




**OneStep
LH Urine Midstream
RapiCard™ InstaTest**

REF 104117-1-20

IVD  See external Label  2-30°C  1 Test

Sensitivity **20 mIU/ml**

INTENDED USE

Cortez Diagnostics, Inc. OneStep LH Urine Ovulation RapiCard™ InstaTest is fast and easy-to-use.



TEST PRINCIPLE

It is a qualitative test that can predict when there is a LH (Luteinizing Hormone) surge, and in turn when you are likely to ovulate.

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

1. Do not use first morning urine samples as LH is synthesized in your body early in the morning. It will not show up in your urine until later in the day.
2. The best time to collect your urine is between 10am and 8pm.
3. Collect urine at about the same time each day.
4. Reduce liquid intake about 2 hour before collecting your urine as a dilute sample can prevent the test from detecting the LH surge.

ASSAY PROCEDURE

1. Allow the sealed LH Midstream test pouch, patient's urine sample and control solution to reach room temperature (18-30°C).
2. Remove the LH Midstream test device from the sealed pouch and use it as soon as possible.
3. Hold the handle of the test with one hand. Use the other hand to remove the cap and expose the absorbent sampler. Put the cap aside for now.

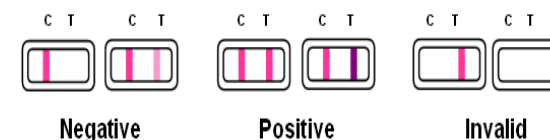
4. Point the absorbent tip downward, place the absorbent tip in urine stream for at least 10 seconds to absorbent pad into the urine for at least 5 seconds. Re-cap the device and wait for color bands to appear. Depending on the concentration of LH, positive result may be observed in as short as 40 be thoroughly wet. Otherwise, you can collect your urine into a clean cup and dip half of the seconds. However, to confirm negative results, the complete reaction time (10 minutes) is required. It is important that the background is clear before the result is read. Do not read results after 30 minutes.

Do not stream pass the arrow



RESULTS

- **No LH Surge:** Only one color band appears on the control (C) region or the test (T) band is lighter than the control band. There is no LH surge.
- **LH Surge:** If 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:** No visible band at all or no colored band appears on the control (C) region. Repeat test with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



PERFORMANCE CHARACTERISTICS

Cross Reactivity

The cross reactivity of LH test kits was evaluated with LH homologous hormones. Homologous hormones FSH and TSH were added to urine samples containing LH at concentration of 0,20 or 100 mIU/mL. No cross reactivity was observed in the study (shown as Table 1).

Non-specific interference

One-step LH test was checked for possible interference from visibly hemolyzed, lipemic and icteric samples. Human hemoglobin, bilirubin or albumin was spiked into samples with different concentration of LH and tested using un-spiked sample as controls. No significant interference was observed in 20 sample testing results that were either positive or negative for LH. The results are shown as Table 2.

Table 1 – Cross-reactivity study of One-step LH test kit
Urine samples spiked with homologous hormones

LH conc. In urine sample (mIU/mL)	Unspiked urine samples	FSH 1000mIU/mL	TSH 1000mIU/mL
0	-	-	-
	-	-	-
	-	-	-
20	+	+	+
	+	+	+
	+	+	+
100	+	+	+
	+	+	+
	+	+	+

Table 2 – Non-specificity study of One-step LH test kits

Sample No	Unspiked Samples	Urine samples spiked with (mg/mL)			
		Hemoglobin		Bilirubin	Albumin
		10	1	0.06	100
1	-	-	-	-	-
2	-	-	-	-	-
3	-	-	-	-	-
4	-	-	-	-	-
5	-	-	-	-	-
6	-	-	-	-	-
7	-	-	-	-	-
8	-	-	-	-	-
9	-	-	-	-	-
10	-	-	-	-	-
11	+	+	+	+	+
12	+	+	+	+	+
13	+	+	+	+	+
14	+	+	+	+	+
15	+	+	+	+	+
16	+	+	+	+	+
17	+	+	+	+	+
18	+	+	+	+	+
19	+	+	+	+	+
20	+	+	+	+	+



LIMITATIONS OF PROCEDURE

- As with all Cortez tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
- The test results should not be affected by pain relievers, antibiotics and other common drugs. After using the pill or patch that contains hCG or LH may affect the test result and should not be taken while using this test kit. In addition, the test will not work properly if you are pregnant or menopausal.
- 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 24-36 hours. However, not every woman

ovulates mid-cycle; therefore, you may not see a positive result during the first 5 days of testing.

PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use test kit beyond expiry date.
- The test device should not be reused.
- The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration.
- The test kit should be kept away from direct sunlight, moisture and heat.

ISO 13485 ISO 9001 	
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