The Micro-albumin Turbidimetric Immunoassay Kit

Catalogue number: 51960

For the quantitative determination of Micro-albumin in human urine

This package insert must be read in its entirety before using this product
Use only the current version of product data sheet enclosed with the kit

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FOR RESEARCH USE ONLY
NOT FOR USE IN DIAGNOSTIC PROCEDURES

Version: 1.1

TABLE OF CONTENT

PACKING SPECIFICATION

Cat. No.	Size	Approximately tests
51960-05	R1: 15ml, R2: 5ml	100
51960-10	R1: 30ml, R2: 10ml	200
51960-20	R1: 60ml, R2: 20ml	400
51960-50	R1: 150ml, R2: 50ml	1000
51960-100	R1: 300ml, R2: 100ml	2000

INTRODUCTION

Micro-albumin(mALB), also known as urine albumin, is an important blood protein predominantly made by liver tissue that balances the blood osmotic pressure and transports hormones, vitamins, and substances like calcium throughout human body. Under normal circumstances, micro-albumin with 66kDa molecular weight is too large to cross the glomerular basal membrane. During kidney diseases, the pathological damage to the glomerular membrane leads to changes in permeability, and eventually causes micro-albumin excess excretion in urine. Therefore, micro-albumin is a sensitive and decisive biomarker for kidney injury. Micro-albumin test can timely detect kidney disease at early stage and help doctors make a right diagnosis to prevent deterioration. A higher level of micro-albumin in urine indicated the more severe kidney damage. The reference of micro-albumin in health human is less than 20mg/L, and Reversible renal injury is among 20mg/L to 200mg/L, and Irreversible renal injury (renal failure or uremia) is above 200mg/L.

PRINCIPLE OF THE ASSAY

This assay is a turbidimetric immunoassay for the quantitative measurement of micro-albumin in human urine. A standard or sample is added into a cuvette and mixed with the reaction buffer R1. After a short incubation, the test reagent R2, which is a suspension of microparticles coated with an antibody highly specific to micro-albumin, is added into the cuvette and mixed. The presence of micro-albumin in the standard or sample causes the immune-particles to aggregate. The extent to which the microparticles aggregate is quantified by the amount of light scattering measured as absorbance by a chemistry analyzer. The concentration of Micro-albumin in unknown samples can be interpolated from a reference curve using the

standards provided.

REAGENTS SUPPLIED

R1 – Reaction buffer, a ready-to-use buffer solution containing salt, polyether compound and preservative

R2 – Test reagent, a ready-to-use suspension of polymer microparticles coated with normal human IgG polyclonal antibodies in storage buffer

OTHER MATERIALS REQUIRED

1. Clinical chemistry analyzer
2. Micro-albumin Calibrator (provided separately, Cat. #51960-S1)
3. Micro-albumin Control (optional, provided separately, Cat. #51960-C1)
4. Deionized water
5. Analyzer-specific reagent containers for R1 and R2

STORAGE

The kit should be stored at 2-8°C upon receipt. Once opened, the reagents may be stored at 2-8°C for up to 4 weeks.

SAMLE HANDLING

This kit can be used to determine Micro-albumin in human urine samples. Urine specimens should be collected aseptically into appropriate tubes. The prepared specimens should be stored in closed vessels. If the assay cannot be performed within 24 hours or specimens are to be shipped, the specimens should be frozen at −20°C or below. For long- term storage of specimens, −70°C or below is recommended. To avoid freeze-thaw cycles, specimens should be aliquoted. Do not use hemolyzed, hyperlipemic, heat-treated or contaminated specimens. No dilution of the sample is required in this assay.

ASSAY PROCEDURE

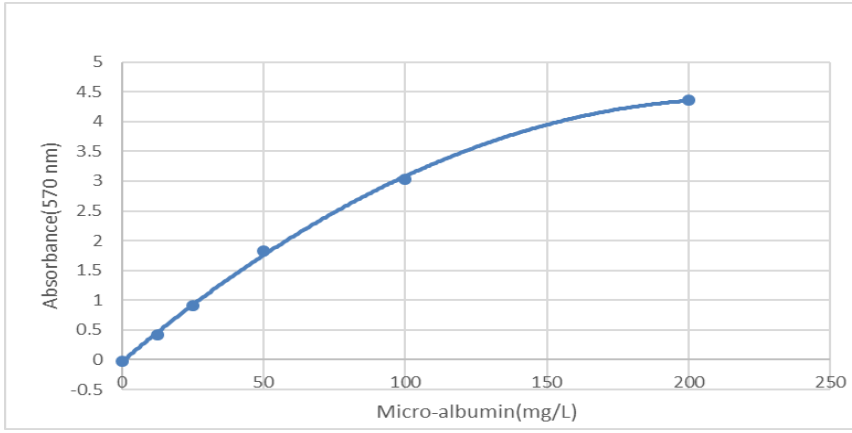
Assay procedures may vary depending on the automated chemistry analyzer to be used. A general example of assay procedures is stated as follow:

1. Dispense 150µl of R1 into a clean cuvette
2. Add 1.5µl of urine sample or Micro-albumin calibrator and incubate at 37˚C for 5 minutes
3. Further add 50µl of R2
4. Read change of absorbance at 570 nm for 8 minutes after the addition of R2
5. Calculate the concentration of Micro-albumin in unknown sample by interpolation from a reference curve using the standards provided

TYPICAL STANDARD CURVE

The following standard curve is provided for demonstration only. A standard curve should be generated for each assay.

Micro-albumin (mg/L)	Absorbance (570 nm)
0	-0.023
12.5	0.418
25	0.909
50	1.833
100	3.037
200	4.356



CALCULATION

1. Subtract the absorbance of the blank from that of standards and samples.
2. Generate a standard curve by plotting the absorbance obtained (y- axis) against Micro-albumin concentrations (x-axis). The best fit line can be generated with any curve-fitting software by regression analysis. 4-parameter curve fitting can be used for calculation.
3. Determine micro-albumin concentration of samples from standard curve.

ASSAY CHARACTERISTICS

A. Sensitivity

The sensitivity is defined as the lower limit of detection and is estimated as the mean of the blank sample plus three times the SD obtained from the blank sample. The sensitivity of Micro-albumin assay is 0.5mg /L.

B. Precision

The precision of the micro-albumin assay is < 5% CV. two human urine samples were assayed 20 times separately.

Sample	Mean Micro-albumin (mg/L)	SD (mg/L)	CV
Panel 1	8.72	0.166	2.15%
Panel 2	2.38	0.072	3.31%

C. Linearity

The micro-albumin assay is linear between 0.5 mg/L to 200 mg/L.

D. Interference

No interference was detected with hemoglobin up to 5g/L, conjugated bilirubin up to 300 mg/L, free bilirubin up to 300 mg/L, and up to 5g/L lipid emulsion.