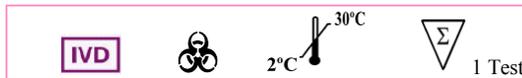




## OneStep hCG Urine 3.5 mm RapiDip™ InstaTest

REF 113043ST-1-20



Sensitivity

20 mIU/ml

### INTENDED USE

Cortez Diagnostics, Inc. OneStep hCG Urine RapiDip™ InstaTest is designed to be used for a qualitative determination of elevated human chorionic gonadotropin in urine. The result can be read visually in minutes to indicate a positive or negative result for pregnancy.

### SPECIMEN COLLECTION AND PREPARATION

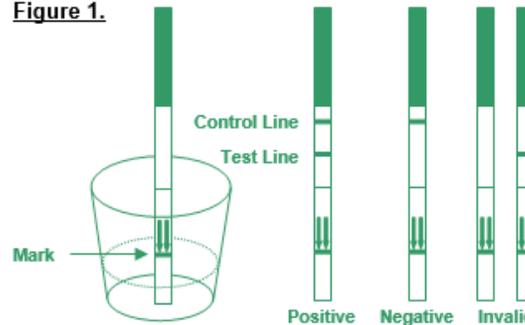
A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

### ASSAY PROCEDURE

1. Open the pouch and remove the test strip.
2. Immerse the strip into the urine sample with the arrow end pointing towards the urine. Do not immerse past the "Mark" Line. Take the strip out after 3 seconds and lay the strip flat on a clean, dry, non-absorbent surface (such as the mouth of the urine container).

3. Wait for the color line(s) to appear. Depending on the concentration of hCG, positive results may be observed in as little as 40 second. For all results, wait 5 minutes to confirm the observation. Do not interpret the result after 30 minutes. It is important that the background is clear before the result is read.

Figure 1.



### RESULTS

(See figure 1)

- **POSITIVE:** Two distinct red lines appear. One line should appear in each control (C) and test (T) regions.
- **NEGATIVE:** One red line appears in the control region (C). No red or pink line appears in the test region (T).
- **INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

*NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.*

### EXPECTED VALUES

The One Step hCG Pregnancy Test has a sensitivity of 20 mIU/mL. The concentration of hCG increases to 5-50 mIU/mL one week after

implantation, and will reach 100 mIU/mL at the time of the first missed menses.

### Questions and Answers

1. Q: How does the test work?  
A: The One Step hCG Pregnancy Test detects a hormone in your urine that your body produces during pregnancy (hCG-human chorionic gonadotropin). The amount of pregnancy hormone increases as pregnancy progresses.
2. Q: How soon after I suspect that I am pregnant can I take the test?  
A: 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.
3. Q: Do I have to test with first morning urine?  
A: Although you can test any time of the day your first morning urine specimen is usually the most concentrated of the day and would have the most hCG in it.
4. Q: How accurate is the test?  
A: In both laboratory and consumer clinical studies, the One Step hCG Pregnancy Test has been proved to be 99% accurate.
5. Q: Which factors may affect the test result?  
A: Drugs which contain hCG (such as Pregnyl, Profasi, Pergonal, APL) can give a false positive result. Alcohol, oral contraceptives, painkillers, antibiotics or hormone therapies that do not contain hCG should not affect the test result.
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.

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

### 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.

### REFERENCES

1. Batzer FR. "Hormonal evaluation of early pregnancy", *Fertil. Steril.* 1980; 34(1): 1-13
  2. 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
  3. 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
  4. 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
  5. Steier JA, P Bergsjo, OL Myking "Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy", *Obstet. Gynecol.* 1984; 64(3): 391-394
  6. 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

### PRECAUTIONS

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

1. Do not use if pouch is torn or damaged before opening.

<b>ISO 13485</b> <b>ISO 9001</b>   <b>Diagnostic Automation/          Cortez Diagnostics, Inc.</b> <b>21250 Califa St, Suite 102 and 116,          Woodland Hills, California 91367 USA</b>	
<b>Date Adopted</b>	<b>2016-09-30</b>
 <b>113043ST- 1-20</b>	<b>CORTEZ- OneStep          hCG Urine 3.5mm          RapiDip™ InstaTest</b>
 	<b>CEpartner4U , Esdoornlaan 13,          3951DB Maarn. The Netherlands.</b> <a href="http://www.cepartner4u.eu">www.cepartner4u.eu</a>
Revision Date: <b>2013-11</b>	