ichroma™ Ferritin Plus

INTENDED USE

ichroma™ Ferritin Plus is a fluorescence Immunoassay (FIA) for the quantitative determination of Ferritin in human whole blood/ 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 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 Ferritin concentration in sample.

COMPONENTS

ichroma™ Ferritin Plus consists of 'Cartridges', 'Detectors, Diluent' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has anti human ferritin at the test line, while Chicken IgY 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 detector contains anti human ferritin-fluorescence conjugate, anti chicken IgY-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detector is pre-dispensed in a tube. 25 detectors are packaged in an aluminum foil pouch.
- The diluent contains sodium azide in sodium phosphate buffer as a preservative. The diluent is dispensed in a vial.
- 25 Detectors sealed in an aluminum foil pouch and diluent are packaged in a buffer 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 (Cartridge, ID chip and detector, diluent) 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™ Ferritin Plus** 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 detector, 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™ Ferritin Plus** will provide accurate and reliable results subject to the following conditions.
  - Use **ichroma™ Ferritin Plus** 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 detector 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-67

Components of **ichroma™ Ferritin Plus**

- Cartridge Box:
  - Cartridges 25

- ID Chip 1
- Instruction For Use 1

■ Buffer Box

✓ For ichorma™ II

- Detectors (Capped with plastic lid) 25
- Diluent 1

✓ For AFIAS-50

- Detectors (Sealed with aluminum foil) 25
- Diluent 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ Ferritin Plus**. Please contact our sales division for more information.

■ Instrument for ichroma™ tests
- **ichroma™ II** REF FPRR021
- **AFIAS-50** REF FPRR022

■ **Boditech Ferritin Control** REF CFPO-99

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ Ferritin Plus** is human whole blood/ 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 Plus**: Sealed Cartridge, Detector, Diluent and ID Chip.

■ Ensure that the lot number of the cartridge matches that of the ID chip as well as the detector & diluent.

■ 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/Start' button of the instrument for ichroma™ tests.
(Please refer to the 'Instrument for ichroma™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

▶ **ichroma™ II**

1) Open the diluent and transfer 150 µL diluent to the detector tube by using pipette
2) Transfer 10 µL of sample (human serum/plasma/whole blood/control) using a transfer pipette to a detector tube.
3) Close the lid of the detector tube and mix the sample thoroughly by shaking it about 20 times. (The sample mixture must be used immediately.)
4) Pipette out 75 µL of the sample mixture and load it into a sample well in the cartridge.
5) Insert the sample-loaded test cartridge at room temperature for 12 minutes.
⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.*
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 has been marked on the cartridge especially for this purpose.
7) Press 'Select/Start' button of the instrument for ichroma™ tests to start the scanning process.
8) 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.

▶ **AFIAS-50**

1) Insert the tip array in the tip station.
2) Insert the detector array in the Reagent station and cover the reagent station.
3) Open the diluent and insert the diluent in the diluent station.
4) Open the cover of the magazine station and pull and lift the cartridge magazine.
5) Insert the cartridges in the cartridge magazine one by one.
6) Insert the cartridge loaded cartridge magazine into the magazine station and close the cover of the magazine station.
7) Insert the sample tube into the blood collection tube rack and load the blood collection tube rack into the sampling station (loading part).
8) Tap the button which is provided in the upper side of the No. of test cartridge region to select ID chip what you want to use.
9) When the selected cartridge slot is activated, set the number of test cartridge by tapping.
10) Tap the button which is provided in the upper side of the No. of reagent region to select ID chip what you want to use.
11) When the selected slot is activated, set the number of Detector by tapping.
12) Set the number of pipette tips by tapping.
13) Tap the 'START' button on the left upper of the main screen to start test.

(Please refer to the AFIAS-50 operation manual for complete information and operation instructions.)

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: 1.5-1,000 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 Plus**. 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**

Sample Type	Whole Blood	Serum/Plasma
Limit of Blank (LOB)	0.2 ng/mL	0.3 ng/mL
Limit of Detection (LOD)	0.7 ng/mL	0.6 ng/mL
Limit of Quantitation (LOQ)	1.5 ng/mL	1.5 ng/mL

- **Analytical specificity**

  - Cross-reactivity

    There was no significant cross-reactivity with Human serum albumin, AFP and Ferric Chloride.

Cross-reactants	Cross-reactivity (%)
Human serum albumin (10g/dL)	0.0003
AFP (1000ng/ml)	0.0002
Ferric Chloride (100mg/dL)	0.0002

  - Interference

    There was no significant interference with D-glucose, L-ascorbic acid, Bilirubin, hemoglobin, cholesterol and Triglyceride.

