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 for quantifying 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 antibodies in buffer bind to antigen in the sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antibodies on test strip.

More antigens in the sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by Instrument for ichroma™ tests to show ferritin concentration in sample.

COMPONENTS

ichroma™ Ferritin consists of 'cartridges', 'detector tubes', 'detector diluent', 'ID chip' and 'instruction for use'.

- The cartridge contains the membrane called a test strip which has anti human Ferritin at the test line, and streptavidin at the control line. All cartridges are individually sealed in an aluminum foil pouch containing a desiccant in a box.
- The detector tube has a granule containing anti human Ferritin-fluorescence conjugate, biotin-BSA-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer in phosphate buffered saline (PBS). All detector tubes are packed in a box.
- The detector diluent contains sodium azide as a preservative in phosphate buffered saline (PBS), and it is pre-dispensed in a vial. The detector diluent is packed in a box.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow 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, detector, detector diluent and ID chip) 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 incorrect test result(s).
- Do not reuse cartridges or detector tubes. A cartridge should be used for testing one sample only. A detector tube should be used for processing of one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use the cartridge, if pouch is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- Allow cartridge, detector tube, detector diluent and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- Used cartridges, detector tubes, detector diluent and pipette tips 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 below conditions.
  - **ichroma™ Ferritin** should be used only in conjunction with Instrument for ichroma™ tests.
  - Have to use recommended anticoagulant sample.

recommended anticoagulant
EDTA, Sodium citrate, Heparin

STORAGE AND STABILITY

Component	Storage condition		
	Storage Temperature	Shelf life	Note
Cartridge	4 - 30 °C.	20 months	Disposable
Detector	4 - 30 °C.	20 months	Disposable
Detector Diluent	4 - 30 °C.	20 months	Unopened
	4 - 30 °C.	20 months	Opened

- 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(s) due to the non-responsiveness of the antigen to the antibodies which is most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may also cause the false negative result 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:
  - Cartridge 25
  - Detector 25
  - Detector Diluent 1
  - ID Chip 1
  - Instruction for Use 1

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™ II** REF FPRR021
- **Printer** REF FPRR007
- **Boditech Ferritin Control** REF CFPO-99

SAMPLE COLLECTION AND PROCESSING

The sample type 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 month at 2-8 °C prior to being tested. If testing will be delayed more than a month, samples should be frozen at -20 °C.
- Samples stored frozen at -20 °C for 3 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.

TEST SETUP

- Check the contents of **ichroma™ Ferritin**: Sealed Cartridges, Detector tubes, Detector diluen, an ID Chip and an Instruction for use.
- Ensure that the lot number of the cartridge matches that of the Detector tube, the Diluent as well as an ID chip.
- If the sealed cartridge, the detector tube and the detector diluent have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
- Turn on the Instrument for ichroma™ tests.
  (Please refer to the 'Instrument for ichroma™ tests Operation Manual' for complete information and operating instructions.)

CAUTION

- To minimize erroneous test results, we suggest that the ambient temperature of the cartridge should be 25 °C during the reaction time after loading sample mixture to the cartridge.
- To maintain the ambient temperature to 25 °C, you can use various devices such as an i-Chamber or an incubator and so on.

TEST PROCEDURE

1) Transfer 150 µL of detector diluent using a pipette to a detector tube containing a granule. When the granule form is completely dissolved in the tube, it becomes detection buffer. (The detection buffer must be used immediately within 3 minutes).
2) Transfer sample 30 µL (human serum / plasma / control) using a pipette to a detector tube.
3) Close the lid of the detector tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately within 3 minutes.)
4) Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
5) Leave the sample-loaded cartridge into the slot of the i-Chamber or an incubator (25°C) for 10 minutes.
6) 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 is marked on the cartridge especially for this purpose.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate test result.*
7) Press 'Select' or Tab 'START' button on the Instrument for ichroma™ tests to start the scanning process.
8) The instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
9) 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 value)
  - 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**

Limit of Blank (LoB)	1.56 ng/mL
Limit of Detection (LoD)	3.46 ng/mL
Limit of Quantitation (LoQ)	10.00 ng/mL

- **Analytical Specificity**
  - Cross reactivity
    Biomolecules such as below the ones in the table were added to the test sample(s) at concentrations much higher than their normal physiological levels in the blood. **ichroma™ Ferritin** test results did not show any significant cross-reactivity with these biomolecules.

