

### Intended Use

Mission's Microalbumin Reagent is for the quantitative determination of albumin in urine.

For Research Use Only. Site validation required for Lab Developed Test (LDT), 510K approval pending.

### Summary and Principle

A small amount of protein is normally excreted in the urine of healthy individuals, primarily mucoproteins, which are largely filtered and reabsorbed by the renal tubules and glomeruli.

Albumin, a protein with a molecular weight of approximately 50,000, is less readily filtered and may appear in small amounts in urine (microalbuminuria).<sup>1,2</sup>

Urinary albumin excretion serves as an early indicator of glomerular dysfunction. Microalbuminuria is defined as elevated urinary albumin excretion in the absence of overt nephropathy.<sup>3,4</sup> It has been shown to predict the onset of diabetic nephropathy and is associated with increased mortality risk in diabetic patients.<sup>2,5-9</sup>

Early detection of microalbuminuria is clinically important, as it may be reversible with effective diabetes management.

This test employs an immunoturbidimetric method for the quantitative determination of microalbumin in human urine. When a sample is mixed with anti-human albumin goat antiserum, agglutination is caused by the antigen-antibody reaction. The turbidity is measured at 340 nm and albumin in the sample is quantitatively determined.

### Reagents

Reagents provided as ready-to-use liquids.

R1 reagent: 100 mM Tris, pH 7.6

R2 reagent: 20% Anti-human albumin goat antiserum in 100 mM Tris buffer, pH 7.6

### Reagent Stability and Storage

Packaged reagents are stored at 2-8°C. The reagents are stable until the expiration date on the label when stored as directed. Do not freeze reagents. Avoid exposure to direct sunlight. Do not use if reagents show evidence of contamination (turbidity). Do not use if reagent fails to achieve assigned assay values of fresh control sera. Evidence of cloudiness or particulate material in solution is cause to discard.

### Cautions

May be harmful if inhaled or swallowed. Avoid contact with skin and eyes. In case of contact, flush affected area with water. Seek immediate medical attention for eyes. Reagents in this kit contain sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of reagents through plumbing fixtures, flush with copious amounts of water.

### Instrumentation

The Mission Microalbumin Reagent Kit is for use on Mission CA200<sup>1</sup> and Beckman AU680 analyzers. Refer to instrument procedure instructions in the instrument manual provided with the specific analyzer.

### Specimen Collection and Handling

The specimen should be fresh or a 24-hour urine. Urine specimens should be stored refrigerated (2-8°C). The specimens may be stored refrigerated up to two weeks.

### Quality Control

Standard practice for quality control should be applied to this procedure. Store and handle reagents properly before and during use. Every laboratory should establish its own test requirements using controls and calibrators.

Mission Diagnostics provides calibrators to meet your program needs and which conform to NLCP Guidelines<sup>10</sup>:

MD-101211 – Microalbumin Calibrator kit

### Specificity, Limitations, and Interferences

Ascorbic acid: No interference up to 200 mg/dL

Glucose: No interference up to 3.0 g/dL

Uric Acid: No interference up to 100 mg/dL

Creatinine: No interference up to 300 mg/dL

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Calcium: No interference up to 30.0 mM

NaCl: No interference up to 900 mg/dL

Mg: No interference up to 30 mM

KCl: No interference up to 300 mg/dL

Urea: No interference up to 3.0 g/dL

### Typical Performance and Characteristics

The following performance data was obtained using the Mission CA200 and Beckman AU680 analyzers. Other instruments may yield different performance data.

<sup>1</sup> Also known as Zybion EXC200 Analyzer

### Linearity

The following results were obtained on Mission CA200 and Beckman AU680 analyzers using the Mission Microalbumin Reagent Kit on samples containing 0, 0.5, 1, 5, 10, 30 mg/dL microalbumin. The table below includes mean, standard deviation (SD) and coefficient of variation (CV) for each value.

| Mean (mg/dL) | SD   | CV%  |
|--------------|------|------|
| 0.03         | 0.02 | 80   |
| 0.44         | 0.04 | 10.1 |
| 0.93         | 0.02 | 1.9  |
| 4.84         | 0.04 | 0.8  |
| 9.76         | 0.15 | 1.6  |
| 28.32        | 1.48 | 5.2  |

### Precision

Studies were performed on Mission CA200 and Beckman AU680 analyzers. The precision of the assay was evaluated following a modification of NCCLS protocol EPT-T2. The within-run precision data was obtained by running two samples in replicates of 20 on the same day. The run-to-run data was obtained by running two samples in replicates over a five-day period.

| Within-Run   |      |     | Run-to-Run   |      |      |
|--------------|------|-----|--------------|------|------|
| Mean (mg/dL) | SD   | CV% | Mean (mg/dL) | SD   | CV%  |
| 3.83         | 0.11 | 2.8 | 4.35         | 0.43 | 10.0 |
| 12.89        | 0.19 | 1.5 | 13.53        | 0.56 | 4.2  |

### Analytical Specificity

Cross contamination studies have not been performed. Certain reagent/instrument combinations used in sequence with this assay may interfere with reagent performance and test results. The existence of, or effects of, any potential cross contamination issues are unknown.

### Test Conditions

For the data presented in this insert, studies using this reagent were performed on Mission CA200 and Beckman AU680 analyzers using the parameters listed below.

### Limitations

Samples exceeding the analytical measuring range should be diluted with water and reanalyzed incorporating the dilution factor in the calculation of the value.

The limit of quantification (LOQ) must be determined by each laboratory according to their SOP.

### Calibration

Calibration material should be used to calibrate the procedure. The frequency of calibration using an automated system is dependent on the system and the parameters used. If control results are found to be out of range, the test may need to be re-calibrated.

### Method Parameters

#### Analyzer Specific Settings

|                          |          |
|--------------------------|----------|
| Method type:             | Endpoint |
| Slope:                   | positive |
| Units                    | mg/dL    |
| DOM wavelength           | 340      |
| SUB wavelength           | 700      |
| Sample volume            | 5        |
| R1 volume                | 160      |
| R2 volume                | 40       |
| Blank rxn read (cycles)  | 16 - 20  |
| Sample rxn read (cycles) | 36 - 40  |

#### Calibrator settings

|                         |                       |
|-------------------------|-----------------------|
| Calibration Type        | Polynomial (Logit-5P) |
| Reagent Blank required  | No                    |
| Calibrator 1 (provided) | 0                     |
| Calibrator 2            | 0.5                   |
| Calibrator 3            | 1                     |
| Calibrator 4            | 5                     |
| Calibrator 5            | 10                    |
| Calibrator 6            | 30                    |

#### Analytical Measuring Range (AMR)

|               |     |
|---------------|-----|
| Range: (low)  | LOQ |
| Range: (high) | 30  |

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