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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.

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 erythematosus (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 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 more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by the instrument for AFIAS tests to show microalbumin concentration in the sample.

COMPONENTS

AFIAS Microalbumin 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 microalbumin at the test line 1, and albumin from human serum at the test line 2 and chicken IgY at the control line.
- The detector part has a granule containing anti microalbumin-fluorescence conjugate, anti-chicken IgY-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in phosphate buffered saline (PBS).
- The diluent part contains tween 20 and sodium azide as a preservative in phosphate buffer solution.

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 open.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations.
- 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 disposed 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.
- **AFIAS Microalbumin** will provide accurate and reliable results subject to the below conditions.
  - **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(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 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 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	Unopened
		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-30

Components of **AFIAS Microalbumin**

- 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 Microalbumin**

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 FPRR038
- **Boditech MAU Control** REF CFPO-4

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 when collected sample is stored at room temperature.
- The samples (urine) may be stored for up to two days at 2-8°C prior to being tested. If testing will be delayed more than two days, samples should be frozen at -20°C.
- The samples (urine) stored frozen at -20°C for 2 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 Microalbumin** 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 150 µL of sample (urine/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 12 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) Take the sample (urine/control) using a pipette and dispense it into the sample tube.
   - If using a empty blood collection tube, take 1 mL of the sample.
   - If using an Eppendorf tube (0.5 mL or 1.5 mL), take 150 µL of the sample.
5) Insert the sample tube into the tube rack.
6) Insert the tube rack into the loading part of the sampling station.
7) Tap the 'Start' button on the screen.
8) The test result will be displayed on the screen after 12 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) Take 150 µL of the sample 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 12 minutes.

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculates the test result automatically and displays microalbumin concentration of the test sample in terms of mg/L.
- Working range: 2 - 300 mg/L
- Reference value: 18 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.
- 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 Microalbumin**. 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) 0.464 mg/L
  - Limit of Detection (LoD) 0.852 mg/L
  - Limit of Quantitation (LoQ) 2.00 mg/L

- **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 urine. **AFIAS Microalbumin** test results did not show any significant cross-reactivity with these biomolecules.

Cross-reactants	Concentration
CEA	500 µg/mL
PSA	50 µg/mL
AFP	500 µg/mL
CRP	25 µg/mL

- **Interference**

Interferents listed in the following table were added to the test sample at the concentration mentioned below. **AFIAS Microalbumin** test results did not show any significant interference with these materials.

Interferents	Concentration
D-glucose	55 mmol/L
L-Ascorbic acid	298.31 µmol/L
Bilirubin [unconjugate]	684 µmol/L
Hemoglobin (human)	2 g/mL
Urea	42.9 mmol/L
Creatinine	442 µmol/L

- **Precision**
  - Single-site study

Repeatability (within-run precision)
within-laboratory precision (Total precision)
Lot to lot precision

3 Lots of **AFIAS Microalbumin** were tested for 20 days. Each standard material was tested 2 times per day. For each test, each material was duplicated.

Single-site study

MAU [mg/L]	Repeatability		within-laboratory precision		Lot to lot precision	
	AVG [mg/L]	CV (%)	AVG [mg/L]	CV (%)	AVG [mg/L]	CV (%)
4.5	4.42	8.8	4.46	9.7	4.42	9.9
100	99.96	7.8	99.83	7.5	99.03	8.5
228	232.01	9.1	227.42	8.9	226.33	8.3

  - Multi-site study

Reproducibility

1 Lot of **AFIAS Microalbumin** was tested for 5 days in 3 different sites (1 person per 1 site, 1 instrument per 1 site). Each standard material was tested 1 time per and 5 replicates per day.

Multi-site study

MAU [mg/L]	Reproducibility	
	AVG[mg/L]	CV(%)
4.5	4.55	8.9
100	98.69	6.5
228	226.68	7.5

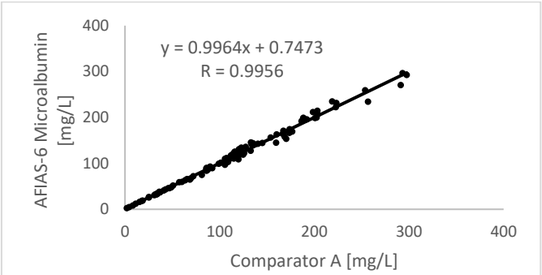
- **Accuracy**

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

MAU [mg/L]	Lot 1	Lot 2	Lot 3	AVG [mg/L]	Recovery (%)
2.94	2.87	2.99	3.00	2.95	100
14.70	14.61	14.76	14.83	14.73	100
29.40	29.32	30.36	27.84	29.17	99
58.80	59.85	58.14	59.98	59.32	101
147.00	147.79	145.46	151.54	148.26	101
220.50	219.77	227.72	221.58	223.02	101
294.00	285.38	283.33	285.16	284.62	97

- **Comparability**

Microalbumin concentration of 100 urine samples were quantified independently with **AFIAS Microalbumin (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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