




**OneStep
 LH Urine
 RapiDip™ InstaTest
 (5mm)**

REF 104115-1-20

IVD  See external Label  2-30°C  1 Test

Sensitivity 20 mIU/ml

INTENDED USE

Cortez Diagnostics, Inc. OneStep LH Urine Ovulation RapiDip™ 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

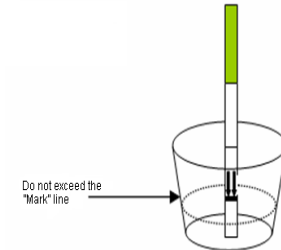
27 days	Day 10
28 days	Day 11
29 days	Day 12
30 days	Day 13
31 days	Day 14
32 days	Day 15
33 days	Day 16
34 days	Day 17
35 days	Day 18
36 days	Day 19
37 days	Day 20
38 days	Day 21

SPECIMEN COLLECTION AND PREPARATION

1. Do not use first morning urine samples as LH is synthesized in your urine until 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.

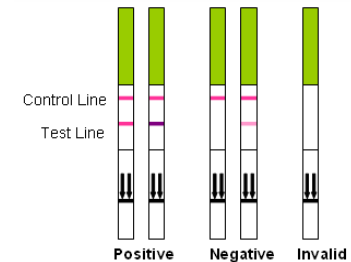
ASSAY PROCEDURE

1. Allow the sealed LH test pouch, urine sample, and control solution to reach room temperature (18-30°C).
2. Remove the LH test strip from the sealed pouch.
3. Immerse the strip into the urine with the arrow end pointing towards the urine. Do not immerse past the MAX (marker line). Take the strip out after 10 seconds and lay the strip flat on a clean, dry, non-absorbent surface (such as the mouth of the urine container).
4. Wait for colored bands to appear. Depending on the concentration of LH in the test specimen, positive results may be observed in as little as 40 seconds. However, to confirm negative results, the complete reaction time of 10 minutes is required. Do not read results after more than 30 minutes.



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. This means that one will probably ovulate in the next 24-48 hours. If trying to get 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 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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