



ichroma™ Ferritin

INTENDED USE

ichroma™ Ferritin is a fluorescence Immunoassay (FIA) for the quantitative determination of Ferritin in human serum / plasma. It is useful as an aid in quantifies human ferritin.

For *in vitro* diagnostic use only.

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

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

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

COMPONENTS

ichroma™ Ferritin consists of 'Cartridges', 'Detection Buffer Tubes' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has anti human ferritin at the test line, while keyhole limpet hemocyanin (KLH) at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip.
- The detection buffer contains anti human ferritin-fluorescence conjugate, anti KLH-fluorescence conjugate, sucrose, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detection buffer is pre-dispensed in a tube. 25 detection buffer tubes are packaged in a box and further packed in a styrofoam box with ice-pack for the shipment.

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 (test 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 test cartridge.
- The test cartridge should remain sealed in its original pouch before use. Do not use the test 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 test cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes.
- **ichroma™ Ferritin** 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 test 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™ Ferritin** will provide accurate and reliable results subject to the following conditions.
 - Use **ichroma™ Ferritin** should be used only in conjunction with instrument for ichroma™ tests.
 - Any anticoagulants other than EDTA should be avoided.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4 - 30°C.
- The detection buffer pre-dispensed 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.

LIMITATION OF THE TEST SYSTEM

- 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.

MATERIALS SUPPLIED

REF CFPC-32

Components of **ichroma™ Ferritin**

- Cartridge Box:
 - Cartridges 25
 - ID Chip 1
 - Instruction For Use 1
- Box containing Detection Buffer tubes
 - Detection Buffer Tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ Ferritin**.

Please contact our sales division for more information.

- Instrument for **ichroma™** tests
 - **ichroma™ Reader** REF FR203
 - **ichroma™ D** REF 13303
 - **ichroma™ Printer** REF FPRR07
- **ichroma™ Universal Control I** REF CFPO-32

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ Ferritin** 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. If longer storage is required, e.g. if the test could not be performed within 24 hours, serum or plasma should be immediately frozen below -20°C. The freezing storage of sample up to 3 months does not affect the quality of results.
- Once the sample was frozen, it should be used one time only for test, because repeated freezing and thawing can result in the change test values.

TEST SETUP

- Check the contents of **ichroma™ Ferritin**: Sealed Cartridge, Detection Buffer Tubes and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip, diluent 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.)

TEST PROCEDURE

- 1) Transfer 30 µL of sample (human serum / plasma / control) using a transfer pipette to a tube containing the detection buffer.
- 2) Close the lid of the detection buffer tube and mix the sample thoroughly by shaking it about 10 times.
- 3) Pipette out 75 µL of the sample mixture and load it into a sample well in the test cartridge.
- 4) Leave the sample-loaded test cartridge at room temperature for 10 minutes.
- 5) 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.
- 6) Press 'Select' button on the instrument for **ichroma™** tests to start the scanning process.
- 7) Instrument for **ichroma™** tests will start scanning the sample-loaded cartridge immediately.
- 8) Read the test result on the display screen of the instrument for **ichroma™** tests.

INTERPRETATION OF TEST RESULT

- Instrument for **ichroma™** tests calculates the test result automatically and displays ferritin concentration of the test sample in terms of ng/mL.
- The cut-off (reference range)
 - Women : 20~250 ng/mL
 - Men : 30~350 ng/mL
- Working range : 10~1,000 ng/mL.

QUALITY CONTROL

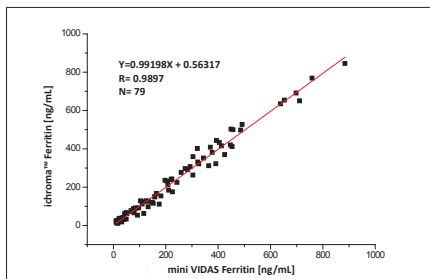
- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are not provided with **ichroma™ Ferritin**. For more information regarding obtaining the control materials, contact **Boditech Med Inc.'s Sales Division for assistance**. (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Analytical Sensitivity:** **ichroma™ 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 **ichroma™ Ferritin** was determined to be 4.51 ng/mL.
- **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.
- **Precision:** The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard twenty times each with three different lots of **ichroma™ Ferritin**. The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing ten times each different concentration.

Ferritin (ng/mL)	Intra-assay			Inter-assay		
	Mean	S.D	CV(%)	Mean	S.D	CV(%)
15	14.89	0.97	6.54	15.16	0.94	6.22
150	149.11	4.08	2.73	149.73	1.80	1.20
450	451.32	7.95	17.6	451.53	7.11	1.58












- 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 **ichroma™ Ferritin** was $7.8 \sim 1,000\text{ng/mL}$.
- Comparability:** Ferritin concentrations of 79 clinical samples were quantified independently with **ichroma™ Ferritin** and mini VIDAS (BioMérieux Inc. France) 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 $Y=0.99198X + 0.56317$ and $R = 0.9897$ respectively.



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

	Read instructions for use
	Use by
	Batch code
	Catalog number
	Caution
	Manufacturer
	Authorized representative of the European Community
	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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