Microalbuminuria (mALB) – Immunoturbidimetric method

Instructions for Use (IFU)

IVD CE

ORDERING INFORMATION

	Code	Composition
OPEN KONELAB INDIKO	REF B78282271	n° 2 vials x 40 mL (R.A) n° 1 vials x 6 mL (R.B)
CHEMILAB	REF B82181031	n° 1 vial x 26 mL (R.A) n° 1 vial x 6 mL (R.B)

INTENDED USE

Immunoturbidimetric diagnostic test for the quantitative determination of Microalbuminuria (mALB) in human urine. All results must be interpreted in conjunction with the clinical context. FOR PROFESSIONAL USE ONLY.

CLINICAL SIGNIFICANCE

Albumin is a protein formed of a single 66-KD polypeptide chain not associated with carbohydrates. Albumin is normally present in very low concentrations in the urine; there may be significant variations in the concentrations eliminated throughout the day. Although there are marked increases in the amount of albumin excreted in the presence of important renal diseases, the major clinical interest in this parameter is related to low excretory levels which may be associated with an incipient diabetic nephropathy. This is generally known, inappropriately, as "microalbuminuria" (mALB).

Increases in urinary albumin in the absence of significant renal disorders may also be seen in the case of pyrexia due to prolonged exposure to cold, in hypertension, after violent physical exercise and in various systemic disorders.

PRINCIPLE OF THE METHOD

Immunoturbidimetric. The mALB contained in the test sample reacts with the specific antibodies, forming immunocomplexes, which cause a degree of turbidity which can be detected photometrically and is proportional to the mALB concentration in the sample. The quantitative analysis is obtained by interpolation of this photometric value with those found by testing known concentrations of mALB.

Storage and Stability

= **Storage temperature 2-8 °C**

If stored at 2-8°C avoiding direct light, the intact reagents remain stable until the expiration date, printed on the label. Do not freeze. Slight variations in composition among batches will not affect test results.

Concentrazione

Reagent A			
		Conc.	**U.M.**
mALB Buffer	TRIS	0.05	mmol/L
	PEG	5	mmol/L
	NaN_3	< 0.1	%
Reagent B			
mALB Goat antiserum	NaN_3	< 0.1	%

Materials included in the kit

Reagent as described above.

Necessary materials not included in the kit

Controls and calibrators

PRECAUTIONS and WARNINGS

1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. Reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. Do not use the reagent if it is visibly degraded (e.g. presence of corpuscles).
5. All human samples shall be handled and disposed of as potentially infectious material.
6. The kit should only be used by qualified and properly trained technical personnel.
7. Diagnoses shall be carried out exclusively by authorised and qualified personnel.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that complies with current regulations.

Reporting of serious incidents

Please inform the manufacturer (through your distributor) and the competent authority of the member state of the European Union in which the user and/or patient is established, of cases of serious incident that has occurred in relation to the device. For other jurisdictions, reports of serious incidents must be made in accordance with the regulatory requirements of the home Member State. By reporting serious incidents, you help provide more information about the safety of your in vitro medical diagnostic device.

PROCEDURE

Quality Control

Use the Sclavo Diagnostics Int. Controls: Urinary Proteins Control Low B47282223 and High B47282224 for your quality control purposes at least once a day. Repeat the analysis also after calibration. Obtained values must be within the range of acceptability.

Calibration

For calibration, use the Sclavo Diagnostics Int. Urine Proteins Single Level Calibrator B47282222.

Traceability

The mALB value has been determined using the Sclavo reference material.

SAMPLE

Sample types and storage

Samples are represented by normal urine specimens that are routinely delivered to the laboratory; the tests can be performed on both early morning specimens and on 24-hour collections. No special preparation of the patient is necessary.

The analytical method does not require pretreatment or dilution of the sample.

Urine samples must be brought to room temperature before testing, and centrifuged at 2500 rpm for 15 minutes. The clear supernatant is used for the analysis.

PREPARATION OF THE REAGENT

The Reagents are liquid, ready for use. After opening, the Reagents are stable until the expiry date if kept as indicated in "Storage and stability".

Automation

The kit can be used with all automatic analyzers that can meet the operating conditions of the reagent while maintaining the volumetric ratios R1/ R2/C. Validated applications are available for Sclavo Konelab® - Indiko® and CHEMILAB instruments. Applications not approved by Sclavo Diagnostics do not guarantee the performance of the reagent and must therefore be approved under the responsibility of the user.

