



CORTEZ DIAGNOSTICS, INC.

23961 Craftsman Road, Suite D/E/F,
Calabasas, CA 91302 USA
Tel: (818) 591-3030 Fax: (818) 591-8383
E-mail: onestep@rapidtest.com
Web site: www.rapidtest.com

IVD See external label 2°C-30°C Σ=25 or 50 Test **REF** Cat. # 104110-1

OneStep LH Ovulation Urine RapiCard™ InstaTest Cat # 104110-1

INTRODUCTION

The OneStep LH Urine Ovulation RapiCard™ InstaTest is fast and easy to use. 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 |

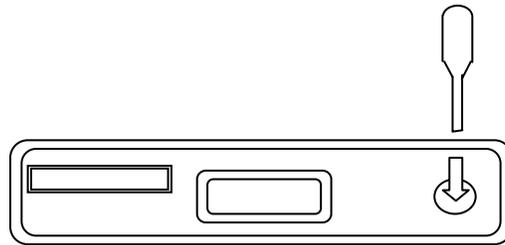
URINE COLLECTION

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 and 8pm.
3. Collect urine at about the same time each day.

4. Reduce liquid intake about 2 hours before collecting your urine as a diluted urine sample can prevent the test from detecting the LH surge.

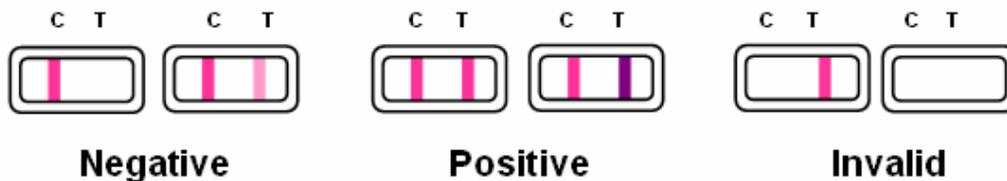
TEST PROCEDURE

1. Allow the sealed LH cassette test pouch, urine sample, and control solution to reach room temperature (18-30°C).
2. Remove the OneStep LH Urine Ovulation RapiCard™ InstaTest device from the sealed pouch.
3. Draw the urine sample to the urine dropper provided.
4. Hold the urine dropper upright about 1/2 inch above the sample well of the device. Add 5 drops of urine to this well.
5. Lay the test device on a flat surface with the result window facing up. 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.



INTERPRETATION OF 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.



LIMITATIONS

1. As with all diagnostic 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.
2. 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.
3. 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.

STORAGE AND STABILITY

The test kit can be stored at temperatures between 4 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.

PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.

| Date Adopted | Reference No. |
|--------------|-------------------|
| 2003-10-12 | DA-LH Urine -2008 |



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