



## **Ovulation (hLH) – dipstick test**

**RAPU02C022**

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**LOT** : 090714/1

**A rapid, one step test for the qualitative detection of  
luteinizing hormone (LH) in human urine.  
For professional in-vitro diagnostic use only**

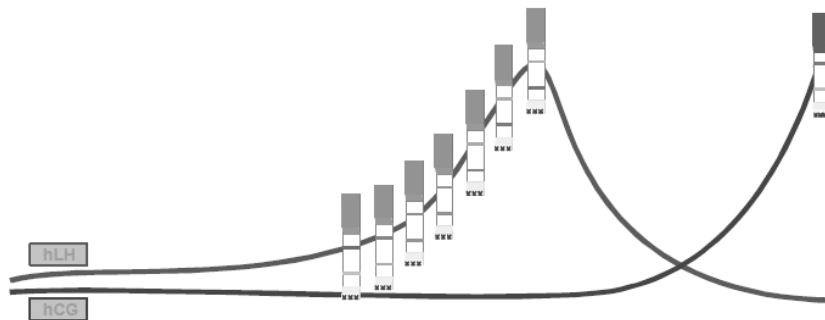
**INTENDED USE**

The **DIAsource Ovulation (hLH) Dipstick Test** is a rapid chromatographic immunoassay for the qualitative detection of luteinizing hormone (LH) in urine to aid in the early detection of ovulation.

**SUMMARY**

Ovulation is the release of an egg from the ovary. The egg then passes into the fallopian tube where it is ready to be fertilized. In order for pregnancy to occur, the egg must be fertilized by sperm within 24 hours after its release. Immediately prior to ovulation, the body produces a large amount of luteinizing hormone (LH) which triggers the release of a ripened egg from the ovary. This "LH surge" usually takes place in the middle of the menstrual cycle. The **DIAsource Ovulation (hLH) Dipstick Test** is a complete system to help you predict the time of ovulation, and peak fertility. It is during this fertile time that pregnancy is most likely to occur. The **DIAsource Ovulation (hLH) Dipstick Test** detects the LH surge in urine, signaling that ovulation is likely to occur in the next 24-48 hours.

Important: The LH surge and ovulation may not occur in all cycles.



**REAGENTS**

The test strip contains anti-LH particles and anti-LH antibody coated on the membrane.

**PRECAUTIONS**

- I For in vitro diagnostic use only
- I Do not use after expiry date
- I The test device should remain in sealed foil pouch until use.
- I Do not moisten nitrocellulose membrane with urine.
- I For single use only. Do not reuse.
- I Do not use if protective pouch is damaged. Testkit must reach room temperature in order to avoid deactivation of special membrane by condensation from air humidity.
- I Do not eat, drink or smoke in the area where the specimens or kits are handled.
- I Humidity and temperature can adversely affect results.
- I Use a new urine cup for each specimen in order to avoid cross contaminations.
- I Urine specimens are to be considered infectious material and to be treated as such with respective precautions.
- I The used test has to be disposed off according to local regulations.
- I Immerse test strip at most until maximum line.
- I If no C-line appears, repeat test with a new test strip.
- I Interpret test results after 5 minutes. Do not interpret after more than 10 minutes.

**STORAGE AND STABILITY**

The kit can be stored at room temperature or refrigerated (2-30°C). The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use.

- I Do not freeze.
- I Do not use beyond the expiration date.

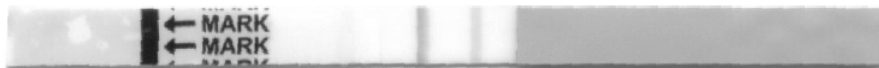
**MATERIALS**

**MATERIALS PROVIDED**

- I  STICK 20 Test strip
- I  Package insert

**REQUIRED BUT NOT PROVIDED MATERIAL**

- I  Specimen collection container
- I  Timer



## SPECIMEN COLLECTION AND PREPARATION

- Determine the time for the urine collection. For best results, collect the urine sample at about the same time each day, for example, between 10:00AM and 8:00PM. Some women have found that their best specimen is after 12 noon. Do not collect the first morning urine.
- Reduce liquid intake approximately 2 hours prior to urine collection.
- A urine specimen must be collected in a clean and dry container.
- Be sure to write down the date, cycle day and time that the urine is collected in the "Test Results Chart" on the last page of these instructions.
- One can store the urine sample for later testing in the day. Urine samples can be stored at room temperature for up to 8 hours or in the refrigerator for up to 24 hours. Do not freeze it. For best results, test the urine sample on the same day that it is collected. If the urine sample was refrigerated, let it reach room temperature before testing (about 30 minutes). Do not shake the container. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing. Use only urine from the top of the container.
- Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

**Note:** urine specimens and all materials that have been in contact with urine should be considered, treated and disposed off as infectious material. A contact with the skin is to be avoided by wearing protective gloves and proper laboratory clothing.