Cross reactants	Concentration
Human Transferrin	100 mg/dL
Ferric Chloride	100 mg/dL
Human Serum Albumin	10 g/dL

  - Interference
    Interference materials such as below the ones in the table were added to the test sample(s) the same as the below concentrations. **ichroma™ Ferritin** test results did not show any significant interference with these materials.

Interference materials	Concentration
Bilirubin(conjugated)	20 mg/dL
Bilirubin(free)	20 mg/dL
Triglyceride	500 mg/dL
Human Hemoglobin	500 mg/dL

- **Precision**
  3 Lots of **ichroma™ Ferritin** were tested for 21days (7days per 1 Lot at 1 site by one operator). Each standard material was tested 2 times per day. For each test, each material was duplicated.
  - Repeatability (within-run precision)
    Repeatability of **ichroma™ Ferritin** was evaluated with results of 1 Lot.
  - Total precision (within-laboratory precision)
    Total precision (within-run, between-run, between-day) of **ichroma™ Ferritin** was evaluated with results of 1 Lot.
  - Lot to lot precision
    Lot to lot precision of **ichroma™ Ferritin** was evaluated with results of 3 Lots.

Ferritin [ng/mL]	Repeatability		Total precision (within-laboratory precision)		lot to lot precision	
	AVG	CV(%)	AVG	CV(%)	AVG	CV(%)
12.5	12.52	5.87	12.4	7.10	12.35	6.52
100	99.59	5.94	100.6	5.55	99.91	5.71
500	501.99	5.79	501.9	5.71	503.40	5.73

  - Between Site
    Three persons tested **ichroma™ Ferritin** at three different sites, ten times at each concentration of standard materials.
  - Between person
    Three persons tested **ichroma™ Ferritin**, ten times at each concentration of standard materials

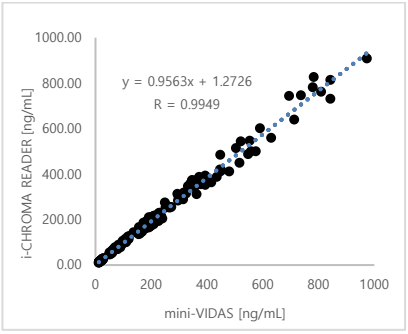
Ferritin [ng/mL]	Between site		Between person	
	AVG	CV(%)	AVG	CV(%)
12.5	12.48	0.96	12.41	1.28
100	100.36	1.66	100.64	1.78
500	499.58	0.68	510.42	1.18

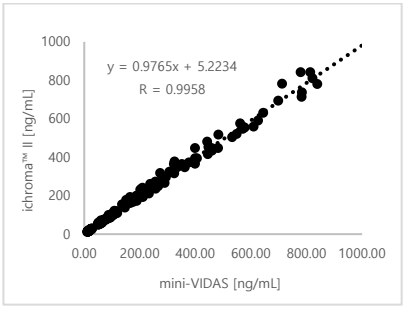
- **Accuracy**
  The accuracy was confirmed by testing with 3 different lots of **ichroma™ Ferritin.** The tests are repeated 10 times in each different concentration.

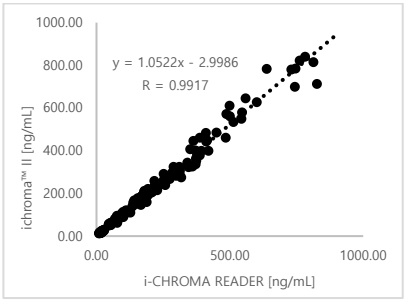
Expected value [ng/mL]	Lot 1	Lot 2	Lot 3	AVG	Recovery (%)
12.5	12.30	12.68	12.67	12.55	100%
25	24.40	25.86	24.63	24.96	101%
100	99.49	100.83	102.84	101.06	102%
500	496.55	503.71	512.12	504.12	102%
1000	1040.19	1031.99	1007.28	1026.49	99%

- **Comparability**
  Ferritin concentrations of 160 serum samples were quantified independently with **ichroma™ Ferritin** and VIDAS Ferrtin (mini-VIDAS) 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 tests were as follows.

X-axis	Y-axis	linear regression	R
Mini-VIDAS	i-CHROMA READER	y = 0.9563x + 1.2726	0.9949
	ichroma™ II	y = 0.9765x + 5.2234	0.9958







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

	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices