Micro Albumin Kit
CliniQuant-TIA

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 Buffer	R2 Antiserum Reagent	R3 Calibrator
MALTIA-01	1 x 40 /1 x 10ml	1 x 40ml	1 x 10ml	1 x 1ml

INTENDED USE

CliniQuant-TIA Micro Albumin Kit is intended for the quantitative determination of micro albumin in human urine by turbidimetric immunoassay.

CLINICAL SIGNIFICANCE

Urinary albumin excretion between 30-300 mg/day (Microalbuminuria), far below the levels found in clinical Proteinuria (> 300 mg/day) is a strong predictor of development of Diabetic nephropathy and vascular complications. Diabetic nephropathy leads to progressive loss of renal function or end stage renal disease (ESRD) and may necessitate need for dialysis or transplantation in most cases. The progression of Microalbuminuria is closely associated with progressive hypertension and loss of blood glucose control. The early presence of Microalbuminuria can be reversed by strict metabolic control and timely intervention of drugs early in the course of disease can arrest the progression of diabetic renal disease. Quantitative values of albumin are useful for differentiating Microalbuminuria from clinical proteinuria and the effective monitoring of intervention strategies. Annual screening of Microalbuminuria is recommended by 'WHO' and 'International Diabetes Foundation' in all patients with IDDM over the age of 12 years and who have had diabetes for five years or more. Microalbuminuria is also a significant risk marker of cardiovascular diseases. Its presence can be regarded as an index of increased cardiovascular vulnerability and a signal for correction of known risk factors. Information regarding the concentration of albumin in urine for the detection of Microalbuminuria can be obtained by using Clinquant-TIA Micro Albumin reagents.

PRINCIPLE OF THE METHOD

CliniQuant-TIA Micro Albumin Test is a turbidimetric immunoassay for the detection of albumin in urine and is based on the principle of agglutination reaction. The test specimen is mixed with the activation buffer (R1) and Antiserum reagent (R2) and allowed to react. Presence of albumin in the test specimen forms an insoluble complex producing a turbidity, which is measured at wavelength 340 nm. The resulting turbidity corresponds to the concentration of albumin in the test specimen.

KIT COMPONENTS

Composition :

R1-Buffer: Phosphate buffered saline, Accelerator, Sodium azide (0.09 %)

R2-Anti serum Reagent: Saline (9 g/l), Polyclonal goat anti-human Albumin (variable), Sodium azide (0.09 %)

R3-Calibrator: Dilution of defibrinated human plasma with phosphate buffered saline. Pooled human serum, liquid and stabilized. Contains 0.09 % sodium azide. Concentration is lot specific, see vial label.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Micro pipettes of appropriate volume (the use of accurate pipettes with disposable plastic tips is recommended).
2. 0.9% Saline
3. Vortex mixer
4. Water bath (37°C)
5. Appendorfs or test-tubes.
6. Instrumentation: Semi auto analyzer

REAGENT STORAGE & SHELF-LIFE

Reagents are ready to use. Keep away from direct light sources.

Stability: up to expiration date on labels at 2-8 °C.

Stability since first opening of bottle: within 15 days at 2-8 °C if contamination is avoided. Do not freeze the reagent.

WARNINGS AND PRECAUTIONS

1. For *in vitro* use only.
2. Do not modify the test procedure or substitute reagents from other manufacturers. It is recommended to handle carefully by entitled and professionally educated person.
3. Shake the R2: Antiserum reagent well before use to improve test performance.
4. Do not pipette by mouth. Specimens should be considered infectious and handled appropriately. Use disposable gloves while performing the assay. Wash hands thoroughly when finished.
5. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines to avoid microbial contamination of reagents as this may reduce the life of the product and cause erroneous results.

SPECIMEN:

Fresh Urine Sample

Programme Parameter for MERILYZER CliniQuant

Reading Mode	Sample blank non-linear
Calibrator Conc.	(mg/L) See vial label
Filter – 1 (nm)	340
Temperature	37 °C
Volume (µl)	450
Delay Time (Sec)	5
Reaction Direction	Increase
Standard nos.	6
Reference Low	0
Reference High	25

TEST PROCEDURE

Bring reagents and specimen to room temperature before use.

Preparation of calibration curve

The concentration of R3: Calibrator is as mentioned on the vial label.

Dilute the calibrator serially as mentioned below for preparation of calibration curve.

