MEDICA

IVD CE

REF 10225-4 4 x 29 mL/8 mL

MICROALBUMIN (µALB)
Wedges each contain usable volumes of 29 mL of R1 reagent and 8 mL of R2 reagent.

Intended Use
The EasyRA µALB reagent is intended for the quantitative determination of microalbumin in human urine, using the Medica EasyRA Chemistry Analyzer in clinical laboratories. Microalbumin measurements using immunological tests aid in the diagnosis of kidney diseases.

For *in-vitro* diagnostic use only.

Summary and Explanation
Low concentrations of protein are normally excreted into the urine of healthy individuals. The excreted proteins are mucoproteins, most of which are filtered out of the uriniferous tubules and the glomeruli. Albumin, a protein of molecular weight of 50,000, is not easily filtered out and is excreted into the urine (microalbuminuria). [1, 2] This makes albumin excretion into the urine a useful indicator of early glomerular disease.

Microalbuminuria is characterized by increased urinary excretion of albumin in the absence of overt nephropathy.[3,4] Microalbumin is recognized as a strong predictor of impending nephopathy in Type 1 Diabetics and its mortality risk in the diabetic patient.[5] Early detection of microalbuminuria may be beneficial for treatment programs for diabetics because renal damage may be reversible if diabetes is well controlled at this stage.

Many of the methods traditionally used for measuring albumin lack the sensitivity and precision required for measuring microalbumin. This Microalbumin method uses an immunoturbidimetric format which provides the sensitivity required for accurate measurement of urinary microalbumin.

Principle of the Procedure
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 700 nm and albumin in the sample is quantitatively determined. The concentration of µALB in unknown samples is derived from a calibration curve using the Spline Curve fit routine.

REAGENTS

µALB Reagent (R1):

Buffer Reagent, pH 7.6	
Tris(hydroxymethyl) aminomethane	<100 mM
Preservative	<0.06%

µALB Reagent (R2):

Antiserum Reagent, pH 7.6	
Anti-human albumin, goat antiserum	<20%
Tris (hydroxymethyl) aminomethane	<100 mM
Preservative	<0.06%

Precautions

1 Good laboratory safety practices should be followed when handling any laboratory reagent. (*CLSI,* GP17-A2).
2 The reagent contains less than 0.1% of sodium azide, which may react with lead and copper plumbing to form highly explosive metal azides. Refer to the Safety Data Sheet for risk, hazard and safety information.
3 As with any diagnostic test procedure, results should be interpreted considering all other test results and the clinical status of the patient.
4 Do not use washed cuvettes.

Instructions for Reagent Handling, Storage and Stability
The reagent is ready to use as supplied. Unopened reagent is stable until the expiration date listed on the label if stored at 2°-8ºC. The reagent is stable on-board in the refrigerated reagent area of the Medica EasyRA Chemistry Analyzer for the number of days programmed on the RFID chip on the reagent wedge. Do not use the reagent if it is turbid or cloudy or if it fails to recover known microalbumin control values.

Specimen Collection and Storage / Stability
The specimen should be a fresh or 24 hour urine. Urine specimens should be stored refrigerated (2º-8ºC). If the assays are not completed within 14 hours, specimens can be stored up to 2 weeks at 2-8ºC. If specimens are hazy or turbid, they must be centrifuged prior to analysis at about 3300 RPM for 5 minutes. Refer to NCCLS H18-A for further instructions on specimen collection, handling and storage. Do not use frozen samples.

PROCEDURE
Materials Provided
Medica µALB Reagent Wedge, REF 10225

Additional materials required
Medica µALB Multi-Calibrator Set, 6 Calibrators: Approx. values: (0, 0.5, 1.0, 5.0, 10.0, 30.0) REF 10656
Bio-RAD Liquichek™ Urine Chemistry Control, Level 1 and 2 or other Urine Chemistry Controls
Medica Precision Test Dye Wedge, REF 10764
Medica Cleaner Wedge – Chemistry & ISE, REF 10660 or
Medica Cleaner Wedge – Chemistry, REF 10661

Instructions for Use
The reagent is ready to use as supplied. Remove the cap and place the reagent in the Medica EasyRA Chemistry Analyzer reagent tray located in the reagent area. Opened reagent is stable on-board in the refrigerated reagent area of the EasyRA Analyzer for the number of days programmed on the RFID chip on the reagent wedge (31 days maximum).

Note: Check the inside of the necks of the wedge for foam after removing the caps and placing the wedge on the analyzer. If there is foam, remove it with a swab or a disposable pipette before performing the test. Use separate swabs or disposable pipettes for R1 and R2.

Note: Any used cuvette containing the µALB test should be discarded and replaced after each worklist. In rare instances, the absorbance of a cuvette used to perform the µALB test approaches an absorbance reading similar to that of an unused cuvette.

Calibration
Medica µALB Multi-Calibrator Set, REF 10656 is required for the calibration of the assay. The multi-point calibration interval (31days maximum) is programmed on the RFID chip on the reagent wedge. Recalibration is required whenever there is a change in reagent lot number or if a shift in quality control values occurs. Approximate values of the µALB Calibrator set are 0, 0.5, 1.0, 5.0, 10.0, 30.0 mg/dL (for actual values see Calibrator Kit insert sheet).

Quality Control
It is recommended that two levels of human urine based controls (normal and abnormal) be run with the assay daily, whenever patient samples are performed and with each reagent lot change. Failure to obtain the proper range of values in the assay of control material may indicate reagent deterioration, instrument malfunction, or procedural errors. The laboratory should also follow local, state, and federal quality control guidelines when using quality control materials.

Results
After completion of the assay, the Medica EasyRA Chemistry Analyzer calculates the µALB concentration of each sample. The concentration is derived from a multi-point calibration curve using an appropriate mathematical model such as spline.

