Luteinizing Hormone (LH) Test Kit

Instructions For Use
For Self-Testing Use Only

Format: Midstream
Specimen: Urine
Catalog Number: A01-03-130

* Please read the instructions carefully before use
INTENDED USE
Artron One-Step Luteinizing Hormone (LH) Test is a rapid and convenient immunochromatographic assay for the qualitative detection of LH in urine at or above the concentration of 30 mIU/ml and predicting the time of LH surge and ovulation. The device is designed for professional and over the counter use. The test provides a visual, qualitative result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY
Luteinizing hormone is always present in human urine. LH increases dramatically just before a woman's most fertile day of the month in a process commonly referred to as the "LH Surge." This LH increase triggers ovulation, the process during which an egg is released from a woman's ovary. Because the egg can only be fertilized between 6 to 24 hours after ovulation, detecting ovulation in advance by testing for the LH surge is very important for women seeking pregnancy.

The best times to test are between 11:00 am to 3:00 pm and between 5:00 pm to 10:00 pm. Early morning testing is not recommended as LH does not appear in the urine until later in the day. To ensure that you do not miss your surge, you may test twice a day, once in the earlier time frame and once in the later time frame. The detection limit for the LH Test Kit is 30 mIU/ml LH. Urine samples with LH concentrations of 30 mIU/ml or greater will induce a positive test result.

When to begin testing: The test can be done at any time of the day, preferably after 10:00 am and before 8:00 pm. If tested twice a day, test at least 8 hours apart to help catch shorter LH surges. Testing should be done at approximately the same time each day. Reduce liquid intake for 2 hours before testing.

To find out on what day to begin testing, determine the length of your normal period cycle. The length of one cycle is from the beginning of one period (the day of first bleeding) to the day before the beginning of the next cycle. The first day of bleeding or spotting is counted as day one (1). If the cycle length is irregular, that is, if it varies by more than a few days each month, take the average number of days for the last 3 months. Use the chart below to determine the day you should begin testing.

<table>
<thead>
<tr>
<th>Length of Normal Cycle (Total days)</th>
<th>Start testing ___ days after your last period began.</th>
<th>Length of Normal Cycle (Total days)</th>
<th>Start testing ___ days after your last period began.</th>
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<td>30</td>
<td>13</td>
<td>40</td>
<td>23</td>
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How to recognize the LH surge: After reading the result of the test, the occurrence of LH surge can be decided. If the test result is positive, you are probably experiencing your LH surge. If your test result is negative, you are probably not experiencing your LH surge. A LH surge can last from one to three days depending on your cycle and other biological factors. A pink test line lighter than the control I shows that there is only a very low level of LH in your urine.

When to stop testing: Stop testing once the LH surge is detected unless specified by your doctor.

Artron One-Step Luteinizing Hormone (LH) Test is an antigen-capture immunochromatographic assay, which detects the presence of LH in human urine samples. Monoclonal antibodies specifically against LH are 1) conjugated with colloidal gold and deposited on the conjugate pad
and 2) immobilized on the test line of the nitrocellulose membrane. When the urine sample is added the gold-antibody conjugate is rehydrated and the LH, if any in samples, interacts with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (T) where it will be captured by immobilized antibodies, forming a visible pink line (Test band), indicating a positive result of LH surge. If LH is absent in the sample, no pink line will appear in the Test Zone (T), indicating a negative result. To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

**PACKAGE CONTENTS**
- Pouches (contain: midstream test cassette, desiccant).
- Test instructions.

**MATERIALS REQUIRED (BUT NOT PROVIDED)**
- Clean, dry urine specimen collection container (plastic or glass).
- Clock or timer.

**WARNINGS AND PRECAUTIONS**
- For *in vitro* diagnostic use only.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch. Do not reuse.
- Do not mix and interchange different specimens.
- Do not eat, drink or smoke in the area where the specimens or kits are being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used kits in a proper biohazard container. The handling and disposal of the hazardous materials should follow local, regional or national regulations.
- Keep out of children’s reach.

**SPECIMEN PREPARATION**
- Collect urine sample in a clean, dry container without preservatives. If specimen cannot be assayed immediately, it can be stored at 2-8°C for up to 72 hours prior to testing, or frozen at –20°C for a longer period of time.
- Allow specimens to reach room temperature before testing if they were refrigerated or frozen.

