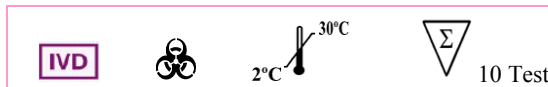


**OneStep
 LH Ovulation Urine
 RapiCard™ InstaTest**

**REF 104110ST-10-20
 For Self Testing**



Sensitivity 20 mIU/ml

INTENDED USE

Cortez Diagnostics, Inc. OneStep LH Ovulation Urine RapiCard™ InstaTest is designed to qualitatively determine elevated luteinizing hormone in urine. The result can be read visually in minutes to indicate a positive or negative result for ovulation.

WHEN TO BEGIN TESTING

First, you must determine the length of your menstrual cycle. This is the number of days from the first day of your menstrual bleeding to the day before your next bleeding begins. Please refer to the chart to determine when you should start testing. If your cycle is shorter than 21 days or longer than 38 days, consult your doctor. If you do not know your cycle length, you may begin the test 11 days after your first period since the average cycle length is 28 days. Perform 1 test each day over a 5 day period, or until the LH surge has been detected.

Your Cycle Length	Start To Test On
21 days	Day 6
22 days	Day 6
23 days	Day 7
24 days	Day 7
25 days	Day 8

26 days	Day 9
27 days	Day 10
28 days	Day 11
29 days	Day 12
30 days	Day 13
31 days	Day 14
32 days	Day 15
33 days	Day 16
34 days	Day 17
35 days	Day 18
36 days	Day 19
37 days	Day 20
38 days	Day 21

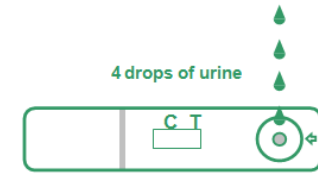
SPECIMEN COLLECTION AND PREPARATION

- Determine the time you will collect your urine. For best results, collect your urine at about the same time each day, for example, between 10:00AM and 8:00PM. Some women have found that their best specimen is after 12 noon. Do not collect your first urine after waking up.
- Reduce your liquid intake approximately 2 hours prior to urine collection.
- Be sure to write down the cycle day, date and time that you collected your urine.
- You can store your urine for testing later in the day. Your urine can be stored at room temperature for up to 8 hours or in the refrigerator for up to 24 hours. Do not freeze it. For best results, test your urine on the same day that it is collected. If you refrigerate your urine, let it reach room temperature before testing (about 30 minutes). Do not shake the container. If sediment forms at the bottom of the collection container, allow the sediment to settle. Use only urine from the top of the container.

ASSAY PROCEDURE

- Open the pouch and remove the test device.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 4 full drops of urine (120µL) to the specimen well of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well.

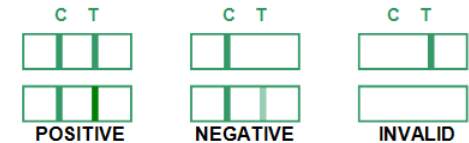
- Wait 10 minutes and read results. It is important that the background is clear before the result is read. Results obtained after 30 minutes should be considered invalid



RESULTS

- No LH Surge:** Only one color band appears on the control (C) region or the test (T) band appears but is lighter than the control band. This means there is no LH surge.
- LH Surge:** Two color bands are visible and the test (T) band is equal to or darker than the control (C) band. One will probably ovulate in the next 24-48 hours. If one wants to be pregnant, the best time to have intercourse is after 24 but before 48 hours.
- 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 LH present in the specimen. However, neither the quantitative value nor the rate of increase in LH can be determined by this qualitative test.



EXPECTED VALUES

The One Step LH Ovulation Urine Test has a sensitivity of 20 mIU/mL. A positive result means your urine contains the level of LH that would indicate you are beginning to ovulate. You can assume that you will ovulate within 24-48 hours. A negative result means that

no LH surge has been detected and you should continue daily testing. Not every woman ovulates mid-cycle; therefore, you may not see a positive result during the first 5 days of testing. Continue testing with the One Step LH Ovulation Urine Test.

Questions & Answers

Q: How accurate is the One Step LH Ovulation Urine Test?

A: The One LH Step Ovulation Test has been shown to be 99% accurate in laboratory testing and 98% accurate in consumer testing.

Q: When can I do the test?

A: After you determine the best day to start testing based on your monthly cycle, you can do the test any time on that day. Testing with first morning urine is not recommended. Testing between 10 am and 8pm is a good time frame, with many REs suggesting testing at 10am. Test at about the same time each day. Reduce your liquid intake for 2 hours before testing.

Q: What if no band appears in the Control Window?

A: If no band appears in the Control Window after 5 minutes, the result is invalid and you should repeat the test with the One Step LH Ovulation Urine Test.

Q: I have tested for five days and I did not see a surge. What do I do?

A: Since every woman does not always ovulate at mid-cycle, you may not detect the LH surge in the first five days of testing. This could mean you have not ovulated yet and you should continue testing with an additional LH One Step Ovulation Tests.

