TRUEchemie Microalbumin (mAlb) Test Kit (Immunoturbidimetry)

For the quantitative turbidimetric test for the measurement of Microalbumin in human urine

INTENDED USE

The TRUEchemie Microalbumin (mAlb) Test Kit (Immunoturbidimetry) is a quantitative turbidimetric test for the measurement of Microalbumin in human Urine

INTRODUCTION

Microalbuminuria is defined as excretion of albumin between 20 and 200 micrograms / L. Persistent microalbuminuria indicates a high probability of damage to the glomerular filtration capacity of the kidney and is of great diagnostic relevance: (a) in diabetes, for early diagnosismof diabetic nephropathy; (b) in patients with hypertension, as an indicator of end-organ damage associated with a lowered life expectancy; (c) in pregnancy, as a possible predictor of developing pre-eclampsia. For screening, a concentration of 20-200 mg/L of albumin in the first morning urine has been proven to be a suitable indicator.

PRINCIPLE

Latex particles coated with specific antibodies anti-human albumin are agglutinated when mixed with samples containing Microalbumin (µALB). The agglutination causes an absorbance change, dependent upon the µALB contents of the patient sample that can be quantified by comparison from a calibrator of known µALB concentration.

PACK SIZE

Kit Size	50 mL
Cat No.	ADX932
Kit contents	
1) Micro albumin Diluent (R1)	1 x 40 mL
2) Micro albumin Latex (R2)	1 x 10 mL
3) Micro albumin Calibrator	1 x 0.5 mL

REAGENTS COMPOSITION

Micro albumin Diluent (R1)	Glycine buffer 100 mmol/L, ph 10.0, preservatives
Micro albumin Latex (R2)	Latex particles coated with goat IgG antihuman Albumin, PH 8.2, Preservatives
Micro albumin Calibrator	Microalbumin concentration is as stated in vial

REAGENT PREPARATION

Ready to use reagents.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Handle cautiously as potentially infectious.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.

CALIBRATION

TRUEchemie Microalbumin calibrator is ready to use. Calibrate with each bottle change or lot change or if control results are found to be out of range.

REAGENT STORAGE & STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8 ºC and contaminations are prevented during their use. Do not use reagents over the expiration date. Do not freeze; frozen Latex or Diluent could change the functionality of the test.
Reagent deterioration: Presence of particles and turbidity.
Working reagent: Stable for 30 days at 2-8 ºC.
Liquid stable Calibrator to be stored at 2-8 ºC

SPECIMEN COLLECTION AND STORAGE

Fresh Urine. It is recommended to adjust the pH at 7.0 with NaOH/HCL (1 mol/L). Stable 7 days at 2-8 ºC when sodium azide 1 g/L is added to prevent contamination. Urine should be centrifuged before testing.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37°C heating block or water bath
5. Photometer capable of measuring absorbance at 540 nm filter

TEST PROCEDURE

Wavelength: 540 nm
Temperature: 37°C
Cuvette light path: 1cm
Prewarm the reagents to reaction temperature

	Blank (µl)	Calibrator (µl)	Sample (µl)
Distilled water	1000	--	--
Micro albumin Diluent (R1)	--	800	800
Micro albumin Latex (R2)	--	200	200
Microalbumin Calibrator	--	10	--
Sample	--	--	10

Reading & Calculations
Blank the Photometer with Distilled water.
Mix well and read absorbance of sample and test against distilled water at 540 nm as follows:
Initial absorbance A_0 – Exactly after 10 sec.
Final absorbance A1 – Exactly after 120 sec. after A_0
Determine Δ A for Calibrator (C) and Sample (S)
$\Delta AC = \Delta AC_1 - \Delta AC_0$
$\Delta AS = \Delta AS_1 - \Delta AS_0$

Calculations:

$$\text{Urine Microalbumin(mg/L)} = \frac{\Delta AS}{\Delta AC} \times \text{Calibrator concentration (mg/L)}$$

QUALITY CONTROL

During operation of the Autochem200 analyser at least two levels of an appropriate quality control material should be tested a minimum of once a day. In addition, controls should be performed after calibration, with each new lot of reagents, and after specific maintenance or troubleshooting steps. Quality control testing should be performed in accordance with regulatory requirements and each laboratory's standard procedure.

EXPECTED VALUE

Up to 15 mg/L
Each laboratory should determine its own expected values as directed by good laboratory practice.

PERFORMANCE CHARACTERISTICS

Sensitivity: 2 mg/L
Linearity limit: Up to 150 mg/L, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit depends on the sample reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
Detection limit: Values less than 2 mg/L give non-reproducible results.
Prozone effect: No prozone effect was detected upon 1000 mg/L

PRECISION:

Intra-assay precision within run (n=10)	Mean (mg/L)	SD (mg/L)	CV (%)
Low	35.7	0.7	2.0
High	151.8	1.5	1.0

Inter-assay precision run to run (n=10)	Mean (mg/L)	SD (mg/L)	CV (%)
Low	35.3	0.8	2.3
High	150.7	1.8	1.2

The reagent was tested for 10 days, using two different Microalbumin concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate Program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie Microalbumin reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.999 and the regression equation is y=1.008x+0.328. The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Glucose (2 g/L), hemoglobin (10 g/L) and creatinine (3 g/L) do not interfere. Urea (≥ 1 g/L) and bilirubin (≥ 10 mg/ dL), interfere. Other substances may interfere

WASTE MANAGEMENT

Please refer to local regulation requirements.

SYSTEMS PARAMETERS

Mode	:	Fixed kinetic
Calibrator concentration	:	As stated on vial
Wave length	:	540 nm
Units	:	mg/L
Flow cell Temp	:	37°C
Blank	:	Distilled water
Reagent volume	:	1000 µl (800 µL (R1) + 200 µL (R2))
Sample volume	:	10 µl
Delay time	:	10 Sec
Read time	:	120 Sec
Normal range	:	up to 15 mg/L
Sensitivity	:	2
Linearity	:	150
Reaction slope	:	Increasing

REFERENCES

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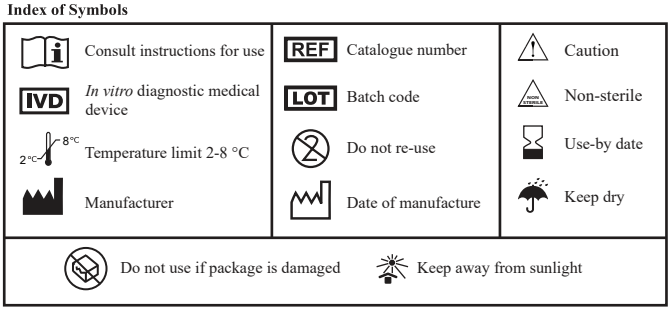
Index of Symbols



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