



CORTEZ DIAGNOSTICS, INC.

23961 Craftsman Road, Suite 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	$\Sigma=25$ or 50 tests	REF Cat. #
------------	--------------------	----------	-------------------------	-------------------

OneStep RapiDip LH Urine Ovulation InstaTest

REF	104113-1
	104114-1
	104115-1

For Self Testing

INTRODUCTION

OneStep LH Urine Ovulation Test 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.

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

REAGENTS AND MATERIALS PROVIDED

1. Testing Device.
2. Dropper

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container.
2. Clock or timer.

WHEN TO BEGIN TESTING

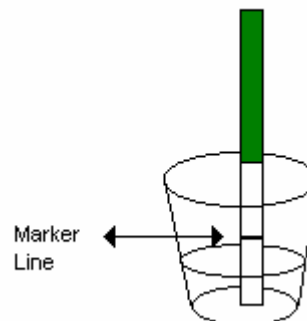
First, you must determine the length of your menstrual cycle. This is the number of days from the first day of your menstrual bleeding to the day before your next bleeding begins again. Please refer to the chart to determine when you should start testing. If your cycle is shorter than 21 days or longer 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.

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

TEST PROCEDURE

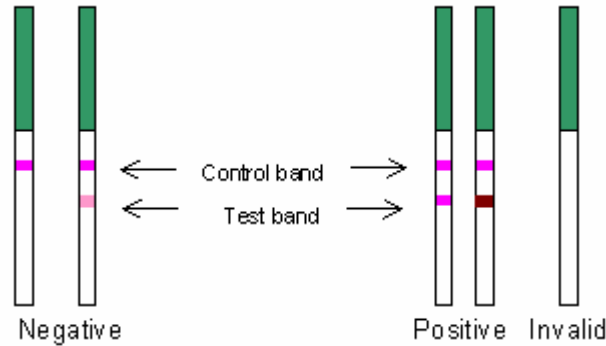
1. Allow the sealed LH test pouch, patient's urine sample and control solution to reach room temperature (18-30°C).
2. Remove the LH test device from the sealed pouch.
3. Immerse the strip into the urine with the arrow end pointing towards the urine. Do not immerse past the MAX (maximum) line. Take the strip out after 5 seconds and lay the strip flat on a clean, dry, non-absorbent surface (e.g., 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 short as 40 seconds. However, to confirm negative results, the complete reaction time (10 minutes) is required. Do not read results after 30 minutes.

INTERPRETATION OF RESULTS

- **No LH Surge:** Only one color band appears on the control region or the test band is lighter than the control band. There is no LH surge.
- **LH Surge:** If two color bands are visible and the test band is equal to or darker than the control 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.



STORAGE AND STABILITY

The test kit can be stored at room temperature (18 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.
4. Do not use if pouch is torn or damaged.
5. For a single testing only.



CORTEZ DIAGNOSTICS, INC.

23961 Craftsman Road, Suite E/F,
Calabasas, CA 91302 USA
Tel: (818) 591-3030 Fax: (818) 591-8383

ISO 13485-2003

Revision Date: 6-5-06