

MICROALBUMIN



Order Information

Cat. No.
OMR1136

Kit Configuration
Reagent 1: 1 x 40 mL
Reagent 2: 1 x 10 mL
Calibrator: 1 x 1 mL

Summary

Microalbuminuria is at present defined as an excretion rate for albumin between 20 and 200 mg/L, which is already above normal values but still below the values seen in patients with "conventional" proteinuria. Microalbuminuria is a marker of an increased risk of diabetic nephropathy as well as cardiovascular disease in patients with insulin-dependent diabetes mellitus as well as with non-insulin-dependent diabetes mellitus. More recently, microalbuminuria has been found to be associated with cardiovascular disease also in the non-diabetic population. In fact, microalbuminuria may show to be a risk factor of cardiovascular disease among otherwise apparently healthy people.

Method

Latex Immunoturbidimetric test

Principle

Urine albumin reacts with antibody specific for human albumin. Latex particles coated with specific antibodies anti-human albumin are agglutinated when they react with samples that contain albumin. The latex particles agglutination is proportional to the concentration of the albumin in the sample and can be measured by turbidimetry.

Reagent Storage Instruction and Stability

The reagent is stable until the expiration date on the label when stored tightly closed at 2-8°C.

Do not freeze; It could change the functionality of the test. All the components of the kit are stable until the expiration date on the label when stored tightly.

Reagent 1: Buffer Solution

Reagent 2: Latex Antibody Solution

Calibrator: Microalbumin Calibrator (Value on Label)

Composition

Reagent contained: Glycine buffer 100 mmol/L, latex particles coated with anti-human Albumin antibodies and Preservative.

Calibrator: Microalbumin calibrator (Microalbumin Value on Label)

Warnings and Precautions

1. Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Take off immediately all contaminated clothing.
3. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
4. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Reagent 1 and 2 ready to use.
Calibrator is ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

24 hours or random/ first morning urine specimen. Stable for 7 days at 2-8°C when sodium azide (1 g/L) is added to prevent contamination.
Urine should be centrifuged before testing.

Assay Procedure

Wavelength 540 nm
Temperature 37°C
Light path 10 mm

| | |
|---|-----------------------|
| | Sample/ Calibrator |
| Reagent 1 | 800 µL |
| Reagent 2 | 200 µL |
| Mix well. | |
| Sample /Calibrator | 7 µL |
| Mix and read the absorbance immediately (A1) and incubate for 2 minutes and read the absorbance (A2). | |

CALCULATIONS

(A2-A1) sample

microalbumin mg/L = ----- x Calibrator concentration
(A2-A1) calibrator

Quality Controls

For internal quality control any normal and abnormal controls should be assayed with each batch of samples. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics Measuring Range

The test has been developed to determine concentration of Microalbumin within a measuring range from 0.8 - 160 mg/L. If such value is exceeded the sample should be diluted 1 + 4 with NaCl solution (9 g/L) and results multiplied by 5.

Interferences

No interference was observed by, Bilirubin up to 20 mg/dL and Triglycerides up to 1000 mg/dL.

Sensitivity/Limit of Detection

The lower limit of detection is 0.8 mg/L.

Linearity

The higher limit of detection is 160 mg/L.

Precision

| Intra-assay n = 20 | Mean (mg/L) | SD (mg/L) | CV (%) |
|--------------------|-------------|-----------|--------|
| Sample 1 | 22.04 | 1.16 | 5.26 |
| Sample 2 | 11.43 | 0.77 | 6.72 |

| Inter-assay n = 20 | Mean (mg/L) | SD (mg/L) | CV (%) |
|--------------------|-------------|-----------|--------|
| Sample 1 | 17.87 | 0.88 | 4.93 |
| Sample 2 | 46.43 | 1.82 | 3.93 |

Method Comparison

A comparison of Nucleus Diagnosys Microalbumin (y) with a commercially available test (x) using 15 samples gave following results:

$$y = 0.999x + 0.160; r^2 = 0.99$$

Reference Range

Normal value upto 30 mg/24 hours in Urine.

Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Elving, L.D., et al., Clin Chem. 1989; 35/2: 308.
2. Bakker, A.J., Clin. Chem. 1988; 34/1: 82.
3. Mogensen, C.E., Christensen, C.K., N. Engl. J. Med. 1984; 311: 89.
4. Fielding, B.A., Price, D.A., Houlton, C.A., Clin. Chem. 1983; 29/2: 355.

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