**INTENDED USE**

*i-CHROMA™ Ferritin* along with *i-CHROMA™ Reader* is a fluorescence immunoassay that quantifies human ferritin in serum / plasma. The test is used as an aid to see body iron stores.

**INTRODUCTION**

Ferritin, a major iron storage protein, is essential to iron homeostasis and is involved in a wide range of physiologic and pathologic processes. Ferritin makes iron available for critical cellular processes while protecting lipids, DNA, and proteins from the potentially toxic effects of iron. In clinical medicine, ferritin is predominantly utilized as a marker of total body iron stores. In cases of iron deficiency and overload, serum ferritin serves a critical role in both diagnosis and management. It is clear that low ferritin values less than reference range are usually representative of body iron deficiency. Recent study suggests that ferritin provides a more sensitive, specific and reliable measurement for determining iron deficiency at an early stage. On other hand, patients with ferritin levels that are higher than the reference range may be indicative of conditions such as iron overload, infections, inflammations, collagen diseases, hepatic diseases, neoplastic disease and chronic renal failure.

**PRINCIPLE**

*i-CHROMA™ Ferritin* is based on fluorescence immunoassay technology. *i-CHROMA™ Ferritin* uses a sandwich immuno-detection method, such that by mixing the detection buffer with serum / plasma specimen in a test tube, the fluorescence-labeled detector anti-ferritin antibody in buffer binds to ferritin antigen in serum / plasma specimen. As the sample mixture is loaded onto the sample well of the Cartridge and migrates through the nitrocellulose matrix of test strip by the capillary action, the complexes of detector antibody and ferritin are captured by the anti-ferritin sandwich pair antibody that has been previously immobilized on the test strip. Thus, the more ferritin antigen in the serum / plasma specimen, the more complexes are accumulated on test strip. The signal intensity of fluorescence of the detector antibody reflects amount of ferritin captured and is processed from i-CHROMA™ Reader to show ferritin concentration in the serum / plasma specimen. The default result unit of *i-CHROMA™ Ferritin* is displayed in unit of ng/mL on i-CHROMA™ Reader. The working range and the detection limit of *i-CHROMA™ Ferritin* are 10 ~ 1,000 ng/mL and 4.51 ng/mL respectively.

* Reference Range: 30 ~ 350 ng/mL for male
  20 ~ 250 ng/mL for female.

▽ It is recommended that each laboratory establishes its own reference range from the population of interest.

**COMPOSITION OF REAGENTS**

*i-CHROMA™ Ferritin* consists of Cartridge, ID Chip, and Detection Buffer. Cartridge is individually sealed with a desiccant in aluminum pouch, and Detection Buffer is dispensed individually in a tube. A pouch containing pre-dispensed tubes is delivered separately from the Cartridge in a Styrofoam box filled with ice packs.

- Cartridge contains a test strip in which anti-ferritin antibody and keyhole limpet homocyanin(KLH) have been immobilized on the test and on the control and line of strip, respectively.
- Detection Buffer contains fluorescence-labeled anti-ferritin antibody, mouse-IgG, fluorescence-labeled anti-KLH antibody, BSA as a stabilizer, and sodium azide as a preservative in PBS.

**WARNINGS AND PRECAUTIONS**

- For In Vitro Diagnostic Use.
- Carefully follow the instructions and procedures described in this insert: CFPC-32
- Don’t use the Cartridge if its lot # does not match with that on the ID chip to be inserted into the instrument.
- *i-CHROMA™ Ferritin* is only operational in the *i-CHROMA™ Reader*. And tests should be performed by professionally trained personnel working in certified laboratories. The sample should be taken by qualified medical personnel.
- Neither inter-change materials from different product lots nor use beyond the expiration date. The use of medical device beyond the expiration date may affect the result.
- *i-CHROMA™ Ferritin* should remain in its original sealed pouch until ready to use. Do not use the Cartridge if the pouch is damaged or the seal is broken. Discard after single use.
- *i-CHROMA™ Ferritin* and Reader should be used away from the mechanical vibration and the excessive magnetic field. During normal usage, *i-CHROMA™ Ferritin* may introduce minute vibration, which should be regarded normal.
- Use separate clean pipette tips and sample vials for different specimens. The pipette tips and sample vials should be used for one specimen only. Discard after single use.
- Blood specimens, used Cartridges, pipette tips and sample vials are potentially infectious. Proper laboratory safety techniques, handling and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.

