopsy logo and place the other end in your urine stream (or dip it into a cup of collected urine) for 10 seconds. Try not to wee past the MAX line. For the most accurate results, test with your first urine of the day.



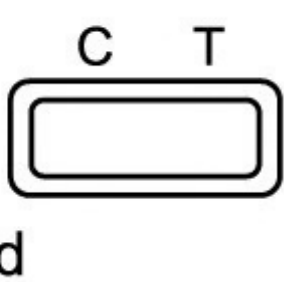
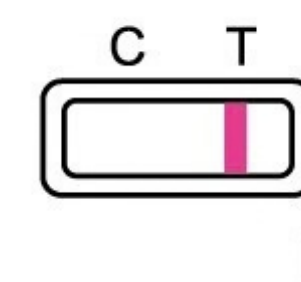
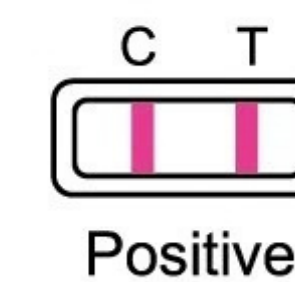
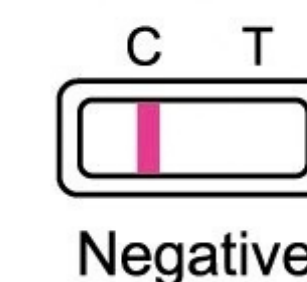
Place the test on a clean, dry, and flat surface with the logo facing you. While you wait for your result (which may take 5 to 10 minutes depending on urine concentration).



Once you have taken your test you can recycle half of it, just cut it in half and throw the half you hold in the paper recycling, and the other half in the bin.

Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 30 minutes.

INTERPRETATION OF RESULTS



POSITIVE:

Two pink lines appear. One line may be lighter than the other. The test is positive and has detected the HCG pregnancy hormone in a concentration of 20mIU/ml or more. You should talk to your doctor for prenatal care advice.

NEGATIVE:

Only one pink line(c line) appears in the results window, as shown above. The test is negative and no hCG has been detected in a concentration of 20mIU/ml or more. However, if after 7 days you still do not get your period, you should retest with another test. If you still get a negative result and your period has not started, you should see your doctor.

INVALID:

If no line appears in the C window, or no lines appear at all then the test is invalid. You should test again with another test following the instructions carefully. You cannot assume that you are or aren't pregnant until you do another test.

For best results:

1. Do not point the test strip down - keep it flat
2. Do not turn the test over, the Hoopsy logo side should be facing you
3. Make sure that you hold the test in your urine stream (or cup of urine) for 10 seconds
4. Wait 5-10 minutes to check the result

STORAGE AND STABILITY

The test kit is stable for at least 24 months at 4-30°C and 21 days at 37°C. The test must be used within 1 hour after opening the pouch, and stable for at least 100 days at transport conditions. The test kit should be kept away from direct sunlight, moisture and heat. The expiration dating was established under these storage conditions.

CROSS REACTIVITY

The following substances were added in hCG free and 20 mIU/mL spiked samples.

luteinizing hormone (LH)	500mIU/m
follicle stimulating hormone (FSH)	1000mIU/m
thyroid stimulating hormone	1000µIU/m

None of the substances at concentration tested interfered with the assay.

INTERFERING SUBSTANCES

The following substances were added in hCG free and 20 mIU/mL spiked samples.

Hemoglobin	10 mg/mL
bilirubin	0.06 mg/mL
albumin	100 mg/mL

None of the substances at concentration tested interfered with the assay.

COMPARISON STUDY

Other commercially available qualitative test kits were used to compare with One Step hCG Pregnancy Test for relative sensitivity and specificity in 201 urine samples. None of samples was discordant, the agreement is 100%.

Test		Predicate Device		Subtotal
		+	-	
AIBO	+	116	0	116
	-	0	85	85
Subtotal		116	85	201

Sensitivity: 100%; Specificity: 100%



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QUALITY CONTROL

A pink line appearing in the control region (C) is the internal procedural control. It confirms sufficient urine volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

External controls should be used to assure that the reagents are working properly and that the assay procedure is followed correctly. It is recommended that a control be tested at regular intervals as good laboratory testing process.

Users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.

LIMITATIONS

1. 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 should be collected 48 hours later and tested.
2. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
3. 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.
4. Very low levels of hCG are present in urine specimen 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 collected 48 hours later.
5. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.
6. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have to be evaluated.
7. Because of hook effect, the test result may be indicate false negative when urine sample of 2-3 months pregnant directly detected.

BIBLIOGRAPHY

- 1) Chez RA: Fetal and placental endocrinology. Clin Obstet Gynecol 1980; 23:719.
- 2) Goebelsmann U: Protein and steroid hormones in pregnancy. J Reprod Med 1979; 23:166.
- 3) Jaffe RB: Endocrine-metabolic alterations induced by pregnancy. Reproductive Endocrinology, 2nd ed. Saunders, 1986.
- 4) Derman R, Edelman DA, Berger GS: Current status of immunologic pregnancy tests. Int J Gynaecol Obstet 1979; 17:190.
- 5) Horne CHW, Nisbet AD: Pregnancy proteins: A review. Invest Cell Pathol 1979; 2: 217.
- 6) Lind T: Clinical chemistry of pregnancy. Advance Clinical Chem 1980; 21:1.
- 7) Batzer FR. "Hormonal evaluation of early pregnancy" Fertil. Steril. 1980; 34(1): 1-13.
- 8) Catt KJ, ML Dufau, JL Vaitukaitis "Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyst", J. Clin. Endocrinol. Metab. 1975;40(3): 537-540.
- 9) Braunstein GD, J Rasor, H. Danzer, D Adler, ME Wade "Serum human chorionic gonadotropin levels throughout normal pregnancy", Am. J. Obstet. Gynecol. 1976: 126(6): 678-681.
- 10) Lenton EA, L Neal, R Sulaiman "Plasma concentration of human chorionic gonadotropin from the time of impantation until the second week of pregnancy", Fertil. Steril. 1982;37(6): 773-778.
- 11) Steier JA, P Bergsjö, OL Myking "Human Chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy", Obstet, Gynecol. 1984;64(3): 391-394.
- 13) Dawood MY, BB Sazena, R Landesman "Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma", Obstet. Gynecol. 1977;50(2): 172-181
- 14) Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross "Ectopic production of human chorionic gonadotropin by neoplasms", Ann. Intern Med. 1973: 78(1): 39-45.

GRAPHICAL SYMBOLS USED

	Storage temperature		Lot number
	In vitro diagnostic device		Expiry date
	Read instruction before use		Manufacturer
	Catalogue Number		Do not reuse
	Keep Dry		Sufficient for one test

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