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 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 antigens in the sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the other immobilized antibodies on a test strip.

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

COMPONENTS

AFIAS Ferritin consists of 'cartridges'.

- Each sealed aluminum pouch contains two cartridges.
- Each cartridge packaged in an aluminum pouch has three components including a cartridge part, a detector part and a diluent part.
- The cartridge part contains the membrane called a test strip which has anti-Ferritin at the test line, and streptavidin at the control line.
- The detector part has a granule containing anti-ferritin-fluorescence conjugate, Biotin-BSA-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer in phosphate buffered saline (PBS).
- The diluent part contains sodium azide as a preservative in phosphate buffered saline (PBS).

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow instructions and procedures described in this 'Instructions 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 incorrect test result(s).
- Do not reuse cartridges. A cartridge should be used for testing one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use a cartridge, if the 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.
- If test components and/or sample are stored in refrigerator, then allow cartridge and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for AFIAS tests may generate slight vibration during use.
- Used cartridges and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- The cartridge contains sodium azide (NaN_3), and it may cause certain health issues like convulsions, low blood pressure, low heart rate, loss of consciousness, lung injury and respiratory failure. Avoid contact with skin, eyes, and clothing. In case of contact, rinse immediately with running water.
- No Biotin interference was observed in **AFIAS Ferritin** when biotin concentration in the sample was below 20 ng/mL. If a patient has been taking biotin at dosage of more than 0.03 mg a day, it is recommended to test again 24 hours after discontinuation of biotin intake.
- **AFIAS Ferritin** will provide accurate and reliable results subject to the below conditions.
  - **AFIAS Ferritin** should be used only in conjunction with the instrument for AFIAS tests.
  - Have to use recommended anticoagulant.

Recommended anticoagulant
K_2 EDTA, Sodium citrate, Sodium heparin

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(s) due to the non-responsiveness of the antigens to the antibodies which is the 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 antigens with time and/or temperature may also cause false negative result as it makes the antigens 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 in conjunction with clinical symptoms and other relevant test results.

STORAGE AND STABILITY

Storage condition			
Component	Storage Temperature	Shelf life	Note
Cartridge	2 - 30 °C	20 months	Disposable
		1 month	Resealed

- Return an unused cartridge to the spare cartridge zipper bag containing the desiccant pack. Reseal along entire edge of zip-seal.

MATERIALS SUPPLIED

REF SMFP-23

Components of **AFIAS Ferritin**

- Cartridge box:
  - Cartridge 24
  - Pipette tip (zipper bag) 24
  - Spare cartridge zipper bag 1
  - ID chip 1
  - Instructions for use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately with **AFIAS Ferritin**.

Please contact our sales division for more information.

- **Instrument for AFIAS tests**
  - **AFIAS-1** REF FPRR019
  - **AFIAS-3** REF FPRR040
  - **AFIAS-6** REF FPRR020
  - **AFIAS-10** REF FPRR028
- **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 when collected sample is stored at room temperature.
- The samples (serum, plasma) should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- The samples (serum, plasma) may be stored for a month at 2-8 °C prior to being tested. If testing will be delayed more than a month, samples (serum, plasma) should be frozen at -20 °C.
- The samples (serum, plasma) stored frozen at -20 °C for 3 months showed no performance difference.
- As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples

TEST SETUP

- Check the components of the **AFIAS Ferritin** as described below. : Cartridges, pipette tips, an ID chip, a spare cartridge zipper bag and an instructions for use
- Ensure that the lot number of the cartridge matches that of the ID chip.
- If the sealed cartridge has 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 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

▶ AFIAS-1, AFIAS-3, AFIAS-6

General mode

1) Insert a cartridge into the cartridge holder.
2) Insert a tip into the tip hole of the cartridge.
3) Select the 'General mode' in the instrument for AFIAS tests.
4) Take 100 µL of sample (serum/plasma/control) using a pipette and dispense it into the sample well of the cartridge.
5) Tap the 'Start' button on the screen.
6) The test result will be displayed on the screen after 10 minutes.

▶ AFIAS-10

Normal mode

1) Insert a cartridge into the cartridge holder.
2) Insert a tip into the tip hole of the cartridge.
3) Tap the 'Load' button of the bay that holds the cartridge with the tip to read the barcode of the cartridge and please confirm the item name written on the cartridge.
4) Insert the sample tube into the tube rack.
5) Insert the tube rack into the loading part of the sampling station.
6) Tap the 'Start' button on the screen.
7) The test result will be displayed on the screen after 10 minutes.