**STORAGE AND STABILITY**

- Store the detection buffer in a refrigerator at 2-8°C. The detection buffer is stable up to 20 months if stored in a refrigerator under the designated temperature.
- Once removed from refrigerator, allow the detection buffer for 30 minutes to warm it up to the room temperature before testing.
• Store i-CHROMA™ Ferritin at 4-30°C in its sealed pouch. i-CHROMA™ Ferritin is stable for 20 months (while in the sealed pouch) if stored at 4-30°C.

• If stored in a refrigerator, allow a minimum of 20 minutes for the Cartridge to warm up to the room temperature with the device still in the pouch.

• Do not remove the device from the pouch until ready to use. The Cartridge should be used immediately once opened.

• The storage and shipping of i-CHROMA™ Ferritin should be complied as indicated in manual. However, it is remotely possible that only part of i-CHROMA™ Ferritin is affected by stability problems.

**SAMPLE COLLECTION AND PREPARATION**

The test can be performed with the serum / plasma specimen.

• For the serum sample, collect the blood in a tube without anticoagulant and allow it to be clotted. Remove the human serum from the clot as soon as possible to avoid hemolysis. For the plasma sample, collect the blood in a tube treated with EDTA. Anticoagulants other than EDTA for the plasma specimen have not been evaluated. If testing cannot be conducted within an hour after preparation of the specimen, the serum/plasma should be stored at -20°C until tested. In case of using whole blood, apply the sample as soon as possible after specimen was taken.

• The specimen must be at room temperature and be homogeneous before testing. Frozen specimens must be completely thawed, thoroughly mixed, and brought to the room temperature prior to testing. If specimens are to be shipped, they should be packed in compliance with regulations.

• It is recommended to not to use excessively hemolyzed specimens whenever possible. If a specimen appears to be excessively hemolyzed, another specimen should be obtained and tested.

**MATERIALS PROVIDED**

Boditech Med Incorporated i-CHROMA™ Ferritin

Catalog No. CFPC-32

Box contains:

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cartridges</td>
<td>25 pouches</td>
</tr>
<tr>
<td>Detection Buffer</td>
<td>25 tubes</td>
</tr>
<tr>
<td>ID Chip</td>
<td>1 each</td>
</tr>
<tr>
<td>Insert</td>
<td>1 each</td>
</tr>
</tbody>
</table>

**MATERIALS REQUIRED BUT NOT PROVIDED**

i-CHROMA™ Reader  REF  FR203

Thermal Printer

Transfer pipette

**PROCEDURE**

• Image of the Cartridge

Note: Best test result comes out when the testing environment is at around 25°C temperature, 40% relative humidity.

1. Set a Cartridge on a dust-free clean place.

2. Check/insert ID Chip onto the instrument. Make sure that the Cartridge lot # matches with ID Chip lot #.

3. Take out one tube of Detection Buffer from refrigerator and leave it at room temperature for 20 minutes or longer.

4. Draw 30 μL of serum, plasma or Control with a transfer pipette and add it to the tube containing Detection Buffer.

5. Mix well the specimen with Detection Buffer by tapping or inverting the tube.

6. Take 75 μL of sample mixture with a pipette and load it onto the well of disposable Cartridge.

7. Leave the Cartridge at room temperature for 10 minutes before inserting the device into the holder.

8. To start scanning, insert Cartridge onto the holder of i-CHROMA™ Reader and press “SELECT” button. Make sure to push the device all the way in. The instrument will automatically start to scan the Cartridge immediately.

9. Read the results on the display screen of i-CHROMA™ Reader.

➢ Refer to i-CHROMA™ Reader Operation Manual for the complete instructions on the use of the reader.

