# MICROALBUMIN

*Turbilatex Method*

**Intended Use:**

Microalbumin is in vitro Medical Device Reagents/Kits for the detection and screening of Microalbumin levels in various conditions including autoimmune disorder in human specimen. It is intended for *in vitro* diagnostics use by trained healthcare professionals in IVD laboratory only and not near patients.

**Clinical Significance**

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

**Principle**

Microalbumin-turbilatex is a quantitative turbidimetric test for the measurement of microalbumin (µALB) in human urine.
Latex particles coated with specific antibodies anti-human albumin are agglutinated when mixed with samples containing µALB. The agglutination causes an absorbance change, dependent upon the µALB contents of the patient sample that can be quantified by comparison from a calibrator of known µALB concentration.

**Reagent Composition**

| | |
|---|---|
| R1 Diluent | Glycine buffer 100 mmol/L, pH 10.0. |
| R2 Latex | Latex particles coated with goat IgG anti-human albumin ,pH 8.2 |
| mALB Calibrator | Human albumin. Albumin conc. is stated on vial label. and it is traceable to the Certified Reference Material BCR-470(IRMM). |

**Precaution**

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.
This reagent contains sodium azide 0.95 g/L. Avoid any contact with skin or mucous.

**Calibration**

Use Microalbumin Calibrator ONLY.
The sensitivity of the assay and the target value of the calibrator have been standardized against the Reference Material BCR-470(IRMM).

**Preparation**

Microalbumin Calibrator: Ready to use.

**Working Reagent:**

Swirl the latex vial before use. Mix Latex and Diluent in a 1:4 ratio (i.e 2 ml R2 + 8 ml R1) prior to use.
Working Reagent is stable during 30 days at 2-8$^0$

**Stability and Storage**

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.
Reagent deterioration: Presence of particles and turbidity.

**Additional Equipment**

- Thermostatic bath at 37°C.
- Spectrophotometer or photometer thermostatable at 37°C with a 540 nm filter.

**Samples**

24hrs or random/ first morning urine specimen. It is recommended to adjust the pH at 7.0 with NaOH/HCL 1mol/L. Stable 7 days at 2-8ºC when sodium azide 1 g/L is added to prevent contamination.
Urine should be centrifuged before testing.

**Assay Parameters**

| | |
|---|---|
| Mode | Two Point / Fixed Time |
| Reaction | Ascending |
| Wavelength | 540 nm (530-550) |
| Blank With | Distilled Water |
| Sample Volume | 5 µl |
| Reagent Volume | 400 µl : 100 µl |
| Delay Time | 10 (Sec) |
| Read Time | 120 (Sec) |
| Calibrator Conc. | See Vial Label |
| Linearity Limit | Up to 150 mg/L |
| Unit | mg/L |

**Procedure**

1. Bring the reagents and the photometer (cuvette holder) to 37°C.
2. Assay conditions:
   Wavelength: 540 nm (530-550)
   Temperature: 37°C
   Cuvette light path: 1 cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette

| **Addition Sequence** | **Test** |
|---|---|
| R1 Diluent | 400 µl |
| R2 Latex | 100 µl |
| Calibrator or sample | 5 µl |

5. Mix and read the absorbance immediately Abs(A1) and after 2 minutes Abs(A2) of the sample addition.

**Calculation**

$$\text{Albumin(mg/L)} = \frac{\text{Abs (A2-A1) sample}}{\text{Abs (A2-A1) calibrator}} \times \text{Calibrator conc.}$$

**Quality Control**

Control Sera are recommended to monitor the performance of manual and automated assay procedures.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

**Reference Values**

Normal Values : Up To 30 mg/24 Hrs Urine

First morning urine specimen: 20 mg/L

**Performance Characteristics**

1. Linearity limit: Up to 150 mg/L, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and retested again. 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.
2. Detection limit: Values less than 2 mg/L give non-reproducible results. Prozone effect: No prozone effect was detected upon 1000 mg/L
2. Prozone effect: No prozone effect was detected upto 250 mg/L.
3. Sensitivity: 3.8mA.mg/L.
4. Precision:

| | Intra assay(n=10) | | | Inter assay(n=10) | | |
|---|---|---|---|---|---|---|
| Mean(IU/ML) | 12.4 | 27.3 | 83.5 | 12.4 | 27.3 | 83.5 |
| SD | 0.28 | 0.40 | 1.61 | 0.28 | 0.56 | 2.13 |
| CV | 2.25 | 1.48 | 1.93 | 2.28 | 2.06 | 2.55 |

Accuracy: Results obtained using this reagent (y) was compared to those obtained using a commercial reagent (x) with similar characteristics. 95 samples ranging from 1 to 150 mg/L of microalbumin were assayed. The correlation coefficient (r) was 0.99 and the regression equation was y= 0.964x – 0.576
The results of the performance characteristics depend on the analyzer used
Interferences: Glucose (2 g/L), hemoglobin (10 g/L) and creatinine (3 g/L) do not interfere. Urea (≥ 1 g/L) and bilirubin (≥ 10 mg/dl), interfere. Other substances may interfere.

**Notes**

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meets 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.
5. For automatic instruments, avoid the presence of bubbles in the reagents that may interfere with the assay results.

**References**


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**Packaging**

R1. Diluent: 1 x 40ml

R2. Latex : 1 x 10ml

mAlb -CAL:1 x 1ml

**For *in vitro* Diagnostic Use Only**