BIO TECHNOLOGY boditech

Diabetes

ichroma™ Microalbumin

INTENDED USE

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

For *in vitro* diagnostic use only.

INTRODUCTION

A Microalbumin test evaluates urine for the presence of a protein called albumin[1]. Albumin is normally found in the blood and filtered by the kidneys[2]. When the kidneys are working properly, albumin is not present in the urine. However, when the kidneys are damaged, small amounts of albumin leak into the urine. This condition 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 the urine[5,6]. This condition is called macroalbuminuria or proteinuria. When the kidneys spill protein, it can mean serious kidney damage is present. 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 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 microalbumin concentration in sample.

COMPONENTS

ichroma™ Microalbumin consists of 'Cartridges', 'Detection Buffer Tubes' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has anti human microalbumin 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 detection buffer 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.
- The detection buffer is pre-dispensed in a tube. 25 detection buffer tubes are packaged in a Box and further packed in a Styrofoam box with ice-pack for the shipment.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow 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 detection buffer) 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 or detection buffer tubes. A detection buffer tube should be used for processing of one sample only. 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 cartridge, if 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.
- Allow cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- Used detection buffer tubes, 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™ Microalbumin** will provide accurate and reliable results subject to the below conditions.
  - **ichroma™ Microalbumin** should be used only in conjunction with instrument for ichroma™ tests.

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(s) due to the non-responsiveness of the antigen to the antibodies which is 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 antigen 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 including clinical symptoms and other relevant test results.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4-30 °C.
- The detection buffer 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.

MATERIALS SUPPLIED

REF i-CHROMA MAU-25

Components of **ichroma™ Microalbumin**

- Cartridge Box:
  - Cartridges 25
  - ID Chip 1
  - Instruction for Use 1
- Detection buffer Box:
  - Detection Buffer Tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ Microalbumin**.

Please contact our sales division for more information.

- Instrument for ichroma™ tests
  - **ichroma™ Reader** REF FR203
  - **ichroma™ II** REF FPRR021
- **ichroma™ Printer** REF FPRR007
- **ichroma™ MAU Control** REF CFPO-4

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ 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 will be delayed 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 contents of **ichroma™ Microalbumin**: Sealed Cartridge, Detection Buffer Tubes and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip as well as the detection buffer.
- 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.
  (Please refer to the 'Instrument for ichroma™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

<Multi Mode>

1) Transfer 10 µL (Human urine/control) of sample using a transfer pipette to a tube containing the detection buffer.
2) Close the lid of the detection buffer tube and mix the sample thoroughly by shaking it about 10 times.
   (The sample mixture must be used immediately.)
3) Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
4) Leave the sample-loaded 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.*
5) 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.
6) Tap the 'Start' or press the 'Select' button on the instrument for ichroma™ tests to start the scanning process.
7) The instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
8) Read the test result on the display screen of the instrument for ichroma™ tests.

<Single Mode>

1) Transfer 10 µL (Human urine/control) of sample using a transfer pipette to a tube containing the detection buffer.
2) Close the lid of the detection buffer tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately.)
3) Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
4) Inserting the cartridge into the 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.
5) Tap the 'Start' or press the 'Select' button on the instrument for ichroma™ test.
6) Cartridge goes inside the Instrument for ichroma™ tests and will automatically start scanning the sample-loaded cartridge after 3 min.
7) Read the test result on the display screen of the instrument for ichroma™ tests.

INTERPRETATION OF TEST RESULT

- The instrument for ichroma™ tests calculates the test result automatically and displays microalbumin concentration of the test sample in terms of mg/L.
- The cut-off (reference range): 18 mg/L
- Working range : 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 **ichroma™ 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.)

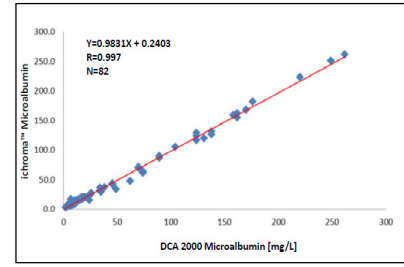
PERFORMANCE CHARACTERISTICS

- **Specificity**
  There, in test samples, are biomolecules such as Hemoglobin, CEA, PSA, AFP, ALP, CRP, Troponin I and myoglobin were added to the test samples at concentrations much higher than their normal physiological levels in urine. **ichroma™ Microalbumin** test results did not show any significant cross-reactivity with these biomolecules.

- **Precision**
  The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard ten times each with three different lots of **ichroma™ Microalbumin.** The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing three times each different concentration.

Microalbumin (mg/L)	Intra-assay		Inter-assay	
	Mean	CV (%)	Mean	CV (%)
25	24.3	4.32	24.5	6.6
100	100.2	5.48	100.7	7.6
200	200.6	3.25	200.0	6.9

- **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

	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:
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