

## CORTEZ DIAGNOSTICS, INC.

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See external label



2°C-30°C



$\Sigma=25$  or 50 tests



Cat #104117-1ST

# OneStep LH Urine Midstream Ovulation InstaTest

## For Self Testing

### INTENDED USE

OneStep LH Urine Midstream Ovulation InstaTest is an immunochromatographic one-step in vitro assay. It will qualitatively or semi-quantitatively detect the presence of human luteinizing hormone in urine and is designed to be used to predict the time of ovulation in women. It is a fast, accurate, and convenient method to determine when the female body will ovulate, the most likely time for conception to occur.

### INTRODUCTION

Ovulation is the release of an egg from the ovary. The few days around ovulation are the most likely times for conception to occur. OneStep LH Urine Midstream Ovulation InstaTest is specifically designed to detect the LH surge. Luteinizing hormone in elevated quantities causes ovulation. During the menstrual cycle only a small amount of LH is made, but in the middle of the cycle LH briefly increases. This increase is called the "LH surge" and precedes ovulation. Conception is most likely to occur within thirty-six hours following the LH surge.

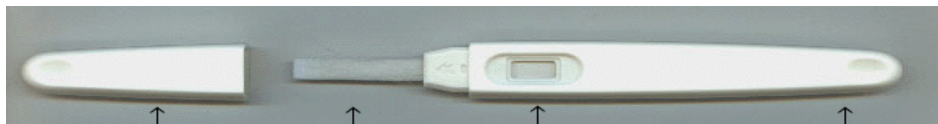
In the test procedure, the test device is partially immersed in a urine and allowed to soak for a period of five minutes. At five minutes the test is complete and the control band intensity and test band intensity are visually compared to determine the concentration of LH present in the urine.

A test band of equivalent or greater intensity than the control band is a positive result, which indicates LH is present in the test sample at or above 25 mIU/ml, and suggests that the LH surge is occurring. A test band of lesser intensity than the control band is considered a negative result, and indicates the LH concentration of the urine is below 25 mIU/ml, a good indicator that the LH surge is not occurring.

### REAGENTS AND MATERIALS PROVIDED

1. Testing Device.

1 single midstream test device(as shown below) individually packed in an aluminum pouch with a desiccant.



Cap   Absorbent Sampler   Show Window   Handle

### MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer.

Revision Date: 6-5-06

## URINE COLLECTION

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 - 8pm.
3. Collect urine at about the same time each day.
4. Always use clean, dry container when collecting urine
5. Reduce liquid intake about 2 hours before collecting your urine as a diluted urine sample can prevent the test from detecting LH surge.

## PROCEDURE

### A. Step 1 : 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 again. 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

*Example:* If your cycle is normally twenty-six days, the *Cycle Chart* indicates testing should begin on day 10. The following calendar shows how to determine day 10.

### Sample Calendar

1	2	3† Day 1	4	5	6	7
8	9	10	11	12Δ Day 10	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

3† =The first day of menstrual bleeding

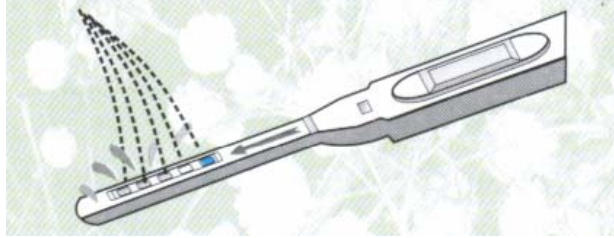
12Δ =The day to begin testing (Day 10)

### B. Step 2: Testing Procedure:

Revision Date: 6-5-06

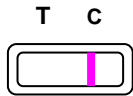
1. Allow the sealed test device pouch and urine to reach room temperature (18-30°C).
2. Remove the test device from the sealed pouch.
3. Hold the round end of cover with one hand. Use the other hand to pull out the test device and expose the absorbent.
4. Point the absorbent tip downward, place the absorbent tip in urine stream for at least 5 seconds to be thoroughly wet. Otherwise, you can collect your urine into a clean, dry container and dip half of the absorbent pad into the urine for at least 5 seconds.
5. 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 seconds. However, to confirm negative results, the complete reaction time (10 minutes) is required. Do not read results after 30 minutes.

Do not stream past the arrow end

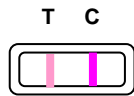


## INTERPRETATION OF RESULTS

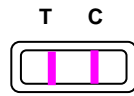
- **No LH Surge:** Only one color band appears on the control (C) region or the test (T) band is lighter than the control band. There is no LH surge.
- **LH Surge:** If two color bands are visible and the test (T) band is equal to or darker than the control (C) band, one will probably ovulate in the 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. Repeat test with a new test kit.



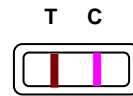
No LH Surge



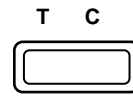
No LH Surge



LH Surge



LH Surge



Invalid

## STORAGE CONDITIONS

The test kit can be stored at room temperature (18 to 30 °C) in the sealed pouch for duration of shelf life. The test kits should be kept away from direct sunlight, moisture and heat. Refer to individual expiration dates of components for stability.

## PRECAUTIONS

1. Do not use test after the expiration dates.
2. For in vitro diagnostic use only.
3. The test devise should not be reused.
4. Do not use if pouch is torn or damaged.
5. For a single testing only.



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