SyRe

TBA-120FR

AGAPPE

MICROALBUMIN

1 x 60/1 x 15 mL
12011050

Intended Use
This reagent is intended for in vitro quantitative determination of microalbumin in human urine
- Turbidimetric Immunoassay
- Linear up to 395 mg/L
- Ready to use reagents
- No need to dilute samples
- Multipoint calibration

Clinical Significance
Albumin is normally found in the blood. When the kidneys are working properly, albumin will not be present in the urine. However, when the kidneys are damaged, small amounts of albumin leak into the urine. This condition is called micro albuminuria.
Micro albuminuria is most often caused by kidney damage from diabetes. However, many other conditions can lead to kidney damage, such as high blood pressure, heart failure, cirrhosis, or systemic lupus erythematosus (SLE). If early kidney damage is not treated, larger amounts of albumin and protein may leak into the urine. This condition is called macroalbuminuria or proteinuria, this can lead to chronic kidney disease.

Principle
The reagents containing polyclonal goat antihuman micro albumin when mixed with the urine sample containing micro albumin cause changes in absorbance, due to the development of turbidity, which is directly proportional to the concentration of microalbumin in the sample.

Kit Components

Reagent/ Component	Product Code 12011050	Description
Microalbumin R1	1 x 60 mL	Saline (9 g/L) Accelerator Sodium azide (0.95 g/L)
Microalbumin R2	1 x 15 mL	Phosphate buffered saline Polyclonal goat anti-human albumin (variable) Sodium azide (0.95 g/L)

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation
Microalbumin R1 & R2 Reagents are ready to use.

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2-8^{o}C.

Open Vial Stability
Once opened the reagents are stable up to 90 days if contamination is avoided.

On-board Calibration Stability
Calibration is stable for 20 days.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
To avoid contamination, use clean laboratory wares. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.
This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Fresh Urine

Interferences
No interference for
Hemoglobin up to 1000 mg/dL
Bilirubin up to 10 mg/dL

Materials provided
Microalbumin R1 & R2 Reagent

Reagents required but not provided
Agappe Microalbumin Calibrator (Product Code: 11618003)
Agappe Microalbumin Control (Bi-Level) (Product Code: 11635002)

Calibration
Agappe Microalbumin Calibrator (Product Code: 11618003) is recommended for calibration of the assay.

Preparation of Calibration Curve
Prepare the following calibrator dilution using Normal saline as diluent. Multiply the concentration of the Microalbumin Calibrator by the corresponding factors stated in the table below to obtain the Microalbumin concentration of each dilution.

Dilution	1	2	3	4	5	6
Cali. (µL)	-	10	10	25	50	100
Normal Saline (µL)	100	150	70	75	50	-
Dil. factor	0	0.0625	0.125	0.25	0.5	1.0

Quality Control
It is recommended to use the Agappe Microalbumin Control (Bi-Level) (Product Code: 11635002) to verify the performance of the assay.
Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

Reference Range
It is recommended that each laboratory should establish its own reference values. The following value may be used as guide line.
Urine : 0 - 25 mg/L (IFCC)
Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance
1. Linearity
The reagent is linear up to 395 mg/L. If the concentration is greater than linearity (395 mg/L), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison
A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.9977 and a regression equation of y = 1.0121x.

3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/L)	28.19	88.98	28.08	88.81
SD	1.21	2.33	1.06	1.86
CV(%)	4.30	2.62	3.78	2.10

Accuracy (mg/L)		
Control	Expected Value	Measured Value
Control Level 1	22.1 ±9.1	23.69
Control Level 2	82.2 ±26.9	85.41

4. Sensitivity
Lower detection Limit is 4 mg/L

Bibliography

1. Mount, J. J. Clin. Pathology, 22, 12 (1986)
2. Schmidtz, A. et al., diabetic Medicine, 5 , 126 (1988)

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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CE ISO 9001:2015
EN ISO 13485:2016