MICROALBUMIN REAGENT KIT
MD-101111

Intended Use
For the quantitative determination of albumin in urine.
NOT FOR USE IN UNPROFESSIONAL SETTINGS.

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).[1,2]
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.[3,4] It has been shown to predict the onset of diabetic nephropathy and is associated with increased mortality risk in diabetic patients.[2,5–9] 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 340nm and 700nm 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
MISSION Microalbumin Kit is For Laboratory Use Only. May be harmful if inhaled or swallowed. Do not pipette by mouth. Avoid contact with skin and eyes. In case of contact, flush 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
MISSION Microalbumin Kit are for use on Mission Diagnostics Affirm C200[1]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[10]:

MD-101211 – Microalbumin Calibrator

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
Creatine: No interference up to 100 mg/dl
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 Affirm C200 and Beckman AU680 Analyzers. Other instruments may yield different performance data.

[1] Also known as Zybio EXC200 Analyzer

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Linearity
The following results were obtained on an Affirm C200 and Beckman AU680 Analyzers using the MISSION Microalbumin Kit on samples containing 0, 0.5, 1, 5, 10, 30 mg/L microalbumin. The table below includes mean, standard deviation (SD) and Coefficient of Variation (CV) for each value.

Mean (mg/L)	SD	CV%
0.008	0.013	163.0
0.490	0.033	6.8
0.964	0.012	2.2
4.782	0.046	1.0
9.594	0.358	3.7
28.188	1.512	5.4

Precision
Studies performed on Affirm C200 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/L)	**SD**	**CV%**	**Mean** (mg/L)	**SD**	**CV%**
3.832	0.108	2.8	4.345	0.434	10.0
12.889	0.194	1.5	13.525	0.564	4.2

Analytical Specificity
Cross contamination studies have not been performed on Affirm C200 and Beckman AU680 Analyzers. 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 Affirm C200 and Beckman AU680 Analyzers using the parameters listed below.

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. Under typical operating conditions manufacturer calibration stability studies have shown the calibration curve will be stable for at least 14 days.

Method Parameters

Analyzer Specific Settings

Method type:	Endpoint
Slope:	positive
Units	mg/L
DOM wavelength	340
SUB wavelength	700
Sample volume	2.0
R1 volume	160
R2 volume	50
Blank rxn read (cycles)	16 - 20
Sample rxn read (cycles)	36 - 40

Calibrator settings

Calibration Type	Logit-5P
Reagent Blank required	No
Calibrator 1	0
Calibrator 2	1
Calibrator 3	5
Calibrator 4	10
Calibrator 5	30

Analytical Measuring Range (AMR)

Range: (low)	0
Range: (high)	30

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