A rapid, one step test for the qualitative detection of luteinizing hormone (LH) in urine.

**INTENDED USE**

The Discover LH Ovulation Rapid Test Midstream (Urine) is a rapid chromatographic immunoassay for the qualitative detection of luteinizing hormone (LH) in urine to aid in the detection of ovulation.

**PRINCIPLE**

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 Discover LH Ovulation Rapid Test Midstream (Urine) is a complete system to help predict the time of ovulation, and peak fertility. It is during this fertile time that pregnancy is most likely to occur. The LH Ovulation Rapid Test Midstream (Urine) detects the LH surge in urine, signaling that ovulation is likely to occur in the next 24-36 hours. The test utilizes a combination of antibodies including a monoclonal LH antibody to selectively detect elevated levels of LH.

**MATERIALS**

- **Materials Provided**
  - Test Midstream
  - Package Insert
  - Desiccant

- **Materials Required But Not Provided**
  - Specimen collection container
  - Timer

**WHEN TO START TESTING**

First, determine the subject’s Menstrual Cycle Length. The Menstrual Cycle Length is the number of days from the first day of the subject’s period (menstrual bleeding) to the last day before the next period starts.

Next, determine the Days to Count Ahead after the period to start testing. Find the subject’s Menstrual Cycle Length on the first row of the chart below, and read the corresponding Days to Count Ahead in the second row. This is the number of days after the period to begin testing.

**INTERPRETATION OF RESULTS**

(Please refer to the illustration above)

**POSITIVE:** Two lines are visible, and the line in test line region (T) is the same as or darker than the one in the control line region (C). This indicates probable ovulation in 24-36 hours.

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

**INVALID:** Control line fails to appear. Re-review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
QUALITY CONTROL
A procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

A positive result indicates that the urine specimen contains the level of LH that would indicate the beginning of ovulation. Ovulation should begin in 24-36 hours.

A negative result indicates that no LH surge has been detected and daily testing should continue.

Not every woman ovulates mid-cycle, therefore, a positive result may not appear during the selected days of testing. If you see no positive result, continue testing with the LH Ovulation Test Midstream (Urine) for several more days. If negative results persist, test again during the next menstrual cycle.

LIMITATIONS
1. For OTC and professional in vitro diagnostic use.
2. This test may not be used as a form of birth control.
3. The test results should not be 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 LH Ovulation Rapid Test Midstream (Urine). In addition, the test will not work properly for subjects who are pregnant, in menopause, or are taking birth control pills.
4. Keep out of the reach of children.

PERFORMANCE CHARACTERISTICS
Laboratory studies show that the sensitivity of the LH Ovulation Rapid Test Midstream (Urine) is 25 mIU/mL and the accuracy is 99.0%.

INTERFERENCE TESTING
The LH Ovulation Rapid Test Midstream (Urine) has been tested with commonly known drugs and hormones including FSH (200 mIU/mL), and TSH (1,000 μIU/mL). At the levels tested, none of these substances interfered with the expected test results.

QUESTIONS AND ANSWERS
1. Q: Can the LH Ovulation Rapid Test Midstream (Urine) be used to avoid pregnancy?
   A: No, the test should not be used as a form of birth control.

2. Q: Do alcohol or common medications affect the test?
   A: No, but a physician should be consulted if taking any hormonal medication. Also, recent oral contraceptive use, breastfeeding or pregnancy could affect the results.

3. Q: How long will the lines remain visible?
   A: The test should be read at 10 minutes for best results. A positive (Surge) result will never disappear. The colored line(s) 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 line region, which prevents complete migration of the test chemicals. Therefore, do not read the result after 10 minutes and discard the test after reading the test.

4. Q: Once a positive result is obtained, when is the best time to have intercourse?
   A: Ovulation is likely to occur within 24-36 hours. This is the most fertile time. Sexual intercourse within this time frame is advised.

5. Q: Does this test replace the basal body temperature method (BBT)?
   A: The shift in basal body temperature primarily indicates that ovulation has already occurred. The LH Ovulation Rapid Test Midstream (Urine) indicates that ovulation is about to occur.

6. Q: Does a positive result guarantee a pregnancy after intercourse within the fertile days?
   A: There are many factors that can affect the ability to become pregnant. Often it may be necessary to use the test kit for 3-4 months before achieving pregnancy. A physician should be consulted if pregnancy is not achieved after 3-4 months.

7. Q: How soon can pregnancy be confirmed?
   A: Rapid pregnancy tests can provide results as early as the first missed period.

8. Q: What time of the day should I perform the test? Do I need to use first morning urine?
   A: First morning urine is not recommended, but any other time of day is suitable. For best results, try to collect urine at approximately the same time each day.

9. Q: Will heavy intake of liquids affect the result?
   A: Heavy intake of fluids prior to testing will dilute the hormone in urine. Limiting fluid intake for about two hours before collecting urine is suggested.

TEST RESULTS CHART

<table>
<thead>
<tr>
<th>Test</th>
<th>Date</th>
<th>Collection time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td></td>
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<tr>
<td>Day 2</td>
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<td>Day 5</td>
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BIBLIOGRAPHY