Microalbumin FIA Rapid Test

(Urine)

FIA-MALB-001

A rapid test for measuring microalbumin (mAlb) in urine with the use of the Biopanda Fluorescence Immunoassay Analyser.
For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda Microalbumin (mAlb) FIA Rapid Test is based on Fluorescence Immunoassay for the quantitative determination of mAlb in urine.

SUMMARY

The steady expulsion of small quantities of albumin with the urine can be the first sign of kidney damage. In the healthy kidney albumin is usually glomerular filtrated and tubular reabsorbed, so that it is hardly detectable in urine. With a damaged kidney this process is disordered. The expulsion of albumin in the range of 20 - 200 mg/L is characterized as microalbuminuria.[1] With this microalbumin test such small concentrations are already securely captured. Especially with diabetics, positive results could point to a beginning diabetic nephropathy. Without appropriate therapeutic intervention it will lead for a high percentage of patients to a progression of this complication. The expulsion of albumin increases continuously (= macroalbuminuria) and ends finally after several years in a renal failure, which makes dialysis or a kidney transplant inevitable. In the USA and Europe diabetes is the main cause for terminal kidney failure. A study (DEMAND), accomplished world-wide, shows that approx. 41% of type-2 diabetics exhibit a microalbuminuria. The frequency of microalbuminuria increases with age, blood pressure and diabetes duration, and is the rarer, the better the blood sugar is adjusted. The high prevalence of the illness reveals how important a microalbuminuria annual screening is for diabetics. For type-1 diabetics the first measurements are usually recommended 5 years after initiation of the illness. For type-2 diabetics the screening should start directly with the first outset of the diagnosis, since it is unknown, how long the illness already exists. The diagnosis of a microalbuminuria is also of special importance, since it can be not only the first sign of a beginning nephropathy but also an indicator for an increased risk for cardiovascular illnesses for type-2 diabetics. An increase of albumin expulsion can be due, to additional factors of influence like physical activity, infections of the urinary tract, high blood pressure, heart insufficiency or surgical interferences (besides damages of renal structures).
If the increased albumin expulsion disappears after removal of these factors, it concerns only a transient albuminuria without any pathological reason.
Since the albumin expulsion can vary substantially from day to day, at least 2 of 3 urine samples, which were collected over a period of 3-6 months, should show increased albumin values, before microalbuminuria is diagnosed.

PRINCIPLE

The mAlb FIA Rapid Test Cassette detects mAlb based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. mAlb in the urine will compete with the mAlb antigen coated on the membrane. The less mAlb in the sample, the more chance that fluorescent microspheres-conjugated anti-mAlb antibodies can be captured by the mAlb antigen coated on the membrane. The concentration of mAlb in the sample is inversely related to the intensity of the fluorescent signal captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of mAlb in the sample can be calculated by the Biopanda Fluorescence Immunoassay Analyser to show mAlb concentration in specimen.

REAGENTS

The test kit includes mAlb antibody coated fluorophores and mAlb antibody coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda mAlb FIA Rapid Test should only be used with the Biopanda Fluorescence Immunoassay Analyser by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS

- 10 x foil wrapped mAlb test cassettes
- 10 x Specimen collection tubes with dilution buffer
- 1 x ID card (mAlb)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Analyser

SPECIMEN COLLECTION AND PREPARATION

Use preferably only fresh morning urine for testing since physical effort can lead to an increase in albumin expulsion. Urine sample should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Samples that have been refrigerated must be equilibrated to room temperature before testing. Avoid repeated freezing and thawing of urine samples.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Analyser Operation Manual for the complete instructions on use of the Test. The test should be conducted at room temperature.
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to the user requirement, select “Standard test” or “Quick test” mode.
2. Take out the ID card and insert it into the Analyser port.
3. Transfer 75 µl of urine into the buffer tube, mix the specimen and the buffer well.
4. Pipette 75 µl of diluted specimen into the sample well of the test cassette. Start the timer at the same time.
5. There are two test modes for the Biopanda Fluorescence Immunoassay Analyser; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser for details.

“Quick test” mode: Insert the test cassette into the Analyser at 10 minutes after sample application and click "New Test", the Analyser will automatically give the test result after a few seconds.
“Standard test” mode: Insert the test cassette into the Analyser immediately after sample application, click "New test" at the same time, the Analyser will automatically count down the 10 minutes. After the countdown, the Analyser will give the result at once.

INTERPRETATION OF RESULTS

The result of tests for mAlb is calculated by the Biopanda Fluorescence Immunoassay Analyser and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser.

Linearity range of the Biopanda mAlb FIA Rapid Test is 5~300 mg/L.

QUALITY CONTROL

Each Biopanda mAlb FIA Rapid Test Cassette contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Analyser. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Analyser indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Biopanda mAlb FIA Rapid Test Cassette is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of mAlb.
2. The Biopanda mAlb FIA Rapid Test Cassette will only indicate the presence of mAlb in the specimen and should not be used as the sole criterion for evaluating microalbuminuria.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The results of the Biopanda mAlb FIA Rapid Tests are based on measuring the levels of mAlb in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

Concentrations	Clinical Reference
<20 mg/L	Healthy
>20 mg/L	Kidney Damage

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **SENSITIVITY**: The mAlb FIA Rapid Test can detect levels of mAlb as low as 5mg/L in Urine.
3. **DETECTION RANGE**: 5~300 mg/L.
4. **LINEARITY RANGE**: 5~300 mg/L, R≥0.990
5. **PRECISION**

INTRA-LOT PRECISION

Within-run precision has been determined by using 10 replicates of 2 specimens containing 20 mg/L, and 50 mg/L of mAlb. C.V. is ≤ 15%.

INTER-LOT PRECISION

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 20 mg/L, and 50 mg/L of mAlb. C.V. is ≤ 15%.

6. METHOD COMPARISON

The assay was compared with commercial Turbidimetric Inhibition Immuno Assay test with 100 samples. The correlation coefficient(r) is 0.990.

REFERENCES

1. "Person—microalbumin level (measured), total micrograms per minute N[NNN].N". Retrieved 2007-07-05.

Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalogue #
	Store between 4-30°C	LOT	Lot Number		Consult instructions
	Do not use if package is damaged		Manufacturer		

Thank you for purchasing Biopanda's mAlb FIA Rapid Test. Please read this manual carefully before operating to ensure proper use.

Biopanda Reagents Ltd.
Unit 14 Carrowreagh Business Park
Carrowreagh Road
Belfast, BT16 1QQ
United Kingdom
Tel: +44 (0) 28 95438774
E-mail: info@biopanda.co.uk
Website: www.biopanda.co.uk

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