Interference material	Interference(%)
D-glucose (60mM/L)	<2
L-Ascorbic acid (0.2mM/L)	<3
Bilirubin (0.4mM/L)	<2
Hemoglobin (2g/L)	<3
Cholesterol (13mM/L)	<4
Triglyceride (10mg/mL)	<4.3

- **Precision**

  - Between Lot
    : One person tested three different lots of **ichroma™ Ferritin Plus,** twenty times at each concentration of the control standard.
  - Between person
    : Three different persons tested **ichroma™ Ferritin Plus,** three times at each concentration of the control standard.
  - Between Lot
    : One person tested **ichroma™ Ferritin Plus** during five days, three times at each concentration of the control standard.
  - Between Lot
    : One person tested **ichroma™ Ferritin Plus** at three different sites, three times at each concentration of the control standard.

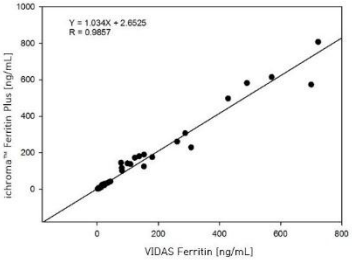
Whole blood type								
Conc. (ng/mL)	between Lot		between person		between day		between site	
	mean	CV (%)	mean	CV (%)	mean	CV (%)	mean	CV (%)
15	14.97	2.78	14.92	3.43	15.04	5.29	14.77	3.5
150	146.12	3.86	150.7	5.24	147.72	4.57	147.71	4.01
450	452.6	3.86	440.76	4.58	447.51	5.24	456.11	4.34
Serum/Plasma type								
Conc. (ng/mL)	between Lot		between person		between day		between site	
	mean	CV (%)	mean	CV (%)	mean	CV (%)	mean	CV (%)
15	14.94	4.01	15.21	3.98	15.06	4.73	15.05	4.38
150	145.59	3.94	148.37	4.98	145.86	5.47	146.88	5.6
450	449.24	5.11	454.68	3.92	457.75	3.66	448.11	3.87

- **Accuracy**

  The accuracy was confirmed by 3 different lots testing ten times each different concentration.

Whole blood type						
Ferritin [ng/mL]	Lot1		Lot2		Lot3	
	AVG	Recovery (%)	AVG	Recovery (%)	AVG	Recovery (%)
900	882.37	98	873.01	97	867.15	96
450	449.36	100	451.24	100	438.43	97
225	219.15	97	219.07	97	228.08	101
22.5	22.61	100	22.44	100	23.19	103
2.5	2.53	101	2.6	104	2.59	104
Serum/Plasma type						
Ferritin [ng/mL]	Lot1		Lot2		Lot3	
	AVG	Recovery (%)	AVG	Recovery (%)	AVG	Recovery (%)
900	902.05	100	880.87	98	883.14	98
450	442.54	98	434.75	97	447.29	99
225	218.06	97	224.64	100	219.98	98
22.5	23.27	103	22.38	99	23	102
2.5	2.56	103	2.54	101	2.61	104

- **Comparability:** Ferritin concentrations of 100 serum samples were quantified independently with **ichroma™ Ferritin Plus** and VIDAS System 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 = 1.034X + 2.6525 and R = 0.9857 respectively.



REFERENCES

1. Bates HM. How to Detect Iron Deficiency Before Anemia Develops. *Laboratory Pathfinder* Jan 1980:17-22.
2. Mary Ann Knovich, Jonathan A. Storey, Lan G. Coffman, and Suzy V. Torti, Frank M. Torti. Ferritin for the clinician. *Blood Rev*. 2009 May ; 23(3): 95–104.
3. Piperno A. Classification and diagnosis of iron overload. *Haematologica*. 1998;83:447–55.
4. Yutaka Kohgo, Katsuya Ikuta, Takaaki Ohtake, Yoshihiro Torimoto, Junji Kato. Body iron metabolism and pathophysiology of iron overload. *Int J Hematol* (2008) 88:7–15
5. Lipschitz DA, Cook JD, Finch CA. A Clinical Evaluation of Serum Ferritin as an Index of Iron Stores. *N Engl J Med* 1974;290:1213-6.
6. Forman DT, Parker SL. The Measurement and Interpretation of Serum Ferritin. *Ann Clin Lab Sci* 1980;10:345-50.
7. Cook JD, Skikne BS, Lynch SR. Serum Ferritin in the Evaluation of Anemia. In: Albertin A, editor. Radioimmunoassay of Hormones, Proteins and Enzymes. Amsterdam: Excerpta Medica, 1980:239-48.

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

For technical assistance; please contact:
Boditech Med Inc.'s Technical Services
Tel: +82 33 243-1400
E-mail: sales@boditech.co.kr

Boditech Med Incorporated
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 24398
Republic of Korea
Tel: +(82) -33-243-1400
Fax: +(82) -33-243-9373
www.boditech.co.kr

EC REP **Obelis s.a**
Bd. Général Wahis 53,
1030 Brussels, BELGIUM
Tel: +(32) -2-732-59-54
Fax: +(32) -2-732-60-03
E-Mail: mail@obelis.net

CE