MANUAL METHOD

The kit, in Open format, can be used manually through the use of spectrophotometer or photometer with the following parameters:

Reaction conditions

Wavelength:	450 nm
Temperature:	37°C
Reaction	Fixed-time

Dispense as follows for the blank, for each calibrator and unknown samples

	Volume (µL)
mALB Buffer (RA)	250
Test Sample	12
Mix and incubate at 37°C for at least 5 minutes, read the absorbance (Abs-1) of the calibrators and samples, then add:	
mALB Reagent (RB)	50
Mix and incubate at 37°C. After 7 minutes, read the absorbance (Abs-2) of the calibrators and samples.	

Note: **The reaction volumes can be varies proportioning without altering the results.**

Results

Concentration of Albumin is obtained as follows:

Generate the calibration curve with the ΔAbs values and the concentration of the single Calibrators. Calculate the analytical result expressed in mg/L. All samples with a concentration of albumin higher than the higher calibration point and/or giving a signal denoting an excess of antigen (in the automated instruments) must be diluted and retested. It is advisable to use doubling dilutions in saline.

Control of the calibration curve

The calibration curve is valid for at least one month. However, its validity should be checked periodically using the SCLAVO Diagnostics Urinary Proteins Control Low B47282223 and High B47282224. The validity is confirmed if the values obtained are within the concentration range of the controls reported on the vial labels.

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Automation
The results are automatically calculated by the analyzer based on the calibration line. The analyzer automatically performs calibration in accordance with the method protocol. The calibration line is calculated automatically by the different instruments.

REFERENCE RANGE
The typical reference range is:
0 – 43.1 mg/L;
0 – 19.6 mg/g Creatinine;
0 – 2.2 mg/mmole Creatinine.
As sex, age, geographical location and other factors can influence the normal values found in the population, each laboratory should determine its own normal, medium and pathological values for its own population.

CHARACTERISTICS/PERFORMANCE
Analytical Range – Antigen excess
The analytical range was tested using a strongly positive sample and serial dilutions of urine in saline solution. The method guarantees a correct response throughout the minimal detectable measurement range and the calibrator higher concentration.
The present method does not show Antigen Excess until 16000 mg/L.

Accuracy
Commercial controls were tested with the present kit and the data obtained with the Konelab analyzer are reported in the table below (mean of three tests).

Level	Replicates	Mean (mg/L)	Expected value (mg/L)	Recovery (%)
Low	25	128.6	127.0	101.25
High	25	385.6	387.0	99.6

Specificity
The method is 100% specific for human Albumin.

Interferences
Influenza was tested on analytical response up to the following concentrations:

Interferent	Limit
Urea	**50 g/L**
Ascorbic Acid	**50 g/L**
Glucose	**100 g/dL**
Haemoglobin	**5 g/L**
Uric Acid	**20 g/L**

Even saturating the urine with boric acid and thymol, or bringing the pH to 3.5, the possible error remains less than 5%. No higher concentrations have been tested. No appreciable interferences were found, and the variations obtained were within the reproducibility of the analytical data. No higher concentrations have been tested. However, given the great heterogeneity of potentially interfering substances and drugs, the results of this test, for diagnostic purposes, must always be evaluated in conjunction with the patient's medical history, clinical examinations and other findings of the medical examination.

Precision of the method

Within-run Precision – Repeatability				
Level	**Replicates**	**Mean (mg/L)**	**DS**	**CV%**
Low	10	32,2	0,4216	1,31
Low	10	32,2	0,4216	1,31
High	10	70,3	1,7129	2,44
Total Precision (Within-lab Precision)				
Level	**Replicates**	**Mean (g/L)**	**DS**	**CV%**
Low	10	23,2	0,7004	3,02
High	10	66,6	1,0143	1,55

Limits of sensitivity
The limit of sensitivity was measured by analyzing scalar dilutions of a concentrated sample. The lowest quantitatively measurable concentration is 2.2 mg/L.

Comparison between methods
The method under consideration was compared with other commercially available method analyzing 57 human urine. The correlation data between the two methods are reported in the table below.

Parameter	Estimation
Intercept	4.62
Slope	0.94
Correlation Coeff. (R)	0.9984

Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

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REVISION	DATE	CHANGE
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