



MICROALBUMIN Latex L

Quantitative turbidimetric latex assay for the measurement of Microalbumin in human urine



ORDER INFORMATION

REF	Kit size
GD8439 00	1x40 + 1x10 ml
KL8439 00	1x40 + 1x10 ml
BK8439 00	2x(40+10 ml)

CLINICAL SIGNIFICANCE⁽⁴⁻⁶⁾

Microalbuminuria is an increased urinary albumin excretion (UAE) in the range of 20 to 200 µg/min (or 30-300 mg/24h) as a consequence of changes in glomerular permeability⁽⁷⁾.

Increased UAE precedes and is highly predictive of diabetic nephropathy, end-stage renal disease, and proliferative retinopathy in type 1 diabetes. In patients with type 2 diabetes, increased UAE is an independent predictor of progressive renal disease, atherosclerotic disease, and cardiovascular mortality. In fact, microalbuminuria may show to be a risk factor of cardiovascular disease among otherwise apparently healthy people.

METHOD PRINCIPLE

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.⁽¹⁻³⁾

COMPOSITION

Reagent A-Diluent

Glycine buffer 100 mmol/l, pH 10.

Reagent B-Latex

Latex particles coated with goat IgG anti-human albumin, pH 8.2.

PREPARATION OF THE REAGENTS

Working reagent

Swirl the latex vial before use. Mix Latex and Diluent in a 1:5 ratio (i.e. 2 ml RB + 8 ml RA) prior to use.

STORAGE AND STABILITY

The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8 °C and contaminations are prevented during their use. Do not use the reagents after the expiration date.

Working reagent: stable 7 days at 2-8 °C.

Shake gently the vial before use.

Reagent deterioration: presence of particles and turbidity.

ANCILLARY EQUIPMENT

- Automatic pipette to measure reagent and sample
- Thermostatic bath at 37 °C
- Spectrophotometer or photometer thermostatable at 37 °C capable to read 540 ± 20 nm
- Analysis cuvettes (optical path = 1 cm)
- NaCl (9 g/l) solution
- Microalbumin Calibrator L (Ref. GD8562 00)
- Microalbumin Turbidimetric Control L (Ref. GD8438 00)

SAMPLES

Fresh urine. It is recommended to adjust the pH at 7.0 with NaOH 1 mol/l. Stable 7 days at 2-8 °C when sodium azide 1 g/l is added to prevent contamination.

Urine should be centrifuged before testing.

PROCEDURE

1. Prewarm the reagent and the photometer (cuvette holder) to 37 °C.
2. Using distilled water zero the instrument at 540 nm.
3. Pipette into a cuvette:

Sample/Calibrator	7 µl
Working Reagent	1000 µl

4. Mix well and insert the cuvette into the photometer. Record the absorbance (A₁) immediately and after 2 minutes (A₂) of the sample or calibrator addition.

CALCULATION

$$\text{Albumin, mg/l} = \frac{(A_2 - A_1) \text{ sample}}{(A_2 - A_1) \text{ calibrator}} \times \text{mg/l calibrator}$$

REFERENCE VALUES⁽⁷⁾

Adults: up to 15 mg/l

It is recommended that each laboratory establishes its own reference range according to the examined population.

QUALITY CONTROL

To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

Each laboratory should establish its own quality control scheme and corrective actions if controls do not meet the acceptable tolerances.

ANALYTICAL PERFORMANCE

Linearity

The method is linear up to 160 mg/l, under the described assay conditions. Samples with higher concentrations should be diluted 1:5 with NaCl 9 g/l and retested again.

Detection limit

Values less than 0.78 mg/l give non-reproducible results.

Analytical sensitivity

5.64 mA/mg albumin/l

Prozone effect

Prozone effect is not observed up to 1000 mg/l.

Precision

	Mean (mg/l)	%CV
Intra-assay n = 10	8.8	5.9
	40.6	2.1
	60.8	1.6
Inter-assay n = 10	8.8	6.1
	40.6	2.8
	60.8	3.9

Accuracy

Results obtained with this reagent did not show systematic differences when compared with commercial reagents of similar characteristics. Details of comparison are available on request.

Interferences

Bilirubin (10 mg/dl), hemoglobin (12 g/l), urea (100 mg/l) and creatinine (300 mg/l), do not interfere. Other substances may interfere⁽⁸⁾.

Note:

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
2. The linearity limit depends on the sample/reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
3. Do not re-use plastic cuvettes, as they may produce erroneous values. Use a new cuvette for each microalbumin assay.
4. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

PRECAUTIONS IN USE

The reagents contain inactive components such as preservatives (Sodium azide or others), surfactants etc. The total concentration of these components is lower than the limits reported by 67/548/ECC and 88/379/EEC directives about classification, packaging and labelling of dangerous substances. However, the reagents should be handled with caution, avoiding swallowing and contact with skin, eyes and mucous membranes.

The reagents from human donors have given negative results to anti-HIV 1/2, HBsAg and anti-HCV. It is recommended to handle with caution.

The use of the laboratory reagents according to good laboratory practice is recommended.⁽⁹⁾

Waste Management

Please refer to local legal requirement.

REFERENCES

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