**i-CHROMATM FSH**

**[INTENDED USE]**

*i-CHROMATM FSH* along with *i-CHROMATM Reader* is a fluorescence immunooassay that measures follicle stimulating hormone (FSH) concentration in human serum/plasma.

**[INTRODUCTION]**

Follicle-stimulating hormone (FSH) is synthesized and secreted by gonadotrophs of the anterior pituitary gland. The alpha subunits of LH, FSH, TSH, and hCG are identical, and contain 92 amino acids. FSH has a beta subunit of 118 amino acids (FSHB), which confers its specific biologic action and is responsible for interaction with the FSH-receptor. FSH regulates the development, growth, pubertal maturation, and reproductive processes of the body, FSH and Luteinizing hormone (LH) act synergistically in reproduction.

The most common reason for high serum FSH concentration is in a female who is undergoing or has recently undergone menopause. High levels of FSH are also present in the blood of prepubertal patients in pubertal development. During the reproductive years, FSH is produced in response to gonadotropin-releasing hormone (GnRH) via a negative feedback loop. FSH is secreted in a pulsatile manner by the pituitary gland. FSH stimulates the formation of a group of follicles in the ovary, a process known as folliculation.

**[PRINCIPLE]**

*i-CHROMATM FSH* is based on immunoassay system using antigen-antibody interaction and fluorescence technology. If sample and a detection buffer is mixed completely and then loaded onto a sample well on a cartridge, the complex of antibody (anti-FSH)-antigen (FSH)-antibody (anti-FSH) -fluorescence is formed on the membrane of the cartridge. Thus, the more FSH is in human serum/plasma, the more complexes are accumulated on the membrane. *i-CHROMATM reader* scans the intensity of the fluorescence on the membrane, and then displays the FSH concentration on the LCD screen of the reader.

**[COMPOSITION OF REAGENTS]**

*i-CHROMATM FSH* consists of Cartridge, ID Chip and Detection buffer including a detection buffer.

- A cartridge contains a test strip in which murine antibody against human FSH and chicken IgY have been immobilized on the membrane.
- A cartridge is individually sealed with a desiccant in an aluminum pouch. 25 pouches of Cartridge are packed into a box with an ID chip that contains an equation.
- A detection buffer is dispensed in plastic tube. 25 tubes of detection buffer are packed into an aluminum pouch.
- A detection buffer contains fluorescence-labeled anti-FSH, fluorescence-labeled anti-chicken IgY, BSA, sucrose as a stabilizer, Tween 20, and sodium azide as a preservative in PBS.

**[SAMPLE COLLECTION AND PREPARATION]**

- For the serum sample, collect the blood in a tube without an anticoagulant and allow it to clot. Take the serum from the clot as soon as possible to avoid hemolysis.
- For the plasma sample, collect the blood in a tube treated with EDTA. Anticoaguulants other than EDTA have not been evaluated. If testing cannot be conducted within an hour after preparation of specimen, the specimen should be stored at -20°C.

**[STORAGE AND STABILITY]**

- *i-CHROMATM FSH* detection buffer tube is stable for up to 20 months if stored at 2 - 8°C.
- *i-CHROMATM FSH* cartridge is stable for up to 20 months (while in a sealed pouch) if stored at 4 - 30°C.
- If stored in a refrigerator, allow a minimum of 30 minutes for Cartridges and Detection buffers to reach room temperature.
- Do not remove a cartridge from a pouch until ready to use. The Cartridge should be used immediately once opened.
- After a cartridge pouch and a detection buffer tube are opened, *i-CHROMATM FSH* should be used within 30 minutes.

**[MATERIALS PROVIDED]**

- Cartridge 25 pouches
- ID Chip 1 each
- Insert 1 sheet
- Detection buffer* 25 each

* Detection buffers are delivered separately from cartridges in a Styrofoam box filled with ice packs.

**[MATERIALS REQUIRED BUT PROVIDED SEPARATELY]**

You can purchase the following items separately from *i-CHROMATM FSH*. Please contact our sales division to request more information.
- i-CHROMA™ Reader \[REF\] FR-203
- Thermal Printer
- i-CHROMA™ Universal Control \[REF\] CFPO-25

**PROCEDURE**

* Refer to i-CHROMA™ Reader Operation Manuals for the complete product instructions.

**Preparation**

1. Check the contents; 1 x ID chip, 25 x Cartridges, 25 x detection buffers. Keep i-CHROMA™ FSH at room temperature for at least 30 min before use. Place a cartridge on a clean, dust-free flat surface.
2. Check and make sure that a cartridge lot number matches the ID chip number provided.
3. Turn on power of i-CHROMA™ Reader.
4. Insert the ID Chip into i-CHROMA™ Reader.
5. Press “Select” Button on i-CHROMA™ Reader.