## WHEN TO START TESTING

Determine the Length of the patient's Menstrual Cycle. Patient's Menstrual Cycle Length is the number of days from the first day of patient's period (menstrual bleeding) to the last day before her next period starts. Think back over the last few months to decide what patient's usual cycle length has been. Circle patient's usual cycle length on the WHEN TO START CHART below. Select the number directly underneath. Starting the first day of patient's last period, count ahead the selected number of days on the calendar. This is the day one should begin testing.

## WHEN TO START CHART

Circle Patient's Usual Cycle Length

Menstrual Cycle Length	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
Day to Start Testing	6	6	7	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23

Count ahead this many days STARTING WITH THE FIRST DAY of patient's LAST period.

**Note:** If one is unsure about patient's cycle length, one may want to use patient's shortest cycle length when reading the chart. If you do this, you may need to test for more than 5 days.

**Example:** patient's usual cycle length is 28 days. Her last period started on the third. The "When to Start Chart" shows that one will count ahead 11 days beginning with the third. When one count 11 days ahead on the calendar, you find that one will collect and test patient's urine starting on the 13th ". (See "Specimen Calendar " below).

## Specimen Calendar

Sun.	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.
	1	2	(3)	4	5	6
7	8	9	10	11	12	<13>
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

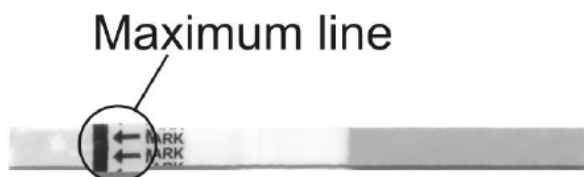
( )--First day of your last period

< >--Begin testing with the **DIASource Ovulation (hLH) Dipstick Test**.

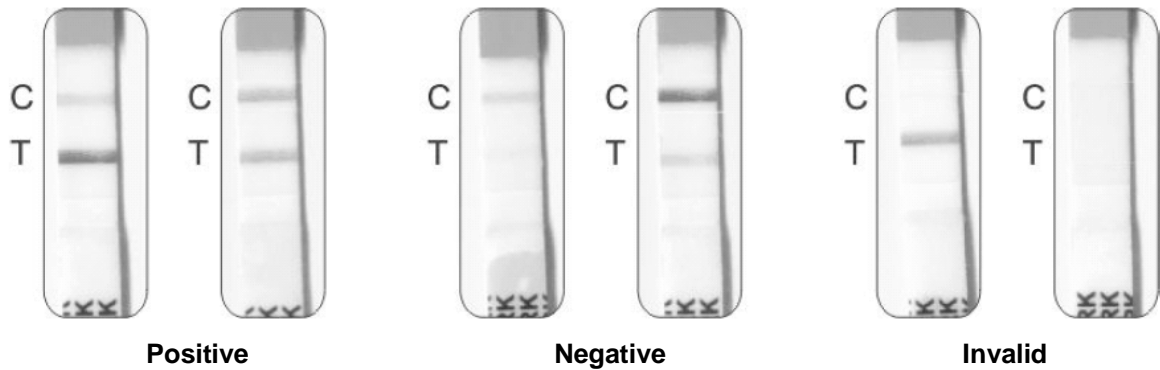
## DIRECTION FOR USE

The above instructions for specimen collection are to be followed. The specimen, test strip and / or controls should be brought to room temperature. Open the protective pouch only shortly before performing the test, as the special membrane is sensitive to humidity.

- 1 Determine the day you will begin testing. (See the above section: "WHEN TO START TESTING").
- 1 Use for each test a new test strip.
- 2 Use only test strips whose foil pouch is not damaged.
- 3 Before performing the test, bring urine specimen, test strips and / or controls to room temperature. (15 – 30 °C).
- 4 Remove test strip from protective pouch from sealed pouch and use it as soon as possible.
- 5 Immediately after removing the test strip from the sealed pouch, mark the test strip with the corresponding patient number.
- 6 Perform the test on a clean an plain surface.
- 7 Immerse the tip vertically in urine for at least 10-15 seconds.
- 8 Do not exceed the maximum line (MAX) when immersing the test strips in urine specimen. See illustration below.
- 9 Wait until chromatography has finished, i. e. that the liquid has proceeded to the end of the result fields.
- 10 Perform the test on a non-absorbent surface, start timer and wait for red lines to appear.
- 11 Interpret the test results after 5 minutes. The confirmation of a negative result should be done after max. 10 minutes.