Test Tube No.	1	2	3	4	5	6
Calibrator dilution No.	D1	D2	D3	D4	D5	D6
0.9% Saline	-	100 µl	100 µl	100 µl	100 µl	100 µl
Calibrator	200 µl	100 µl	100 µl	100 µl	100 µl	100 µl

The above five dilutions of the calibrator including the highest (D1) and lowest (D6) concentrations of measuring range must be used for the preparation of the calibration curve.

"The calibration curve so obtained is valid only for the same lot of reagents.

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Test procedure:

(Note: During calibration on instrument with programming facilities, increasing concentration of standards must be used for preparing the calibration curve).

1. Pipette 800 µl Buffer (R1) and mix 24 µl standards, controls and samples.
2. Read optical density (OD1) of samples, controls and standards at 340 nm.
3. Add 200 µl of antiserum to the above mixture.
4. Mix and incubate for 5 minutes at 37°C.
5. Read the optical densities (OD2) of samples, controls and standards at 340 nm.

RESULTS

Calculate ΔOD's, plot a standard curve and read the concentration of controls and samples.

1. Interpolate ΔOD of the diluted test specimen on the calibration curve and obtain the albumin concentration 'C' of the diluted test specimen.
2. Multiply the albumin concentration 'C' with the dilution factor (F) of the test specimen for obtaining the concentration of albumin in the neat test specimen.
3. Concentration of albumin in the neat test specimen in mg/L=C x F
4. (Where 'F' is the dilution factor of the test specimen, for e.g. 2 for 1:2 dilution of test specimen and so on)

VALIDATION CRITERIA

If the ΔOD of the test specimen is less than ΔOD obtained for the calibrator of highest concentration (D1) then the concentration of albumin in the test specimen can be determined directly by interpolating ΔOD of the test specimen on the obtained calibration curve. If the ΔOD of the test specimen is higher than ΔOD of standard with highest concentration (D1) then the test has to be rerun by carrying out serial dilutions of test specimen such as 1:2, 1:4 etc. till the ΔOD of the diluted test specimen is less than ΔOD of D1.The albumin concentration for such samples can be determined as mentioned in calculations.

EXPECTED VALUES

Urinary albumin: < 25 mg/L.

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL

It is recommended to perform internal quality control with assayed normal and assayed abnormal control, to confirm the validity of the test and assure the accuracy of patient result.

Using the kit calibrator included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARCTERISTICS

1. Linearity

The linearity is upto 400 mg/L.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 0.4 mg/L.

3. Interferences

No interference has been observed for the following
Ascorbate up to 20mg/dl; creatinine up to 25 mg/dl;
glucose up to 300 mg/dl

4. Accuracy

mg/L

Control	Assigned	Measured
Level 1	32.7 (26.2 - 39.2)	33.1
Level 2	151.2 (120.9 - 181.3)	150.6

5. Precision

Intra-assay precision

	Mean	SD	CV
n = 30	mg/L	mg/L	%
sample 1	20.0	0.44	2.18
sample 2	155.5	0.73	0.47

Inter-assay precision

	Mean	SD	CV
n = 60	mg/L	mg/L	%
sample 1	20.26	0.50	2.47
sample 2	156.32	1.10	0.70

6. Methods Comparison

Comparison was done between reference Micro albumin Reagent and Micro albumin Kit CliniQuant TIA (test)

N = 20 $y = 1.0026x + 1.4789$

$r^2 = 0.999$

LIMITATIONS

Samples with values above 400 mg/L, it should be diluted with 0.9% saline, re-run and multiply the results by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. S.Basi, A.Mimran, P.Fesler, et al., Microalbuminuria in Type 2 Diabetes & Hypertension, Diabetes Care, vol.31, Supplement 2, 2008.
2. T.Wang, Q.Wang, Z.Wang et al., Diagnostic Value of the Combined Measurement of Serum Hcy, Serum Cys C, and Urinary Microalbumin in Type 2 Diabetes Mellitus with Early Complicating Diabetic Nephropathy., ISRN Endocrinology, Article ID 407452.,2013.
3. B.O.Kwak, S.Chung, K.S.Kim., Microalbuminuria in children with urinary tract infection. Korean J Pediatr, 53(9):840-844.,2010.
4. Data on file: Meril Diagnostics.

IFU/MALTIA01/01
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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged
EC REP	Authorized European Representative in the European Community		