UnityPoint Health Pekin
Department of Pathology
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Effective Date: 02/18/19
Date Reviewed/ Date Revised: 02/18/19

MICROALBUMIN

CHEMISTRY, DIMENSION® RXL
MALBU/MACRA

I. PRINCIPLE

The microalbumin (MALB) method is the direct quantitation of albumin in urine samples based on a particle-enhanced turbidimetric inhibition immunoassay (PETINA).

II. CLINICAL SIGNIFICANCE

Measurement of albumin in urine aids in the diagnosis of kidney diseases.

III. SPECIMEN

A. Urine samples can be collected using recommended procedures**.**
B. Specimens are tested straight and untreated.
C. Centrifuge prior to testing when the urine is cloudy or turbid.
D. Verify the identity of all patient specimens by the original label, and/or barcode.
E. Label any aliquots with the patient full name and/or accession number or patient MRN.
F. Specimens should be processed as soon as possible after receipt or refrigerated at 2-8°C.
G. Urine specimens may be stored at 8°C for up to 14 days. The use of frozen samples is not recommended.
H. The following samples are acceptable:
    1. Second morning urine
    2. First-morning sample for simultaneous albumin and creatinine measurement.
    3. 24-hour collection
    4. Overnight (8-12 hour) collection
    5. One to two hour collection
I. Samples should not be collected after exertion, in the presence of urinary tract infection, during acute illness, immediately after surgery, or after an acute fluid load.
J. Specimens should be collected without preservatives.
K. Specimens visibly contaminated with blood are not suitable for analysis of albumin concentration.

IV. REAGENT

A. Microalbumin (MALB) Flex® reagent cartridge, Cat. No DF114.
B. Wells 1 and 2 contain liquid particle reagent at 2 mg/mL and Microbial inhibitors
C. Wells 3 and 6 contain liquid NaOH at 0.5N.
D. Wells 4 and 5 contain liquid antibody to human albumin at 140ug/mL from mouse monoclonal and Microbial inhibitors.

E. Wells 7 and 8 are liquid Buffer and Microbial inhibitors.
F. Open well stability is 3 days for wells 1-8.
G. All reagents are liquid and ready to use. Store at 2 -8°C

V. INSTRUMENTATION/EQUIPMENT

A. Dimension® RXL Max® Chemistry analyzer

VI. CALIBRATION

A. Microalbumin Calibrator, Cat No. DC114
B. Five calibration levels at 0, 1.2, 2.5, 5.0 and 11 mg/dL.
C. Calibration frequency is every 30 days for one lot, with each new lot of reagent Flex® cartridges, after major maintenance or service, if indicated by quality control results, as indicated in laboratory quality control procedures, and when regulated by government agencies.

VII. QUALITY CONTROL

A. Quality Control is performed daily using the Bio-Rad Urine Chemistry control consisting of two levels of control.
B. All QC procedures must be followed if results are outside the acceptable limits.

VIII. PROCEDURE:

MICROALBUMIN, Random Urine (MALBU)
MICROALBUMIN/CREATININE RATIO (MACRA)

1. Urine specimen is tested straight and untreated.
2. Identify specimen with two forms of information. Specimen should have a Sunquest generated barcode label with the patient information.
3. Specimen should be centrifuged before testing if cloudy or turbid.
4. Place patient barcoded tube onto analyzer and start by pressing "RUN"

~~4.~~

5. If the microalbumin result exceeds the linear range of the analyzer, the analyzer automatically performs a 1:10 dilution of the urine, and the results print out with the dilution correction already applied. The word "dilution" is on the printout next to the result. If it has been diluted and is still out of the assay range, the words "assay rng/diluted" are on the printout and manual 1:2 dilution must be performed with CLR water. See the AMR chart.

~~a.~~6. If the creatinine result exceeds the linear range of the analyzer, a manual dilution must be performed with CLR water. The recommended manual dilution factor is 1:2

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IX. REPORTING RESULTS

A. Microalbumin:random (MALBU)
1. Microalbumin **r**esults are reported as mg/dL**.**

2. Analytical Measurement Range (AMR) for Microalbumin is 0.13 – 10.0 mg/dL
3. Clinically Reportable Range (CRR) is 0.13 – 200 mg/dL

C. Microalbumin/creatinine ratio (MACRA)
The calculation is performed by Sunquest when results are entered.
The calculation is:

$$\frac{\text{Urine microalbumin (mg/dL)}}{\text{Urine creatinine (mg/dL)}} \times 1000$$

X. PROCEDURAL NOTES/PROBLEM-SOLVING TIPS

A. Turbidity and particles in the sample may interfere with the determination.
B. The analyzer reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in albumin results. Refer to the Siemens Dimension® Rxl Max® Operator Guide for report flags and comments. Any report containing flags and/or comments should be addressed before reporting patient results.

XI. REFERENCES

A. Siemens Healthcare Diagnostics, Inc. Method Insert Sheet, 03/2015
B. Dade Behring Inc. Dimension® RxL Max® Operator's Guide 06/2008

POLICY CREATION :		***Date***
Author:	***Suzanne Behle, MT (ASCP)***	***02/18/2019***
Medical Director:	***Lori Racsa, DO***	***02/18/2019***

MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
SECTION MEDICAL DIRECTOR		

REVISION HISTORY (began tracking 2011)			
Rev	Description of Change	Author	Effective Date

Lead	Date	Coordinator/ Manager	Date	Medical Director	Date

Reviewed by