

Rapid LH Ovulation Prediction Test LH-DS0420

Introduction

By detecting elevated level of gonadotropin leutinizing hormone (LH) in urine, the Rapid LH Ovulation test provides a quick and easy means for predicting when the female body will ovulate and assessment of the most likely time for contraception. Prior to a woman's ovulation, a large amount of the LH, which stimulates the liberation of the egg, is released from the pituitary gland. The release of the egg usually occurs 24 – 48 hrs after an elevated amount of LH is discharged. This elevated level of LH (known as the "LH surge") can be detected in the urine.

The 3 days before through to 3 days after ovulation is the most fertile time of the menstrual cycle when a woman has the best chance of conceiving.

Principle of the test

The dipstick rapid LH test device is a porous membrane assay strip, which contains antibody reagents that reacts with LH in urine sample. Once the sample application zone of the test strip (the arrow pointed end) is submerged in a urine sample, the sample solution migrates along the test strip by capillary attraction. When the urine sample contacts the reagents embedded in the test strip, any LH that is present will be bound by an anti-β subunit antibody-gold conjugate forming a complex. This complex migrates to the test zone (T) of the device where it is captured by an immobilized antibody specific to the α subunit forming a pink or red-colored line. The rest of the particles in the sample migrate to the control zone (C) of the strip, where another immobilized reagent producing a pink-colored control line even in the absence of LH captures the dye conjugate. If the sample contains an elevated level of LH, the test line (T) will appear the same or darker than the control line (C). In this test design, the control line intensity remains constant regardless of the LH concentration in urine. When there is no LH surge, the LH level in urine is low, the resulting test line is weaker than the control line.

When to Start Testing

Using the following chart, determine which day to begin the test by the length of your menstrual cycle. The length of your cycle is from the beginning of one menstrual bleeding period to the beginning of the next (count the first day of your period as day 1).

<i>Cycle Length</i>	<i>Day of Cycle to Begin Testing</i>
21 days	day 5
22 days	day 6
23 days	day 7
24 days	day 8
25 days	day 9
26 days	day 10

27 days	day 11
28 days	day 12
29 days	day 13
30 days	day 14
31 days	day 15
32 days	day 16
33 days	day 17
34 days	day 18
35 days	day 19
36 days	day 20
37 days	day 21
38 days	day 22
39 days	day 23
40 days	day 24

If your cycle is irregular (where it varies more than a few days of each month) count your shortest cycle length within the past 6 months.

For example, if your period normally begins every 30 days, then begin testing 14 days after the beginning of the last period.

Usage Instructions

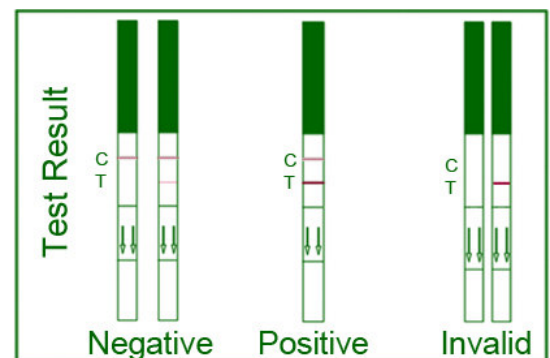
- Important**-DO NOT USE THE FIRST URINE IN THE MORNING
- Try to collect urine around the same time of the day if more than one test is used afterwards. For example, collect urine at 3 – 4 pm daily.

Test Procedure

1. Bring test components including urine to room temperature.
2. Remove the test strip from the pouch.
3. Dip the arrow pointed end of test strip into the urine sample, ensuring that the level of the urine sample does not surpass the arrowhead. Keep contact between the test strip and the urine specimen for more than 5 seconds (the strip can be left in the container till the end of the test).
4. Read results at 5-10 minutes; do not interpret results after 10 minutes. (See Figure1).

Interpretation of Results

Figure 1 Test Results.



- a. **A Negative** test result ($LH \leq 20 \text{ mIU/ml}$) is indicated by the presence of a control line (C) and the absence of a test line (T) or the presence of a test line that is fainter than the control line (C). A negative result means LH surge has not been detected. Continue to test once per day until the LH surge has been detected. (A faint test line means that the LH surge will occur soon.)
- b. **A positive** test result ($LH > 20 \text{ mIU/ml}$) is indicated by a control line and a colored test line (T) that is darker than the control line
- c. **Invalid** test result is indicated by the absence of a control line (C). If an invalid test result is obtained, it is recommended that the specimen be retested.

Females: Follicular phase	8-20 mIU/mL
Ovulatory phase	>>25mIU/mL
Luteal phase	8-20 mIU/mL

Quality Control

When performing quality control on this test it is advised to use LH standards with a concentration of 20-100 mIU/mL for positive control samples, as well as 0 mIU/mL for a negative.

The control band is an internal reagent and procedural control. If the test is performed correctly the control line will appear.

Storage

Store the test 2 - 28 °C. Prior to use bring test and components to room temperature.

Precautions

1. Wear gloves and other appropriate laboratory attire while handling kit reagents or specimens. Wash hands thoroughly afterwards.
2. Avoid splashing or aerosol formation.
3. Clean up spills thoroughly using an appropriate disinfectant.
4. Decontaminate and dispose of all specimens and potentially contaminated materials as if they were infectious.
5. Do not use reagents after the expiration date.
6. The device is for in vitro diagnostic use only

Limitations of the Test

1. Pregnancy, menopause, or Human Chorionic Gonadotropin (hCG) injection may cause inaccurate results.
2. Drugs containing hCG or LH will affect the outcome of the test. It is recommended to consult with a doctor before testing.

Expected Values

Below is a chart of the expected LH values for each individual^{1,2}.

Children	4-20 mIU/mL
Adult Males	5-20 mIU/mL

Performance Characteristics

Sensitivity

The assay limit of detection is 20mIU/ml.

Specificity

Below is the reactivity to common gonadotropins.

Compound	Specificity(%)
β -hCG	90%
β -LH	100%
α -hCG	$\leq 1\%$
FSH	$\leq 0.1\%$
TSH	$\leq 0.1\%$

Interfering Substances

None of the substances at the concentrations listed below, affected the expected test results.

Acetaminophen	20 mg/dL
Albumin	1000 mg/dL
Ascorbic Acid	40 mg/dL
Atropine	40 mg/dL
Caffeine	40 mg/dL
Gentistic Acid	40 mg/dL
Hemoglobin	10 mg /dL
Urea	4000 mg/dL
Uric Acid	10 mg/dL

References

1. Biocheck Inc. Product Catalog 1999-2000, Burlingame, CA.
2. Scott M. G., and Ladenson J.H., "Hormonal Evaluation of Female Infertility and Reproductive Disorders," Clinical Chemistry. 35(4): 620-629, 1989.

