The test uses a sandwich immunodetection method; the detector antibody in buffer binds to antigen in sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antibody on test strip.

The more antigen in sample forms the more antigen-antibody complex and leads to stronger intensity of fluorescence signal on detector antibody, which is processed by instrument for ichroma™ tests to show LH concentration in sample.

**INTENDED USE**

ichroma™ LH is a fluorescence Immunoassay (FIA) for the quantitative determination of Luteinizing hormone (LH) in human serum/plasma. It is useful as an aid in management and monitoring of determination of evaluating fertility issues, function of reproductive organs (ovaries or testicles), or detection of the ovulation.

For in vitro diagnostic use only.

**INTRODUCTION**

Human luteinizing hormone (LH, lutropin) is a glycoprotein hormone with two dissimilar subunits (α and β). LH has a molecular weight of approximately 29,000 daltons. The α-subunit of LH contains 92 amino acid residues and is essentially identical to the β-subunits of follicle stimulating hormone (FSH, follitropin), thyroid stimulating hormone (TSH, thyrotropin), and human chorionic gonadotropin (hCG). The β-subunit of LH contains 112 amino acid residues and is considerably different from that of FSH and TSH. However, the β-subunits of LH and hCG are very similar. The structural similarities between LH and hCG are responsible for the observed similarity in biological properties. In the female, LH stimulates the final maturation of the follicle, follicular rupture, and ovulation. Human LH is secreted by the gonadotrophic cells of the anterior lobe of the pituitary gland in response to gonadotropin releasing hormone (GnRH) from the medial basal hypothalamus. Both LH and FSH are secreted in a pulsatile nature; however, this is less noticeable for FSH perhaps due to the longer half-life in the circulation. In a normal menstrual cycle negative feedback by estradiol suppresses LH secretion in the follicular phase. As the follicle develops (in response to FSH) estradiol production increases which triggers an increase in GnRH and an increased sensitivity of the pituitary to GnRH. A GnRH surge results in the preovulatory (mid-cycle) surge of LH and ovulation. Following this surge, LH is suppressed during the luteal phase due to negative feedback from progesterone and estradiol. Variation in cycle lengths are observed in normally menstruating females due to variations in the length of the follicular phase. In the menopausal female, LH levels are elevated in response to decreased production of ovarian estrogens and progestogens, which eliminates the negative feedback mechanism on the pituitary gland. As a result, ovulation and menstrual cycles decrease and eventually cease. In the male, LH is often referred to as interstitial cell-stimulating hormone and influences the production of testosterone by the Leydig cells of the testes.

At menopause, or following ovarioectomy in women, concentrations of estrogens decline to low levels. The lowered concentrations of estrogens result in a loss of the negative feedback on gonadotropin release. The consequence is an increase in the concentrations of LH and FSH. Concentrations of LH and hFSH are commonly determined in investigations of menstrual cycle, fertility, and pubertal developmental abnormalities, such as premature ovarian failure, menopause, ovulatory disorders and puerperal failure. The ratio of LH/hFSH has been used to assist in the diagnosis of polycystic ovary disease. Low concentrations of LH and FSH may indicate pituitary failure while elevated concentrations of LH and hFSH along with decreased concentrations of gonadal steroids may indicate gonadal failure. In the male, elevated LH and hFSH with low concentrations of gonadal steroids may indicate testicular failure or anorchia. In Klinefelter’s syndrome LH may be elevated due to Sertoli cell failure.

**WARNINGS AND PRECAUTIONS**

- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this ‘Instruction for use’.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (Cartridge, ID chip and detection buffer) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield misleading of test result(s).
- Do not reuse. A detection buffer tube should be used for processing one sample only. So should a cartridge.
- The cartridge should remain sealed in its original pouch before use. Do not use the cartridge, if is damaged or already opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with the regulations. Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes.
- ichroma™ LH as well as the instrument for ichroma™ tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that instrument for ichroma™ tests may produce minor vibration.
- Used detection buffer tubes, pipette tips and cartridges should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- ichroma™ LH will provide accurate and reliable results subject to the following conditions.
  - Use ichroma™ LH should be used only in conjunction with instrument for ichroma™ tests.
  - Any anticoagulants other than EDTA, sodium heparin, sodium citrate should be avoided.
The cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4-30 °C.

The detection buffer pre-dispersed in a tube is stable for 20 months if stored at 2-8 °C.

After the cartridge pouch is opened, the test should be performed immediately.

The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.

The test may yield false negative result. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.

Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.

Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

Components of ichroma™ LH
- Cartridge Box: 25
- ID Chip: 1
- Instruction For Use: 1
- Box containing Detection Buffer Tubes: 25

Following items can be purchased separately from ichroma™ LH.

Instrument for ichroma™ tests
- ichroma™ Reader REF: FR203
- ichroma™ II REF: FPRR021
- ichroma™ D REF: 13303
- ichroma™ Printer REF: FPRR007
- Boditech Hormone Control REF: CFPO-95

The sample type for ichroma™ LH is human serum/plasma.

It is recommended to test the sample within 24 hours after collection.

The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.

Samples may be stored for up to a week at 2-8 °C prior to being tested. If testing will be delayed more than a week, samples should be frozen at -20 °C.

