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Diabetes

AFIAS Microalbumin

INTENDED USE

AFIAS Microalbumin is a fluorescence Immunoassay (FIA) for quantitative determination of Microalbumin in human urine. It is useful as an aid in management and monitoring of determination of kidney damage from diabetes mellitus.

For *in vitro* diagnostic use only.

INTRODUCTION

A Microalbumin test tests urine for the presence of a protein called albumin[1]. Albumin is normally found in blood and filtered by kidneys[2]. When kidneys are working properly, albumin is not present in urine. However, when kidneys are damaged, small amounts of albumin leak into urine. This albumin is called Microalbumin[1, 2, 3, 4].

Microalbumin is most frequently caused by kidney damage from diabetes. However, many other conditions can lead to kidney damage, such as high blood pressure, heart failure, cirrhosis, or systemic lupus erythmatosus(SLE). If kidney damage is not treated at an early stage, larger amounts of albumin and protein may leak into urine[5,6]. This condition is called macroalbuminuria or proteinuria. When kidneys spill protein, it may indicate the presence of serious kidney damage. This can lead to chronic kidney disease. A microalbumin urine test can be done on a sample of urine collected randomly (usually after the first time you urinate in the morning), a sample collected over a 24 hour period, or a sample collected over a specific period of time, such as 4 hours or overnight[7].

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 the nitrocellulose matrix to be captured by the other immobilized-antibody on the test strip.

The more antigen in sample forms the more antigen-antibody complexes are fromed and the stronger intensity of fluorescence signal on detector antibody should be produced. This signal is processed by the instrument for AFIAS tests to produce microalbumin concentration in the sample.

COMPONENTS

AFIAS Microalbumin 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 microalbumin at the test line, while Chicken IgY at the control line.
- Detector part contains anti human microalbumin-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.

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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 agree with each other.
- Do not interchange test components between different lots or use test components after the expiration date, either of which might yield misleading test result(s).
- The cartridge should remain sealed in its aluminum pouch until use. Do not use the cartridge if found damaged or already opened.
- Frozen samples should be thawed only once. For shipping, samples must be packaged in accordance with the regulations.
- Just before use, allow the cartridge and sample to reach the room temperature by leaving them in the room for approximately 30 minutes.
- **AFIAS Microalbumin** as well as the instrument for AFIAS tests should be used away from vibration and/or magnetic field. During normal usage, the instrument for AFIAS tests may produce minor vibration, which is normal.
- 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 Microalbumin** will provide accurate and reliable results subject to the following conditions.
  - Use **AFIAS Microalbumin** should be used only in conjunction with the instrument for AFIAS tests.

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.
- Return an unused cartridge to the spare cartridge zipperbag containing the desiccant pack. Reseal along entire edge of zip-seal. May be stored for up to 1 month at 2-8 °C.

MATERIALS SUPPLIED

REF SMFP-30

Components of **AFIAS Microalbumin**

- Cartridge Box Contains
  - Cartridge 24
  - Pipette Tip (Zipperbag) 24
  - ID Chip 1
  - Instruction For Use 1
  - Spare Cartridge zipperbag 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

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

- **AFIAS-1** REF FPRR019
- **AFIAS-6** REF FPRR020
- **ichroma™ MAU Control** REF CFPO-4
- **AFIAS Microalbumin Calibrator (2 level)** REF CFPO-78

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS Microalbumin** is human urine.

- It is recommended to test the sample within 24 hours after collection.
- Samples may be stored for up to two days at 2-8 °C prior to being tested. If testing should be delayed for more than two days, 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 components of the **AFIAS Microalbumin** 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 on the instrument.
- Insert an 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 pipette 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 12 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 microalbumin concentration of the test sample in terms of mg/L.
- Reference value: 18 mg/L
- The working range of the **AFIAS Microalbumin** is 2-300 mg/L.

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 Microalbumin**. 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)	1.37 mg/L
Limit of Detection (LoD)	1.78 mg/L
Limit of Quantification (LoQ)	2.00 mg/L

- **Analytical specificity**

- **Cross-reactivity**
  There was no significant cross-reactivity from these materials with the **AFIAS Microalbumin** test measurements.

Material	Concentration
IgA	20 mg/L
hemoglobin	100 mg/dL

- **Interference**
  There was no significant interference from these materials with the **AFIAS Microalbumin** test measurements.

material	Concentration
IgG	20 mg/L
L-ascorbic acid	3 mg/mL
Bilirubin	0.06 mmol/L
D-glucose	45 mg/mL
Urea	30 mg/mL

- **Precision**

- Between Lot
  One person tested three different lots of **AFIAS Microalbumin**, ten times at each concentration of the control standard.

- Between Person
  Three different persons tested **AFIAS Microalbumin**, ten times at each concentration of the control standard.

- Between Day
  One person tested **AFIAS Microalbumin** during five days; five times at each concentration of the control standard.

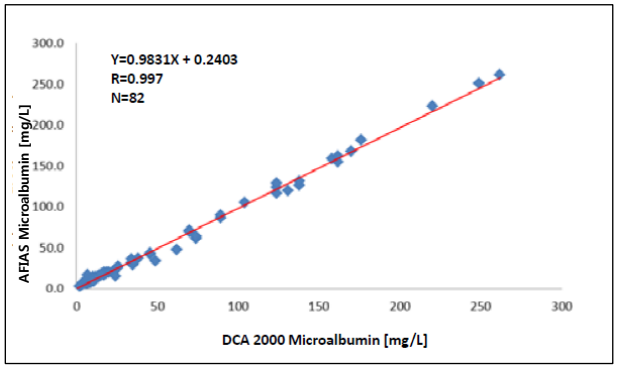
- Between Site
  Three different persons tested **AFIAS Microalbumin** at three different sites; five times at each concentration of the control standard.

Con.	Between Lot		Between Person		Between Day		Between Site	
[mg/L]	AVG	CV(%)	AVG	CV(%)	AVG	CV(%)	AVG	CV(%)
25	25.48	3.91	25.81	3.84	25.8	4.24	25.78	3.89
100	98.07	4.15	97.81	4.11	99.7	4.16	100	3.96
200	199.06	2.83	200.71	3.03	198.68	2.2	200.26	2.58

- **Accuracy**
  The accuracy was confirmed by 3 different lots testing six times each different concentrations.

No. of sample case	Conc.of samples [mg/L]	Recovery (%)		
		Lot 1	Lot 2	Lot 3
1	2.5	98.30	98.21	97.11
2	12.5	105.29	105.51	104.85
3	50	103.16	105.37	104.14
4	62.5	102.08	103.31	101.59
5	150	102.88	103.83	102.27

- **Comparability**
  Microalbumin concentrations of 82 urine samples were quantified independently with ichroma™ Microalbumin and DCA2000 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= 0.9831X + 0.2403 and R = 0.997 respectively.



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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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