**TEST PROCEDURES**

1. Remove the testing device from the sealed pouch by tearing at the notch and uncap the device.
2. Point the absorbent tip downward in urine stream for about 5 seconds to wet it thoroughly, or collect the urine in a clean cup and dip half of the absorbent pad into the urine for at least 5 seconds until the urine sample move into test window.
3. Re-cap the device.
Read the result in 10 minutes, following instructions under the “Result Interpretations” section.

NOTE: Strong positive specimens may produce positive results in as little time as 1 minute. Confirm negatives in 10-20 minutes.

RESULT INTERPRETATIONS

Negative
Only one pink colored line appears in the control region (C), or the test line (T) is lighter than the control line (C), indicating a negative result for ovulation.

Positive
Distinct pink colored lines appear in the control and test regions, and the test line (T) is equal to or darker than the control line (C), indicating a positive result for ovulation.

Invalid
No visible line in the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

QUALITY CONTROL
Although each test device contains an internal quality control (pink colored line in the control region), good laboratory practice recommends the use of an outside control to ensure proper performance of the test device. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY
- Test device in a sealed pouch can be stored at 2-30°C up to the expiration date.
- Do not freeze the test device. Do the test in 1 hour when the pouch is opened.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS
- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting LH, a low incidence of false results may still occur. Therefore, other clinically available tests should also be done in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity:

Analytical Sensitivity of the test is 30 mIU/ml LH in urine sample.

Analytical Specificity:

Analytic Specificity: The test results show negative for the 1000 mIU/ml hFSH and 1000μIU/mL hTSH samples.
Diagnostic sensitivity and Diagnostic specificity:

To compare the performance of the Artron One-Step LH Urinary Ovulation Test Device with other commercial kits, a comparison study with a currently marketed LH Urinary Ovulation test device was conducted at external clinical sites. The corresponding specificity and sensitivity were calculated based on the above tests, the result was demonstrated as below:

<table>
<thead>
<tr>
<th>Results of commercial kits</th>
<th>Results of Artron One-step LH test</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Positive</td>
<td>184</td>
<td>1</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
<td>264</td>
</tr>
<tr>
<td>Subtotal</td>
<td>185</td>
<td>265</td>
</tr>
</tbody>
</table>

Diagnostic sensitivity=99.46% (184/185)
Diagnostic specificity=99.62% (264/265)

Interfering Substances:

To evaluate the potential for interference by certain exogenous compounds, negative urine samples and negative urine samples spiked with 30 mIU/mL LH were spiked with potential interferents and tested. No interferences were observed at the concentrations tested. The concentrations of substances/conditions that showed no interference are listed below: The following conditions were found not to interfere with the test.

- Acetaminophen: 20 mg/dl
- Acetylsalicylic acid: 20 mg/dl
- Ascorbic acid: 20 mg/dl
- Caffeine: 20 mg/dl
- Gentisic acid: 20 mg/dl
- Phenylpropanolamine: 20 mg/dl
- Salicylic acid: 20 mg/dl
- EDTA: 80 mg/dl
- Benzoylecgonine: 10 mg/dl
- Atropine: 20 mg/dl
- Cannabinol: 10 mg/dl
- Ethanol: 1%
- Methanol: 1%
- Biological Analytes
  - Albumin: 2,000 mg/dl
  - Glucose: 2,000 mg/dl
  - Bilirubin: 1,000 µg/dl
  - Hemoglobin: 1,000 µg/dl

Urinary Test pH
- pH 9
- pH 8
- pH 6
- pH 5

Reproducibility:

The precision was determined by replicate assays of both positive and negative urine samples with devices from three different production lots. The resultant data indicated no appreciable between lot variation when testing both positive and negative samples across three different lots.

Expiration Date: 36 months from Date of Manufacture
INDEX OF SYMBOL

Do not reuse

Batch code

In vitro diagnostic medical device

Use by

Temperature limitation

Contains sufficient for < n > tests

Caution

Catalog number

Manufacturer

Consult instructions for use

Authorized representative in the European community

CE Mark

BIBLIOGRAPHY


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Doc No. A01-03-130P
VER. 2
REVISION: FEB 25, 2014