Samples stored frozen at -20 °C for 2 months showed no performance difference.

Once the sample was frozen, it should be used one time only for test, because repeated freezing and thawing can result in the change of test values.

Check the contents of ichroma™ LH: Sealed Cartridge, Detection Buffer Tubes and ID Chip.

Ensure that the lot number of the cartridge matches that of the ID chip as well as the detection buffer.

Keep the sealed cartridge (if stored in refrigerator) and the detection buffer tube at room temperature for at least 30 minutes just prior to the test. Place the cartridge on a clean, dust-free and flat surface.

Turn on the instrument for ichroma™ tests.

Insert the ID Chip into the ID chip port of the instrument for ichroma™ tests.

Press the ‘Select’ button on the instrument for ichroma™ tests.

(Please refer to the ‘Instrument for ichroma™ tests Operation Manual’ for complete information and operating instructions.)

Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.

To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the cartridge especially for this purpose.

Press ‘Select’ button on the instrument for ichroma™ tests to start the scanning process.

Instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.

Read the test result on the display screen of the instrument for ichroma™ tests.

The cut-off (reference range)

<table>
<thead>
<tr>
<th>Type</th>
<th>mIU/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>1.0 – 8.0</td>
</tr>
<tr>
<td>Females – Ovulatory phase</td>
<td>17.0 – 77.0</td>
</tr>
<tr>
<td>Females – Luteal phase</td>
<td>0.0 – 15.0</td>
</tr>
<tr>
<td>Postmenopausal</td>
<td>11.0 – 40.0</td>
</tr>
</tbody>
</table>

Working range: 1.0 – 100.0 mIU/mL
**PERFORMANCE CHARACTERISTICS**

- **Cross-reactivity:** There, in test samples, are biomolecules such as below the table were added to the test sample(s) at concentrations much higher than their normal physiological levels in blood. ichroma™ LH test results did not show any significant cross-reactivity with these biomolecules.

<table>
<thead>
<tr>
<th>Cross reactivity materials</th>
<th>Concentration of cross reactivity materials</th>
<th>Cross reactivity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>hCG</td>
<td>200,000 mIU/ml</td>
<td>0.5</td>
</tr>
<tr>
<td>FSH</td>
<td>1,000 mIU/ml</td>
<td>N/D</td>
</tr>
<tr>
<td>PRL</td>
<td>1,000 ng/ml</td>
<td>N/D</td>
</tr>
<tr>
<td>TSH</td>
<td>1,000 µIU/ml</td>
<td>0.7</td>
</tr>
</tbody>
</table>

- **Interference:** Study of interference from table below with ichroma™ LH showed following results.

<table>
<thead>
<tr>
<th>Interference materials</th>
<th>Concentration of interference materials</th>
<th>Interference (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-glucose</td>
<td>600 mM/L</td>
<td>&lt; 1.5</td>
</tr>
<tr>
<td>L-Ascorbic acid</td>
<td>2 mM/L</td>
<td>&lt; 1.7</td>
</tr>
<tr>
<td>Bilirubin (unconjugated)</td>
<td>4 mM/L</td>
<td>&lt; 4.3</td>
</tr>
<tr>
<td>Hemoglobin (human)</td>
<td>20 g/L</td>
<td>&lt; 4.9</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>130 mM/L</td>
<td>&lt; 1.5</td>
</tr>
<tr>
<td>Triglyceride</td>
<td>100 mg/mL</td>
<td>&lt; 6.9</td>
</tr>
</tbody>
</table>

* ND : Not Detected

- **Precision:** The intra-assay precision was calculated by one evaluator, who tested different concentrations of control standard ten times each with three different lots of ichroma™ LH. The inter-assay precision was confirmed by 2 different evaluators with 3 different lots, testing three times each different concentrations.

- **Comparability:** LH concentrations of 117 serum samples were quantified independently with ichroma™ LH and Access2 (Beckman Coulter Inc. USA) as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y = 0.9842X + 0.2949 (1st trial), Y = 0.9891X + 0.1295 (2nd trial) and R = 0.994 (1st trial), 0.995 (2nd trial) respectively.

**REFERENCES**

17. Bonnar J. The hypothalmus and reproductive function. In The Medical Annual 1973; Edited by Scott RB and Walker RM,
Bristol, England, J. Wright and Sons, 251-258.


**Note:** Please refer to the table below to identify various symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>🔄</td>
<td>Sufficient for &lt;n&gt; tests</td>
</tr>
<tr>
<td>📚</td>
<td>Read instruction for use</td>
</tr>
<tr>
<td>📅</td>
<td>Use by Date</td>
</tr>
<tr>
<td>📟</td>
<td>Batch code</td>
</tr>
<tr>
<td>🔄</td>
<td>Catalog number</td>
</tr>
<tr>
<td>🔴</td>
<td>Caution</td>
</tr>
<tr>
<td>🏭</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>🇪🇺</td>
<td>Authorized representative of the European Community</td>
</tr>
<tr>
<td>🧪</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>℃</td>
<td>Temperature limit</td>
</tr>
<tr>
<td>🗑️</td>
<td>Do not reuse</td>
</tr>
<tr>
<td>🌐</td>
<td>This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices</td>
</tr>
</tbody>
</table>

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For technical assistance, please contact:

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