Expected Values
It is recommended that each laboratory establish its own range of expected values, since differences exist among instruments, laboratories and local populations.

The expected value for Microalbumin is 30-300 mg/24 hours[6]. Microalbumin concentrations of random urine specimens should be expressed as albumin-to-creatinine ratio[5].

Procedural Limitations (e.g., if sample is above assay range)
The Medica EasyRA Chemistry Analyzer flags any result above 30 mg/dL as Linearity High “LH”. Samples exceeding the upper limit of linearity should be diluted and repeated. If the “Re-run” icon is selected by the operator, the sample may be re-tested using an automatic dilution of one tenth (1/10) the sample volume. The instrument automatically replaces the reduced sample volume with saline solution. The retest results are calculated to reflect the use of the smaller sample volume. Therefore, for samples in the µALB range of 30 to 300 mg/dL (extended range), the EasyRA will provide the “True Value” taking into account the 1:10 dilution of the sample. This will effectively extend the reportable range of the µALB test to 300 mg/dL.

Prozone (hook effect)
The hook effect has been observed above 400 mg/dL. It is recommended that urine samples be prescreened for high levels of protein by an alternative method. Samples with grossly elevated protein levels should not be assayed for microalbumin.

Performance characteristics [7]

Reportable Range
The reportable range is 0.5 to 30 mg/dL.
Extended range is 0.5 to 300 mg/dL when 1/10 of the sample is used (1:10 dilution).

Inaccuracy / Correlation (CLSI, EP9-A2)
The following table lists the data obtained in a comparison of the Medica Reagent for µALB (y) on the Medica EasyRA Chemistry Analyzer to the performance of the Pointe Scientific µALB reagent (x) on the Roche COBAS MIRA Analyzer. The data shown below represents single determinations obtained on the Medica EasyRA Chemistry Analyzer vs. the average of 2 replicate values obtained on the Roche COBAS MIRA Analyzer.

Number of samples	91	Range of Samples	0.62 to 28.72 mg/dL
Slope	1.0081	y Intercept	0.0117
Correlation Coefficient	0.9974	Regression Equation	Y = 1.0081*X + 0.0117

Imprecision (CLSI, EP5-A2)
Duplicate measurements of each levels of QC material were tested twice a day for 20 days. Both total and within-run imprecision were calculated from these data.

Within run imprecision:

QC Level mg/dL	Within Run SD mg/dL	Within Run CV %
0.86	0.02	2.56
5.36	0.061	1.14
22.96	0.483	2.10

Total Imprecision:

QC Level mg/dL	Total Imprecision SD mg/dL	Total Imprecision CV %
0.86	0.032	3.79
5.36	0.167	3.11
22.96	0.940	4.09

Linearity (CLSI, EP6-A)
Linear from 0.5 to 30 mg/dL, based on the linear regression Y = 0.9830*X + 0.0629. The linear range can be extended above 300 mg/dL .

Interfering Substances (NCCLS, EP7-A)
Less than 10% change in the value was classified as “no significant interference”.

Substance	µALB at 10 mg/dL No Significant Interference up to:	µALB at 1.0 mg/dL No Significant Interference up to:
Hemoglobin	100 mg/dL	100 mg/dL
Bilirubin	23.6 mg/dL	23.6 mg/dL
Ascorbic Acid	250 mg/dL	250 mg/dL
Glucose	560 mg/dL	560 mg/dL
Calcium	200 mg/dL	200 mg/dL
Creatinine	800 mg/dL	800 mg/dL
Urea	10 g/dL	10 g/dL
Uric Acid	150 mg/dL	75 mg/dL
Acetone	350 mg/dL	700 mg/dL
Urobilinogen	50 mg/dL	30 mg/dL
Kappa Light chain	50 mg/dL	50 mg/dL
Lambda Light chain	50 mg/dL	30 mg/dL
Furosemide	800 µg/mL	800 µg/mL
Trichloromethiazide	50 µg/mL	50 µg/mL
Acetaminophen	0.5 mg/mL	0.5 mg/mL
Ibuprofen	5 mg/mL	5 mg/mL
Glybenclamide	30 µg/mL	30 µg/mL
Metformin HCl	8 µg/mL	8 µg/mL

Note:
In addition to the above substances, other compounds/drugs may interfere with the urine µALB assay on the EasyRA.
Consult “Effects of Drugs on Clinical Laboratory Tests”, by D.S. Young, AACC Press, 5th edition or later.

References

1 Harmoinen, A. et.al. Clinica Chimica Acta 149: 269-274, 1985.
2 Morgensen, C.E., N. Engl. J. Med., 310: 356-360, 1984.
3 Morgensen, C.E., N. Christensen, C.K., N. Engl. J. Med. 311: 89-93, 1984.
4 V. berti, G.C., et al. Lancet. 1430-32, 1982.
5 Tietz, N.W. (Ed), Fundamentals of Clinical Chemistry, W.B. Saunders C., Toronto, 636-638, 937 (1970).
6 Stephenson, J.M., et al, Diab. Med. 12:149-155 (1995).
7 Data on file at Medica.

EasyRA Assay Parameters (µALB)

Primary Wavelength (nm)	340
Secondary Wavelength (nm)	700
Reaction Type	TIA – Turbidimetric Immunoassay
Reaction Direction	Increase
Reagent Blank	No
Sample Blank	Yes
Reaction Time (Incubation Period)	9.6 min
Reaction Temperature	37ºC
Calibration interval (maximum)	31 days
Reagent on-board stability	31 days

Urine

Sample volume (µl)	15
Reagent volume R1 (µl)	150
Reagent volume R2 (µl)	40
Decimal Places (default values)	2
Units (default values)	mg/dL
Linearity	0.5 to 30 mg/dL

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