**RESULT**

i-CHROMA™ Reader calculates ferritin test results automatically and displays the concentration of ferritin in the blood sample on the LCD in units ng/mL.

**Quality Control**

Quality control

• A quality control test using commercially available controls should be performed as a part of good testing practice, to confirm the expected QC results, to confirm the validity of the assay, and to assure the accuracy of patient results.

• A quality control test should be performed at regular intervals, and before using a new kit with patient specimens, controls should be tested to confirm the test procedure, and to verify the tests produce the expected QC results. QC specimens should also be run whenever there is any question concerning the validity of results obtained. Upon confirmation of the expected results, the Cartridge is ready to use with patient specimens.
Control standards are not provided with this test kit. For information about obtaining the controls, contact the technical assistance section at Boditech Med Inc.

Procedure control

- Each i-CHROMA™ Ferritin contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This 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.

**LIMITATIONS OF THE PROCEDURE**

- The results of i-CHROMA™ Ferritin should be evaluated with all clinical and laboratory data available. If ferritin Test results do not agree with the clinical evaluation, additional tests should be performed.

- The false positive results include cross-reactions with some components of serum / plasma from individual to antibodies, and non-specific adhesion of some components in serum / plasma that have similar epitopes to capture and detector antibodies. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of ferritin antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.

- Plasma using anticoagulants (e.g. heparin or citrate) other than EDTA has not been evaluated in i-CHROMA™ Ferritin and thus should not be used.

- Since the flow characteristic on nitrocellulose membrane and related test result are influenced by temperature and relative humidity, controlled testing environment is required for the best test results. To obtain best test result, check ‘Note’ in procedure section.

- Other factors may interfere with i-CHROMA™ Ferritin and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

**PERFORMANCE CHARACTERISTICS**

1. **Analytical Sensitivity**: i-CHROMA™ Ferritin was evaluated on the limit of detection. Three different lots of Cartridges were evaluated with 10 times of each lot. Minimum detection was calculated by average of specimens (0 at value) + 3SD. The limit of i-CHROMA™ Ferritin was determined to be 4.51 ng/mL.

2. **Specificity**: Some bio-molecules such as heterophilic antibodies consist of both natural antibodies and autoimmune antibodies that exhibit weak binding and polyspecificity, bilirubin, hemoglobin, triglycerides, and cholesterol may interfere with the measurement.

3. **Imprecision**: For the intra-assay imprecision, 20 replicates were tested at each control sample. For the inter-assay imprecision, tests were conducted on 10 sequential days, with 10 runs per day and with 10 replicates at each ferritin concentration.

<table>
<thead>
<tr>
<th>Ferritin (ng/mL)</th>
<th>Intra-assay</th>
<th>Inter-assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>S.D</td>
<td>CV(%)</td>
</tr>
<tr>
<td>15</td>
<td>14.89</td>
<td>0.97</td>
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<tr>
<td>150</td>
<td>149.11</td>
<td>4.08</td>
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<tr>
<td>450</td>
<td>451.32</td>
<td>7.95</td>
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</tbody>
</table>

4. **Linearity**: The high concentration was diluted with the low concentration to the following final percentages; 100%, 50%, 25%, 12.5%, 6.25%, 3.125%, 1.56%, 0.78%. Sample was assayed in triplicate in one analytical run at each ferritin level. The coefficient of linear regression was $R^2=0.986$. Linearity of i-CHROMA™ Ferritin was 7.8 ± 1.00ng/mL.

5. **Comparability**: Ferritin concentrations of 79 clinical specimens were quantified independently with i-CHROMA™ Ferritin and bioMérieux VIDAS automatic analyzer. The test results were compared and their compatibilities were investigated with linear regression and correlation of coefficient ($R$). i-CHROMA™ Ferritin was comparable well to other method ($R^2=0.979$).

**REFERENCES**


**Boditech Med Inc.**’s express and implied warranties (including implied warranties of merchantability and fitness) are conditional upon observance of Boditech Med Inc.’s published directions with respect to the use of Boditech Med Inc.’s products.

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