## INTERPRETATION OF RESULT



**POSITIVE:** If two lines are visible, but the line in test region (T) is the same as or darker than the one in the control region (C). It indicates that the patient will probably ovulate in the next 24-48 hours.

**NEGATIVE:** If two lines are visible, but the line in the test region (T) is lighter than the one in the control region (C), or if there is no line in the test region (T). It indicates that no LH surge has been detected.

### INVALID: Control line fails to appear.

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## QUALITY CONTROL

A positive result means that the urine sample contains the level of LH that would indicate the patient is beginning to ovulate. You can assume that the patient will ovulate in 24-48 hours. A negative result means that no LH surge has been detected and you should continue daily testing. Not every woman ovulates mid-cycle, therefore, you may not see a positive result during the first 5 days of testing. Continue testing with the **DIAsource Ovulation (hLH) Dipstick Test**.

## LIMITATIONS

1. The test works only when the test procedures are precisely followed.
2. Do not reuse the test strip.
3. For in vitro diagnostic use only.
4. This test may not be used as a form of birth control.
5. The test result is usually not affected by pain relievers, antibiotics and other common drugs. Medication containing hCG or LH may affect the test and should not be taken while using the **DIAsource Ovulation(hLH) Dipstick Test**. In addition, the test will not work properly if the patient is pregnant, in menopause, or is taking birth control pills.
6. Keep out of the reach of children.

## PERFORMANCE CHARACTERISTICS

In laboratory studies show the sensitivity of the **DIAsource Ovulation (hLH) Dipstick Test** is 40 mIU/mL and the accuracy is 98.7%.

## INTERFERENCE TESTING

The **DIAsource Ovulation(hLH) Dipstick Test** has been tested with commonly known drugs and hormones including FSH (1000 mIU/mL), TSH (1000  $\mu$ IU/mL), and hCG (10000 mIU/mL). At the levels tested, none of these substances interfered with the expected test results.

## QUESTIONS AND ANSWERS

1. Can I use the **DIAsource Ovulation (hLH) Dipstick Test** to avoid pregnancy?  
- No, the test shouldn't be used as a form of birth control.
2. Do alcohol or common medications affect the test?  
- No, but the patient should consult her physician if she is taking any medication.
3. How long will the line remain visible?  
- The test should be read at 5 minutes for best results. A positive (Surge) result will never disappear. The color line may become darker and a tinted background may appear after several hours. Some negative results may later display a faint second color line because of evaporation from the test region, which prevents complete migration of the test chemicals. Therefore, you should discard the test strip once you have read the test.
4. Once I see a positive result, when is the best time to have intercourse?  
- Ovulation is likely to occur within 24-48 hours. This is patient's most fertile time. Sexual intercourse within this time frame is advised in case pregnancy is desired.
5. I am now using the basal body temperature method (BBT). Does this test replace BBT?  
- The shift in basal body temperature primarily indicates that ovulation has already occurred. The **DIAsource Ovulation (hLH) Dipstick Test** indicates that ovulation is about to occur.






6. I have received a positive result and patient had intercourse during these fertile days. Patient has not become pregnant. What shall I do?  
 - There are many factors that can affect the ability to become pregnant. Often one may need to use the test kit for 3-4 months before achieving pregnancy. Patient and her partner should consult your physician if pregnancy is not achieved after 3-4 months.
7. I have had a positive result and patient had intercourse during these fertile days. Patient thinks she may be pregnant. How soon can I find out?  
 - The pregnancy products can provide you with results as early as the first day patient missed her period.
8. What time of the day should I perform the test? Do I need to use first morning urine?  
 - We do not recommend first morning urine, but any other time of day is suitable. For best results, try to collect urine sample at approximately the same time each day.
9. Will the amount of liquid patient drink affect the result?  
 - Heavy intake of fluids prior to testing will dilute the hormone in the urine sample. We suggest that she limit her fluid intake for about two hours before patient collect her urine.

#### TEST RESULTS CHART

Test	Collection time	DIAsource Ovulation Result
Day 1		
Day 2		
Day 3		
Day 4		
Day 5		

#### REFERENCE

1. Elkind-Hirsch, K; Goldzieher, JW; Gibbons, WE and Besch, PK. *Obstetrics and Gynecology*, 67(3): 450-453,1986.

 Consult instructions for use	 Manufacturer
 Storage temperature	 Contains sufficient for n tests
 Use by	<b>IVD</b> In vitro diagnostic medical device
<b>LOT</b> Batch code	<b>STICK</b> Strip Test
<b>REF</b> Catalogue number	

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