selectra MACH

MICROALBUMIN IP

IMAL
IMAL-M230
R1 : 2 x 25 mL
R2 : 1 x 12 mL

CE

PIMAC-IMAL-EN-V2 (12/2021)

INTENDED USE

This *in vitro* diagnostic reagent is intended for the quantitative determination of albumin in human urine samples on Selectra Mach Series analyzers.

This *in vitro* diagnostic reagent is for professional use only.

CLINICAL SIGNIFICANCE [1-3]

Albumin represents approximately 50% of plasma proteins. In a healthy person, it is present in very low quantity in urine, and any increase of this concentration usually reflects renal glomerular damage. Urinary albumin is also increased in case of physical exercise, high fever or stress. While in case of declared nephropathy the excretion of albumin is higher than 300 mg/day, an excretion rate ranging from 30 to 300 mg/day (called microalbuminuria) is an early marker of chronic kidney disease. In the general population, an increase of urinary albumin is also associated with an increased risk of developing a cardiovascular disease.
In practice, albumin measurement in urine is performed to help in the early diagnosis and monitoring of kidney diseases, especially for patients at risk (diabetic and hypertensive).

LIMITATION OF USE

The quantitative assay of urinary albumin alone can not be used to diagnose a disease or a specific pathology.
The results must be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

METHOD & PRINCIPLE

Immuno-turbidimetry - End Point.

The formation of Albumin/anti-Albumin antibody complexes is started by the addition of the antiserum to the sample in presence of an accelerator. These complexes agglutinate leading to an increase of turbidity measured at 340 nm.

COMPOSITION

Reagent 1: R1
Sodium chloride
Accelerator
Sodium azide < 0.1 % (w/w)
Reagent 2: R2
Buffer pH 7.43
Polyclonal anti-human albumin antibody (goat)
Sodium azide < 0.1 % (w/w)

MATERIALS REQUIRED BUT NOT PROVIDED

- IMAL-0043 µALBUMIN IP CALIBRATOR SET
- IMAL-0046 µALBUMIN IP CONTROL I
- IMAL-0047 µALBUMIN IP CONTROL II
- Normal saline solution (NaCl 9 g/L)
- General Laboratory equipment (e.g. pipette).
- Selectra Mach analyzer and accessories.
- Do not use materials that are not required as indicated above.

PRECAUTIONS OF USE AND WARNINGS

- Consult Safety Data Sheet (SDS) for a proper handling.
- The reagents contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagents always flush with copious amounts of water to prevent azide buildup.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- Do not interchange reagent vials from different kits.

STABILITY

Store at 2-8 °C and protect from light. Do not freeze.
Do not use after expiration date indicated on the vial labels.
On board stability : 8 weeks.

PREPARATION

The device is ready to use.

PRODUCT DETERIORATION

- The product should be clear. Cloudiness would indicate product deterioration.
- Do not use the product if there is visible evidence of contamination or damage (e.g. particle matter).
- Damage to the reagent container may impact on product performance. Do not use the product if there is physical evidence of deterioration (e.g. leakages or punctured container).

SAMPLES

Specimens required [3]
- Urine.
- Using any other specimen type should be validated by the laboratory.

Warnings and precautions
- Sample collection must not be done neither after exertion nor in case of urinary tract infection.[2]
- Samples should be collected in accordance with Good Laboratory Practice and appropriate guidelines that may be in place.

Storage and stability [3]
Urine (no stabilizer)
- 7 days at room temperature
- 1 month at 2-8°C
- Storage at -20°C is not recommended.

REFERENCE VALUES [2]

Urine	Albumin excretion (24h collection) (mg/day)	Albumin/Creatinine ratio (random sample) (mg/g)	(mg/mmol)
Normal	<30	<30	<3.4
Microalbuminuria	30 – 300	30 – 300	3.4 – 34
Macroalbuminuria	>300	>300	>34

Note : *The quoted range should serve as a guide only. It is recommended that each laboratory verifies this range or establishes a reference interval for the intended population.*

INSTALLATION AND USE

Consult Selectra Mach operator manual.
Special Programming instructions: Programming special instructions is mandatory when some combinations of tests are performed together on the analyzer. Refer to Instructions For Use for WASH SOLUTION A & WASH SOLUTION B for adequate programming (See PIMAC-WASH).

PROCEDURE

The application is included in the 2D barcode on this insert.