**Test procedure**

6. Draw 75 µL of serum/plasma or control with a transfer pipette and add it to the tube containing detection buffer.
7. Mix well the specimen with detection buffer by tapping or inverting the tube.
8. Take 75µL of the mixture using a transfer pipette
9. Apply the mixture onto the sample well of the cartridge
10. Leave the cartridge at room temperature for 15 min.
11. To start scanning, insert a cartridge onto the holder of i-CHROMA™ Reader and press “SELECT” button.
12. The instrument will automatically start scanning the cartridge immediately.
13. Read the results on the display screen of i-CHROMA™ Reader.

**INTERPRETATION OF RESULT**

- i-CHROMA™ Reader calculates FSH test results automatically and displays the concentration on the LCD in units of mIU/mL.
- The working ranges of i-CHROMA™ FSH are 3 ~ 100 mIU/mL.
- This test is meant only as a screening tool, if you get a positive result, visit your doctor and discuss the result. Your doctor may decide to run more tests.
- **Reference range**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Range (mIU/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mid-Cycle Surge</td>
<td>6.3-24.0</td>
</tr>
<tr>
<td>Follicular Phase</td>
<td>3.9-12.0</td>
</tr>
<tr>
<td>First Half</td>
<td>2.9-9.0</td>
</tr>
<tr>
<td>Second Half</td>
<td>1.5-7.0</td>
</tr>
<tr>
<td>Luteal Phase</td>
<td>17.0-95.0</td>
</tr>
<tr>
<td>Menopause</td>
<td>1.7-12.0</td>
</tr>
</tbody>
</table>

It is recommended that each laboratory establish its own reference range for the population of interest.

**QUALITY CONTROL**

- Control test should be performed as a part of good testing practice, to confirm the expected QC results, to confirm validity of the assay, and to assure accuracy of patient results.

- Control test should be performed at regular intervals, and before a new kit with patient specimens is used, controls should be tested to confirm the test procedure, and to verify tests produce the expected QC results. QC specimens should also be run whenever there is any question concerning validity of results obtained.
- Controls are not provided with i-CHROMA™ FSH. For more information about obtaining controls, contact Boditech Med Inc.’s Technical Services for assistance.

- **PROCEDURE CONTROL**: i-CHROMA™ FSH contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. A valid control indicates that the cartridge was inserted and read properly by i-CHROMA™ Reader. An invalid result from the internal control causes an error message on i-CHROMA™ Reader indicating that the test should be repeated.

**PERFORMANCE CHARACTERISTICS**

1. **Specificity (Interference)**: Bio-molecules such as glucose, bilirubin, hemoglobin, cholesterol, ascorbic acid and disease related makers such as hCG, LH, TSH were added to test samples with a much higher level than their physiological level in normal sample. There was neither significant interference with FSH measurement, nor was there any significant assay cross-reactivity with those bio-molecules tested.

2. **Precision (Inter & Intra assay)**: For intra-assay precision, one person tested three different lots of i-CHROMA™ FSH, ten times per concentration by controls. For inter-assay precision, three persons under the same conditions tested three different lots of test devices, 10 times per concentration wht the controls known.

<table>
<thead>
<tr>
<th>FSH (mIU/mL)</th>
<th>Intra-assay Mean</th>
<th>CV%</th>
<th>Inter-assay Mean</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.13</td>
<td>3.36</td>
<td>5.0</td>
<td>3.27</td>
<td>6.9</td>
</tr>
<tr>
<td>25.0</td>
<td>29.93</td>
<td>7.5</td>
<td>24.50</td>
<td>5.2</td>
</tr>
<tr>
<td>100.0</td>
<td>96.89</td>
<td>2.2</td>
<td>96.96</td>
<td>1.8</td>
</tr>
</tbody>
</table>

3. **Comparability (Correlation)**: The FSH concentrations of 136 clinical specimens were quantified independently with i-CHROMA™ FSH and a mini VIDAS FSH automatic analyzer. The test results were analyzed and their compatibilities were investigated with linear regression and correlation of coefficient (R). The correlation value of coefficient was 0.986 between two methods.

Note: Please refer to the table below to identify symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consult instructions for use</td>
<td></td>
</tr>
<tr>
<td>Use by</td>
<td></td>
</tr>
<tr>
<td>Batch code</td>
<td></td>
</tr>
<tr>
<td>Catalog number</td>
<td></td>
</tr>
<tr>
<td>Caution</td>
<td></td>
</tr>
<tr>
<td>Do not reuse</td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
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<tr>
<td>Sufficient for</td>
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<tr>
<td>Authorised representative of the european community</td>
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<tr>
<td>In vitro diagnostic medical device</td>
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<tr>
<td>Temperature limitation</td>
<td></td>
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<tr>
<td>This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices</td>
<td></td>
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</table>

For Technical Assistance call
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