Q: I have tested for 8 days or more and I still did not see my LH surge, what is wrong?

A: About 90% of ovulating women with regular cycles will see their surge during 8-10 days of testing. If you do not, it could mean that you have not ovulated this month. If you are having a short cycle this month, it is possible that you have ovulated before you started testing. If you are having a long cycle this month, you may not have ovulated yet. You may continue testing or test again next month. Don't worry;

it is normal to have an occasional short or long cycle, or to have a cycle without ovulating.

Q: I have used the ovulation test for three months, and each month I have seen a surge and have had intercourse that day or night. I have not become pregnant yet. What is wrong?

A: First, it is important to remember that it can take normal, healthy couples many months to become pregnant. There are many factors that can affect your ability to become pregnant even if you have been able to have intercourse during your most fertile days. If after several months you have no success, consult with your physician or healthcare provider.

Q: What could interfere with my test result?

A: If you are already pregnant, have recently been pregnant, or have reached menopause you may get a misleading result. Some prescription drugs, such as menotropins for injection and danazol may affect the results you see. Please consult your physician if you have any questions about prescription drug interactions.

Q: Will oral contraceptives affect the result?

A: After using the pill your cycle may be irregular and may take some time to stabilize again. You may wish to wait until you have had two normal periods before starting to use the One Step LH Ovulation Urine Test.

Q: If the One Step Ovulation LH Test can determine my most fertile time, why can't I use it for contraception?

A: Sperm can survive up to 72 hours, and this test predicts your LH surge only up to 24 to 36 hours in advance. Therefore, it you have intercourse before you discover your surge, the egg can still be fertilized.

PERFORMANCE CHARACTERISTICS

Laboratory Studies have shown that the sensitivity of the One Step LH Ovulation Urine Test is 20 mIU/mL in studies with spiked urine samples. The results are shown in Table 1.

Table 1: Cutoff Conc. Study of One Step LH Ovulation Urine Test

LH mIU/mL	0	10	20	40	100
Negative	20	19	0	0	0
Positive	0	1	20	20	20

Laboratory Studies have shown that the Diagnostic Automation, Inc. One Step LH Ovulation Urine Test has 99% accuracy in comparison studies with a predicate device. The results are shown in Table 2.

Table 2: Comparison Studies with Predicate Device

		Predicate		Subtotal
		+	-	
DAI LH (Strip)	+	41	1	42
	-	0	78	78
Subtotal		41	79	120

Specificity has been determined from cross reaction with high physiological concentrations of FSH and TSH at 1000 mIU/mL. Under these circumstances, the Diagnostic Automation, Inc. One Step LH Ovulation Urine Test did not show any cross reactivity with the expected test results. The results are shown in Table 3.

Table 3: Cross-reactivity study of One Step LH Ovulation Urine Test

LH Conc. in Sample (mIU/mL)	Without Spiking	Spiked Urine Samples (mg/mL)	
		FSH	TSH
		1000 mIU/ml	1000 mIU/ml
0	-	-	-
20	+	+	+
100	+	+	+

Interference testing was tested on the Diagnostic Automation, Inc. One Step LH Ovulation Urine Test with the following compounds. None of these compounds at the concentration interfered with the assay. The results are shown in Table 4.

Table 4: Interference Studies

Acetaminophen	20 mg/mL
Acetylsalicylic Acid	20 mg/mL
Ascorbic Acid	20 mg/mL



Atropine	20 mg/mL
Caffeine	20 mg/mL
Gentesic Acid	20 mg/mL
Glucose	2 g/dL
Hemoglobin	1mg/dL

- Lenton E, Meal L, Sulaiman R, Fertility & Sterility, Vol 37, 773, 1982.
- Dawood M, Saeba B & Landesman R, Ob. Gyn., Vol 126, 678, 1976.
- Braunstein GD et al, Ann. Inter. Med., Vol 78, pp 39-45
- Engvall E, Methods in Enzymology, Vol 70, pp 419-439, 1980.
- Uotila M, Ruoslahi E, Engvall E, J. Immun. Meth, Vol 42, 11, 1981.

LIMITATIONS OF PROCEDURE

- The test works only when the test procedures are precisely followed.
- Do not reuse the test device.
- This test may not be used as a form of birth control.
- The test results should not be affected by pain relievers, antibiotics and other common drugs. Medication containing hCG or LH may affect the test and should not be taken while using the One Step LH Ovulation Urine Test. In addition, the test will not work properly if you are pregnant, menopausal, or taking birth control pills.
- Keep out of the reach of children.


PRECAUTIONS

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

- Do not use if pouch is torn or damaged.
- 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 reach of children.
- For in vitro diagnostic use. Not to be taken internally.

REFERENCES

- Batzer FR, Fertility & Sterility, Vol 34, 1, 1980
- Catt KI, Dufan ML & Vaitukaitis JL, Journal of Clinical Endocrinol. Metlab., Vol 40, 537, 1975
- Braunstein GD, Rason J, Alder D, Danzer H, Wade ME, Am. J., Obstet. Gynecol., Vol 126, 677, 1976.

<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>	
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