

6. Q: What should I do if the result shows that I am pregnant?
A: 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.
7. Q: Does the result mean anything other than normal pregnancy if it shows that I am pregnant?
A: 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. Q: How do I know that the test was run properly?
A: The appearance of a red line in the control window (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed.
9. Q: What should I do if the result shows that I am not pregnant?
A: 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 midstream test. If you receive the same result after repeating the test and you still do not get your period, you should see your doctor.

LIMITATIONS OF PROCEDURE

- This test provides a presumptive diagnosis for pregnancy. The user should not take any decision of medical relevance without first consulting her medical practitioner.
- 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 specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
- 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.
- 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.

- Very low levels of hCG (less than 50 mIU/mL) 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 specimen collected 48 hours later.

PRECAUTIONS

(Please read all the information in this leaflet before performing the test.)

- Do not use if pouch is torn or damaged before opening.
- Check expiration date before use. Do not use after the expiration date.
- Do not reuse.
- Store in a dry place at 2-30°C but do not freeze.
- Ensure the test foil pouch is at room temperature before opening.
- Once open, use as soon as possible. When handling, avoid touching the test membrane.
- Keep out of the children's reach.
- For in vitro diagnostic use only. Not to be taken internally.

REFERENCES

- Batzer FR. "Hormonal evaluation of early pregnancy", Fertil. Steril. 1980; 34(1): 1-13
- Catt KJ, ML Dufau, JL Vaitukaitis "Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte", J. Clin. Endocrinol. Metab. 1975; 40(3): 537-540
- Braunstein GD, J Razor, H. Danzer, D Adler, ME Wade "Serum human chorionic gonadotropin levels throughout normal pregnancy", Am. J. Obstet. Gynecol. 1976; 126(6): 678-681
- Lenton EA, LM Neal, R Sulaiman "Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy", Fertil. Steril. 1982; 37(6): 773-778
- Steier JA, P Bergsjø, OL Myking "Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy", Obstet. Gynecol. 1984; 64(3): 391-394

- Dawood MY, BB Saxena, R Landesman "Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma", Obstet. Gynecol. 1977; 50(2): 172-181
- Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross "Ectopic production of human chorionic gonadotropin by neoplasms", Ann. Intern Med. 1973; 78(1): 39-45

<p>ISO 13485 ISO 9001</p>  <p>Diagnostic Automation/ Cortez Diagnostics, Inc. 21250 Califa St, Suite 102 and 116, Woodland Hills, California 91367 USA</p>	
Date Adopted	2016-01-31
REF 113028ST-1-20	CORTEZ- OneStep hCG Urine RapiCard™ InstaTest
EC REP	CEpartner4U , Esdoornlaan 13, 3951DB Maarn. The Netherlands. www.cepartner4u.eu
Revision Date: 2013-11-01	