Emergency mode – General tip

1) The test procedure is same with the 'Normal mode 1) – 3)'.
2) Convert the 'Emergency mode' in AFIAS-10.
3) Select the tip type (general tip) on the screen.
4) Select the sample type (serum/plasma) on the screen.
5) Take 100 µL of the sample using a pipette and dispense it into the sample well of the cartridge.
6) Tap the 'Start' button on the screen.
7) The test result will be displayed on the screen after 10 minutes.

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculates 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
- 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.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with **AFIAS Ferritin**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.
  (Please refer to the instructions for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Analytical Sensitivity**

Limit of Blank (LoB)	2.68 ng/mL
Limit of Detection (LoD)	3.59 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. **AFIAS 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
    Interferents listed in the following table were added to the test sample at the concentration mentioned below. **AFIAS Ferritin** test results did not show any significant interference with these materials.

Interferents	Concentration
Bilirubin(conjugated)	20 mg/dL
Triglyceride	500 mg/dL
Human Hemoglobin	500 mg/dL

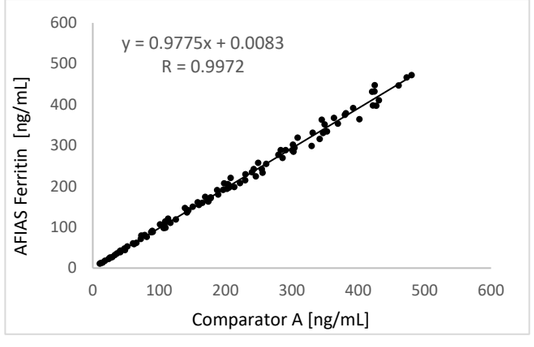
- **Precision**
  3 Lots of **AFIAS Ferritin** were tested for 21 days (7 days per 1 lot at 1 site by one reader). Each standard material was tested 2 times per day. For each test, each material was duplicated.
  - Repeatability (within-run precision)
    Repeatability of **AFIAS Ferritin** was evaluated with results of 1 Lot.
  - Total precision (within-laboratory precision)
    Total precision (within-run, between-run, between day) of **AFIAS Ferritin** was evaluated with results of 1 Lot.
  - Lot to lot precision
    Lot to lot precision of **AFIAS Ferritin** was evaluated with results of 3 Lot.
  - Between person
    Three persons tested **AFIAS Ferritin**, ten times at each concentration of standard materials
  - Between site
    One person tested **AFIAS Ferritin** at three different sites, ten times at each concentration of standard materials.
  - Between reader
    Three different persons tested same lot of **AFIAS Ferritin** with three different readers, ten times at each concentration of the control standard.

Ferritin [ng/mL]	Repeatability (within-run)		Total precision (within-laboratory precision)	
	AVG	CV (%)	AVG	CV (%)
25	25.43	6.1	25.17	6.4
100	100.37	6.9	99.79	6.3
500	500.32	7.4	499.54	6.5
Ferritin [ng/mL]	Lot to lot precision		Between-person	
	AVG	CV (%)	AVG	CV (%)
25	25.03	6.3	24.53	6.7
100	99.68	6.1	100.91	6.7
500	499.12	6.3	502.41	6.1
Ferritin [ng/mL]	Between-site		Between-reader	
	AVG	CV (%)	AVG	CV (%)
25	25.15	6.3	25.23	5.5
100	98.66	6.6	100.81	7.0
500	494.63	5.9	494.20	5.9

- **Accuracy**
  The accuracy was confirmed by testing with 3 different lots of **AFIAS Ferritin.** The tests were repeated 10 times at each concentration of the control standard.

Ferritin [ng/mL]	Lot 1	Lot 2	Lot 3	AVG [ng/mL]	Recovery (%)
12.5	11.94	12.60	12.44	12.33	99
25	24.20	25.82	24.93	24.98	101
100	97.29	102.87	103.75	101.30	102
500	504.99	497.20	482.03	494.74	102
1000	946.60	948.04	934.16	942.93	94

- **Comparability**
  Ferritin concentrations of 100 clinical samples were quantified independently with **AFIAS Ferritin (AFIAS-6)** and **comparator A** as per prescribed test procedures. Test results were compared, and their comparability was investigated with linear regression and correlation coefficient (R). The regression equation and correlation coefficient are as follows.



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

Σ	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

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