CALCULATION

Calculations and/or unit conversions are performed by the analyzer.

CALIBRATION

Calibrators from µALBUMIN IP CALIBRATOR SET are traceable to ERM-DA470k/ IFCC reference material.

Calibration frequency : 8 weeks.
Recalibrate when reagent lots change, when quality control results fall outside the established range and after a maintenance operation.

QUALITY CONTROL

It is recommended that quality control sera such as µALBUMIN IP CONTROL I and µALBUMIN IP CONTROL II be used to monitor the performance of the assay.
Controls have to be performed :
- prior to assaying patient samples,
- at least once per day,
- after every calibration,
- and/or in accordance with laboratory and regulatory requirements.

Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take necessary corrective measures.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local, state and federal regulatory requirements (please refer to the Safety Data Sheet (SDS)).

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PERFORMANCES

Performances were obtained on Selectra Mach5, following CLSI technical recommendations, under controlled environmental conditions.

- Measuring range

2.00 – 40.00 mg/dL (20.0 – 400.0 mg/L)

Samples having greater concentrations will automatically be diluted 1:3 with NaCl 9 g/L solution and re-assayed. Results take the dilution into account. This procedure extends the measuring range up to 120.00 mg/L (1200.0 mg/L).
The exact range depends on the calibrator used.
Do not report results outside this extended range.

- Hook effect

No hook effect up to 250.00 mg/dL (2500.0 mg/L).

- Limit of Detection (LoD) and Limit of Quantification (LoQ)

LoD: 0.44 mg/dL (4.4 mg/L)
LoQ: 2.00 mg/dL (20.0 mg/L)

- Precision

Imprecision data has been obtained on 2 Selectra Mach5 analyzers over 20 days (2 runs per day, tests performed in duplicate).

Representative results are presented below.

		Mean		Within-run	Total
	n	mg/dL	mg/L	CV (%)	
Level 1	80	2.44	24.4	2.8	5.9
Level 2	80	4.71	47.1	3.9	6.7
Level 3	80	10.84	108.4	2.9	3.6

- Correlation

A comparative study has been performed between MICROALBUMIN IP reagent on a Selectra Mach5 analyzer and a similar commercially available system on 80 human urine samples.
The sample concentrations ranged from 0.78 to 39.58 mg/dL (7.8 - 395.8 mg/L).
The results are as follows :
Correlation coefficient : (r) = 0.995
Linear regression: 1.028 x + 0.20 mg/dL (2.0 mg/L).

☛- Limitations/Analytical interferences

- Studies have been performed to determine the level of interference from different compounds.
The following albumin levels were tested: 2.40 mg/dL and 10.00 mg/dL.
No significant interference is defined by a recovery ≤±10% of the initial value.

Conjugated bilirubin: No significant interference up to 29.5 mg/dL (505 µmol/L).
Haemoglobin : No significant interference up to 500 mg/dL.
pH: No significant between pH 5.2 and 8.1. Do not acidify or alkalinize urines before measurement.

- Many other substances and drugs may interfere. Some of them are listed in reviews plublished by Young.[4-5]

DECLARATION OF SERIOUS INCIDENT

Please notify the manufacturer (through your distributor) and competent authority of the Member state of the European union in which the user and/or the patient is established, of any serious incident that has occurred in relation to the device. For other jurisdictions, the declaration of serious incident should be in accordance with local, state and federal regulatory requirements.
By reporting a serious incident, you provide information that can contribute to the safety of *in vitro* medical devices.

BIBLIOGRAPHY

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2. Sacks, D.B., *Carbohydrates*. Tietz Fundamentals of Clinical Chemistry, 6th Ed., Burtis, C.A., Ashwood, E.R., Bruns, D.E. (W.B. Saunders eds.), (2008), 373.
3. Kaplan, J.M. & First, M.R., *Renal Function*. Clinical Chemistry: Theory, Analysis, Correlation, 5th Ed., Kaplan, L.A, Pesce, A.J., (Mosby Inc. eds), (2010), 567 and appendix.
4. Young, D.S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).
5. Young, D.S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).

SYMBOLS

Symbols used are defined in ISO 15223-1 standard, except those presented bellow :

CONT	Content
R1	Reagent 1
R2	Reagent 2
☛	Modification from previous version
CE	European Conformity

TECHNICAL ASSISTANCE

Contact your local distributor or ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

IMAL

Place for 2D barcode

ELITech Clinical Systems SAS
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