

mAlb Test Kit (Dry Fluorescence Immunoassay) User Manual

[PRODUCT NAME]

mAlb Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

5 Tests/Kit
25 Tests/Kit

[INTENDED USE]

For the in vitro quantification of microalbumin in human urine. Albumin is a normal protein in the blood and is found in very small amounts in the urine under normal physiological conditions, hence the term microalbumin. Studies have shown that when the body suffers from hypertension, diabetes and cardiovascular damage from kidney disease, lesions in the blood vessels of the kidneys can alter the function of the kidneys in filtering protein, causing the protein to leak into the urine and increasing the level of microalbumin in the urine. Microalbumin is used to monitor the development of kidney disease and is the most sensitive and reliable diagnostic indicator for the early detection of kidney disease, compensating for the lack of sensitivity of routine urine tests in the early stages of kidney damage. Common clinical and laboratory methods for mAlb testing include chemiluminescence, immunochromatography and enzyme-linked immunoassay.

[TEST PRINCIPLE]

This kit uses an immunofluorescence competition method for the quantitative determination of mAlb. A highly specific and sensitive monoclonal antibody is labelled as fluorescent microspheres and immobilized in a binding pad; an mAlb recombinant antigen is encapsulated in the test area on a nitrocellulose membrane. During testing, the antigen in the sample binds to the mAlb antibody-labelled fluorescent microspheres in the binding pad and the unbound labelled antibody microspheres are subsequently captured by the mAlb recombinant antigen immobilized on the test zone, forming a fluorescent microsphere sandwich structure; the chicken IgY-labelled fluorescent particle complex in the binding pad binds to the goat anti-chicken IgY immobilized on the quality control zone of the nitrocellulose membrane, forming a quality control zone. The complex is measured and analyzed by a companion instrument to quantify the amount of mAlb in human urine.

[MAIN COMPONENTS]

1. Test strip in a foil pouch with desiccant
 2. QR code card for calibration
 3. User manual
 4. Quantitative suction and dropping tube (Optional).
- Note: Do not mix or interchange different batches of kit.**

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a shelf life of 24 months.
Test strip should be used within 1 hour once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1100 Dry Fluorescence Immunoassay Analyzer
2. LS-2100 Dry Fluorescence Immunoassay Analyzer
3. LS-4000 Dry Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Urine should be collected from the middle section of random urine, other body fluids and samples may not yield accurate results.
2. Samples should be used as soon as possible, with immediate samples tested and measured on the same day. If it is impossible, store the samples at 2-8°C for 2 days and do not freeze them. Urine samples should avoid long-term storage.
3. Avoid using samples contaminated with microorganisms.

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample and test strip should be recovered to room temperature (15°C-30°C).
3. Perform QR code calibration when necessary. (Details refer to User Manual)
4. On the main interface of the analyzer, press the "Test" icon to enter the testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. Pipette 100µL of sample into the reagent card and start timing. The reagent card is left to stand at room temperature (15°C-30°C) for 10 minutes before being inserted into the analyzer for testing (Details refer to the User Manual).

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[REFERENCE INTERVAL]

The following reference intervals were derived from the statistical analysis of the 95% distribution range of microalbumin levels measured in urine samples from 180 healthy individuals.

mAlb: ≤20mg/L

Note: Due to differences in geography, ethnicity, gender and age, it is recommended that each laboratory establishes its own reference range.

[INTERPRETATION OF RESULT]

1. When the sample is >200mg/L, the instrument will display >200mg/L, and when the sample is <10mg/L, the instrument will display <10mg/L. If specific data is required, it can be exported through the relevant software.
2. When the sample concentration exceeds the upper limit of the test, the sample should be diluted with 0.9% physiological saline. The maximum dilution of this kit is 5 times.

[LIMITATION]

1. The test result of this kit is only used as one of the diagnostic aids for clinicians' reference.
2. Samples containing interfering substances can affect the test results. The maximum permissible concentrations are: creatinine ≤ 10mg/mL, glucose ≤ 10mg/mL and urea ≤ 100mg/mL.

[PRODUCT PERFORMANCE]

1. Limit of blank: ≤10 mg/L
2. Linearity range: 10mg/L-200mg/L, r≥0.990.
3. Accuracy: Verify with comparison experiments, the relative deviation is within ±15%.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.

[PRECAUTIONS]

1.  Only used for in vitro diagnostics.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix the components of different kits.

[REFERENCES]

1. Rowe DJF, Daenay A, Watts GF. Urinary microalbumin in diabetes mellitus; a review and recommendations for urinary albumin testing. Ann Clin Acta 1997; 258:3-20.
2. Duan L, Liu P, Wu HH. The significance of changes in ultrasensitive C-reactive protein and urinary microalbumin levels in the diagnosis and treatment of co-infection in type 2 diabetes mellitus [J]. Chinese Journal of Hospital Infection, 2011,21 (18):3881-3882.

[SYMBOL DESCRIPTION]

	For in vitro diagnostic use only
	Catalog number
	Manufacturer
	Lot number
	EU Authorized Representative
	Date of Manufacture
	Use by date
	Consult instructions for use
	Store at 4°C-30°C
	Contents Sufficient for < n > Tests
	Do not reuse
	Keep away from sunlight
	Fragile handle with care
	Keep dry
	Forbidden to inversion



Lansion Biotechnology Co., Ltd.

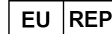
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Production date and expiration see the label.