quantex MICROALBUMIN

CE

Kit Configuration

P/N 3000-2272	1 x 75 mL MAU R1
	1 x 4 mL MAU R2

Reagent Preparation

P/N 3000-2272 MAU R1: Ready to use.
MAU R2: Ready to use.
Place the bottles into reagent tray.

In Use Stability

For optimal stability remove reagents from the system and store them at 2-8°C in the original vial securely closed.
On board: 20 days.

Specimen

Urine.

Calibration

Use quantex MICROALBUMIN standard multipoint Cat. No 3000-2273. See calibrator insert sheet for specific concentrations.
Recalibrate every 60 days or when a new lot of reagent is used.

Quality Control

Use quantex MICROALBUMIN Control I/II Cat. No 3000-2274.

Calculation of Analytical Results

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 600/650 Operator's Manual.

Reference Interval

Normal urinary excretion of albumin for adults is less than 20 mg/L measured by an immunoassay technique. Concentrations of albumin excreted in the urine between 20 and 200 mg/L are indicative of microalbuminuria. Higher values are indicative of albuminuria.

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No significant interference from bilirubin up to concentrations of 20 mg/dL (340 µmol/L), creatinine up to concentrations of 280 mg/dL (24752 µmol/L), human IgG up to concentrations of 200 mg/dL, transferrin up to concentrations of 10 mg/dL and urea up to 70 mg/dL (11.6 mmol/L). For a comprehensive review of interfering substances, refer to the publication by Young *et al*.[1]

Precision

	Samples/Runs	Mean (mg/L)	CV(%)
Within run	3/10	39.6	1.8
Total	3/10	39.6	2.6

Linearity

no rerun 20 - 500 mg/L ; with rerun 20 - 5000 mg/L

Instrumentation Laboratory

Instrumentation Laboratory SpA – V.le Monza 338 – 20128 Milano (Italy))
Instrumentation Laboratory Company - Lexington, MA 02421-3125 (USA)

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Instrument Settings

Photometric Test Parameters		***Serum***
Test No.		**
Test Name, Test Code		MAU, MAU
Sample Type		Urine
Reporting Unit, Decimal Points		mg/L, 0
Reation Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		End Point, 17/33
Photometric Methodology		1 Wavelength
Primary/Secondary Wavelenght		510
Sampling Conditions		
Sampling 1	Sample Vol.	10
	Sample/Diluent Vol.	0/0
Sampling 2	Sample Vol.	10
	Sample/Diluent Vol.	15/135
Sampling 3	Sample Vol.	20
	Sample/Diluent Vol.	0/0
Sampling 4		***
Diluent Code		Saline
Diluent Warning Limit		N/A
First Run		Sampling 1
Below/Above Normal Range		***
Panic L		***
Panic H		Sampling 2
Noise		***
Prozone		N/A
High!, ABS!		Sampling 2
Sample Volume Reduction		**
Reagent Volumes		
R1	Code	01841
	Rgt/Dil. Vol. Stirring	260/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	**
R2	Code	01842
	Rgt/Dil. Vol. Stirring	20/20, ON
	Low Vol. Warning Limit	***
	Stability (days)	**

Ranges and Evaluation Criteria	***Serum***
Normal Range-Male	**
Normal Range-Female	**
Normal Range-Other	**
Valid Range	0 - 500
Hemolysis/Icterus/Lipemia Limit	***
Reaction Slope	Positive
Absorbance Limit	Above, 3200
Prozone Limit	N/A
Non Linear Limit	N/A
Slope/Intercept Correction	1/0
Qualitative Report	OFF
Calibration Conditions	
Calibration	5 Points, point to point, 2 Reps
Stability (days)	60
Calibrator, Concentration	Microalbumin Std, *
R-Blank Limit (mAbs)	200
Cal. Reps Range (%)	***
Min Cal. Response (mAbs)	***
Cal. Factor Change (%)	***
M-Point Curve Fit (%)	N/A
Reagent Blank	ON
Auto R-Blank by Bottle	ON

*	Lot dependent
**	operator definable
***	optional
N/A	not applicable to this test

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