Micro Albumin (µALB)
(Immunoturbidimetric Method)

- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **MA0011**	R.1: 1 x 50 ml R.2: 1 x 10 ml total 60 ml	2-8°C
Cat. No.: **MA0017**	R.1: 1 x 50 ml R.2: 1 x 10 ml total 60 ml	2-8°C

- **Intended Use:**
In Vitro Diagnostic reagent pack for the quantitative determination of Micro Albumin **(µALB)** in human urine on automated and semi-automated photometric systems.

- **Summary and Explanation:**
In the normal condition only the few amount of albumin should pass from glomerular flirtation. Micro albumin urea is a termed that when the disposal of albumin in the urine increase 30 to 300 milligrams during 24 hours which this occurrence indicates disorder and escalation of kidney glomerular filtration with physiological and pathological reasons. This marker is independence can predict mortality from kidney, heart vascular disease, type II diabetes and high blood pressure. In the diabetes, the amount of the albumin urea is indicating that how long they afflicted and how they control the glycemic. The diabetes patient's albumin urea incidence 5 years early than diabetes nephropathy patients. Therefore. It is highly recommended to check this marker annually when the patients are more than 12 years old. Measurement this marker interval can prevent any serious damage. Micro albumin can be observed in heavy exercised, kidney infection and urinary tract bleeding.

Principle of the Method:
The principal on this assay is a reaction of between in antigen and antibody. The ALB in the sample been sensitive by anti-body against ALB in human. Therefore, make turbid complex, the density of this turbidity measured on 340 Nano meter which directly related to amount of ALB in the sample.

ALB antigen + Anti-ALB antibody ⟶ Antigen/Antibody Complex

- **Reagent Preparation and Stability:**
Reagents is ready for use.
Before use, mix reagent by gently inverting each bottle.
Reagent is stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.
Do not use reagents over the expiration date.
Do not freeze and protect from light.
The R1 is transparent and colorless and R2 is light beige.
The following table is the preparation of calibrator with normal saline.
The normal saline 0.9%NaCl use as a zero.

Dilution	Neat	1:2	1:4	1:8	1:16
Dilution Factor	1	0.5	0.25	0.125	0.063

Waste Management:
Refer to local legal requirements for chemical disposal regulations.
Warning: Handle waste as potentially biohazardous material.
Dispose of waste according to accepted laboratory instructions and procedures.

- **Warnings and Precautions:**
For In Vitro Diagnostics Use Only.
For Professional Use Only.
Carefully read instructions for use.
In case of serious damage to the bottle or cap, resulting in product leakage or contamination, do not use the reagent pack and contact your distributor.
Take all necessary precautions required when handling laboratory reagents.
Do not use components past the expiry date stated on the Bottles.
Do not interchange caps among components as contamination may occur and compromise test results. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.

- **Type of Specimen:**
Use the first, fresh Urine at morning. The stability of micro albumin in the samples at 2-8°C for 15 days and at-20°C with any preservative maximum 3 months. Should prevent to contaminated samples.

- **Required but not Supplied:**
Micro Albumin **(µALB)** calibrator from TKS or other valid calibrators.
Micro Albumin **(µALB)** Control Level 1 & 2 from TKS or other valid controls.
Saline solution 0.9 % NaCl
General laboratory equipments

- **Notes:**
Carefully read instructions for use.
It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with hydrochloric acid 1 N and then thoroughly rinsed it with distilled water.
Use clean disposable pipette tips for its dispensation.
Disposable and glassware material used must be free of metals, ions and detergents.
The urine sample at first should be verified by the urine strip. If the amount of protein in urine is high so, then should be diluted and use the macro measurement to evaluated protein in urine.

- **Performance Characteristics:**
Performance results can vary with the instrument used.
Data obtained in each individual laboratory may differ from these values.

The Maximum concentration will be obeying base of calibrator
LOD: 0.3 mg/L
For samples with a higher concentration (base on maximum concentration of your calibrator), dilute 1:1 with 0.9 % NaCl and re-assay. Multiply result by 2.

Prozone:
In this assay, till 1250mg/dl concentration no prozone will not be observed.

Precision:
Intra Assay-Within run µALB

Sample	n	Mean (mg/L)	SD (mg/L)	CV (%)
1	20	24.4	0.39	1.61
2	20	41.0	0.66	1.62

Inter Assay-Between run µALB

Sample	n	Mean (mg/L)	SD (mg/L)	CV (%)
1	20	24.2	0.77	3.19
2	20	41.5	1.02	2.45

- **Accuracy:**
Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).
Correlation coefficient (r): 1.000
Regression equation: Y = 0.957 (X) + 0.104 mg/L
The results of the performance characteristics depend on the analyzer used.

- **Interfering Substances:**
the less concentration of below table is not interfering in this assay.

Bilirubin (mixed isomer)	Less than 10% interference up to 25 mg/dl Bilirubin
Hemolysis	Less than 10% interference up to 200 mg/dl hemoglobin
Urea	Less than 10% interference up to 35 mg/dl

- **Reference Values:**

Urine	mg/24 hours	Random Urine
Normal	**<30mg/24 hours**	**<20 mg/L**
Micro albuminuria	**30-300 mg/24 hours**	**20-200 mg/L**
Macro albuminuria	**>300 mg/24 hours**	**>200 mg/L**

Each laboratory should establish its own expected values. The Micro Albumin results should always be reviewed with the patient's medical examination and history.

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Micro Albumin (µALB)
(Immunoturbidimetric Method)

Manufactured by | This way up
Biological Risks | Keep away from sunlight

- **Assay Procedure:**

Allow reagents to reach working temperature before using.
A proportional variation of the reaction volumes indicated does not change the result

Assay conditions:

340nm	**Wavelengths**
37 °C	**Incubation Temperature**
1 cm	**Cuvette**

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	**Blank**	
1000 µl	1000 µl	**R1**
70 µl	-	**Control/Sample/Calibrator**
Gently mix and incubate for 5 minute at 37°C. then measure the absorbance from the first OD1 and then added R2.		
Control/Sample/Calibrator	**Blank**	
200 µl	200 µl	**R2**
Gently mix and incubate for 10 minute at 37°C. then measure the absorbance from the second OD2.		

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ISO 13485:2016
ISO 9001:2015

IVD

- **Calculations:**

ΔAbs = OD2 – OD1

The **ΔAbs is calculated as in above formula. These changes should be done by different calibrators. Then put them in the logarithm table in the base of curve to determine the concentration of control and samples.**

Urine collection 24hours follow up the below calculation.

Micro Albumin (µALB) = Micro Albumin (mg/L) x Urine Volume (ml) / 1000

Conversion units:

(mg/L = mg/dl x 10)

TOSE'E KIMIA SA'ADAT has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

- **References:**

1-Harmoinen A, Jokela H. Turbidimetric measurement of Microalbuminuria. Clin Chem Acta 1987,166.85.9.
2-Burtis CA. Ashwood ER. Tietz Fund. Of Clin.Chem. 5th ed.:30-54 and 428-459 and 962.
3-Bakker AJ (1988) 34:1:82.
4-Gilbert RE et al. Diabetic Medicine 1994; 11:636-645.

Symbols:

The following symbols are used in the labelling of TOSE'E KIMIA SA'ADAT systems:

IVD	In Vitro Diagnostics	Σ	Contains sufficient for <n> tests
LOT	Batch Code		Temperature limit
REF	Catalogue No.		Consult instruction for use
	Expiry Date		Caution
	Date of Manufacture		Keep dry

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