



AFIAS

Ferritin

INTENDED USE

AFIAS 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 the instrument for AFIAS tests to show ferritin concentration in sample.

COMPONENTS

AFIAS Ferritin consists of 'Cartridge', 'Pipette tip', 'ID chip' and 'Instruction for use'.

- Each cartridge packaged in an aluminum pouch has two components, a detector part and cartridge part.
- Cartridge part contains a test strip, the membrane which has anti human ferritin at the test line, while keyhole limpet hemocyanin (KLH) at the control line.
- Detector part 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.

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 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 misleading of test result(s).
- The cartridge should remain sealed in its aluminum pouch until use. Do not use the cartridge if that is damaged or already opened.
- 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 and sample to be at room temperature for approximately 30 minutes.
- AFIAS Ferritin** as well as the instrument for AFIAS tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that the instrument for AFIAS tests may produce minor vibration.
- Used pipette tips, and cartridges should be handled carefully and disposed 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.
- AFIAS Ferritin** will provide accurate and reliable results subject to the following conditions.
 - Use **AFIAS Ferritin** should be used only in conjunction with the instrument for AFIAS tests.
 - Any anticoagulants other than EDTA should be avoided.

LIMITATIONS 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.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum pouch) if stored at 2-8 °C.

MATERIALS SUPPLIED

REF SMFP-23

Components of **AFIAS Ferritin**

- Cartridge Box Contains
 - Cartridge 24
 - Pipette Tip (Zipper bag) 24
 - ID Chip 1
 - Instruction For Use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

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

- AFIAS-1** **REF** FPRR019
- AFIAS-6** **REF** FPRR020
- Boditech Ferritin Control** **REF** CFPO-99
- Boditech Ferritin Calibrator** **REF** CFPO-111

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS 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.
- Serum or plasma sample stored frozen at -20 °C for 3 months showed no performance difference.
- Once the sample was frozen, it should be thawed one time and only for test, because repeated freezing and thawing can result in the changed test values.

TEST SETUP

- Check the components of the **AFIAS Ferritin** as described below. : Cartridge, pipette tip, ID chip and instruction for use
- Keep the sealed cartridge (if stored in refrigerator) 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 AFIAS tests.
- Empty the tip box.
- Insert the ID chip into the "ID chip port".
- Please refer to the instrument for AFIAS tests 'Operation Manual' for complete information and operating instructions.

TEST PROCEDURE

- 1) Take 100 µL of sample with a pipette and dispense it into the sample well on the cartridge.
- 2) Insert the cartridge into the cartridge holder
- 3) Insert a tip into the tip hole of the cartridge.
- 4) Tap the 'START' icon on the screen.
- 5) The test result will be displayed on the screen after 10 minutes.

※ Note: Refer to the instrument for AFIAS tests Operation Manual to select sample type.

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculate the test result automatically and displays ferritin concentration of the test sample in terms of ng/mL.
- Reference range
 - Women 20-250 ng/mL
 - Men 30-350 ng/mL
- The working range of the **AFIAS Ferritin** is 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 **AFIAS 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**
AFIAS 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 **AFIAS 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 **AFIAS Ferritin**. The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing ten times each different concentration.

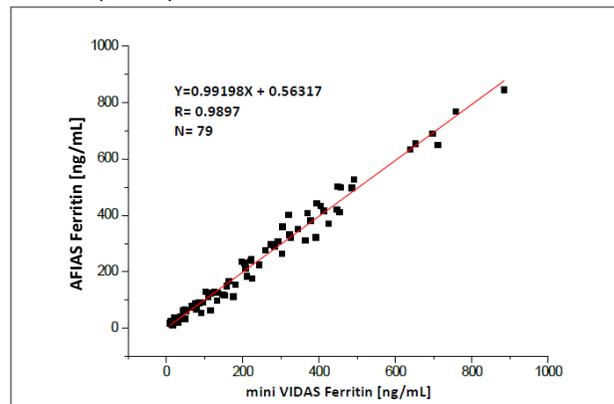
Ferritin (ng/mL)	Intra-assay			Inter-assay		
	Mean	SD	CV (%)	Mean	SD	CV (%)
15	14.89	0.97	6.54	15.16	0.94	6.22
150	149.11	4.08	2.73	149.73	1.80	1.20
450	451.32	7.95	17.6	451.53	7.11	1.58

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 **AFIAS Ferritin** was 7.8-1,000 ng/mL.

Comparability

Ferritin concentrations of 79 clinical samples were quantified independently with **AFIAS 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.



REFERENCES

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3. Piperno A. Classification and diagnosis of iron overload. *Haematologica.* 1998;83:447-55.
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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
	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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