

quantex MICROALBUMIN



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.

Specimen

Urine.

Calibration

Use quantex MICROALBUMIN standard multipoint Cat. No 3000-2273. See calibrator insert sheet for specific concentrations. Recalibrate every 90 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 350 Operator 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, human IgG up to concentrations of 200 mg/dL, transferrin up to concentrations of 10 mg/dL and urea up to 70 mg/dL. For a comprehensive review of interfering substances, refer to the publication by Young *et al.*

Precision

	Samples/Runs	Mean (mg/L)	CV(%)
Within run	4/10	41	3.4
Total	4/10	41	8.8

Method Comparison

Comparison Method (x)	same reagent
Comparison Instrument (x)	ILab 300
Slope	0.978
y intercept	1.1
Mean X (mg/L)	483
Mean Y (mg/L)	466
r	0.99
n	45

Linearity

no rerun 5 - 500 mg/L ; with rerun 5 - 5000 mg/L

Minimum Detection Limit

1.5 mg/L

Quantification Limit

7.5 mg/L



Instrument Settings

Chemistry Parameters				R1			
Method Name	<input type="text" value="MALB"/>	Reagent Name	<input type="text" value="MALB"/>	Volume	<input type="text" value="260 μL"/>		
Unit	<input type="text" value="mg/L"/>	R2	<input type="text" value="enable"/>	Reagent Name	<input type="text" value="MALB"/>	Volume	<input type="text" value="20 μL"/>
Assay Type	<input type="text" value="End"/>	Wash	<input type="text" value="disable"/>	Reagent Name	<input type="text"/>		
Measuring Points	1 enable	start	<input type="text" value="12"/>	Reagent Type	<input type="text"/>		
		end	<input type="text" value="13"/>	Diluent	<input type="text" value="enable"/>	Reagent Name	<input type="text" value="Saline"/>
	2 enable	start	<input type="text" value="25"/>	Decimal Points	<input type="text" value="0"/>		
		end	<input type="text" value="26"/>	Normal Range	<input type="text" value="0"/>	<input type="text" value="20"/>	
Wave Length					Technical Range (Conc)		
Prim	<input type="text" value="510"/>	Sec	<input type="text"/>		<input type="text" value="0.0"/>	<input type="text" value="500"/>	
					mAbs/10 <input type="text" value="-30000 / 30000"/>		
Sampling Volume	<input type="text" value="10 μL"/>				RPT Wash (R1) <input type="text" value="Sys Water"/>		
Dilution	<input type="text" value="disable"/>				(R2) <input type="text" value="Sys Water"/>		
Rerun (High)	<input type="text" value="10 μL"/>				Instrument Factor a <input type="text" value="1"/>		
Dilution	<input type="text" value="enable"/>				b <input type="text" value="0"/>		
	<input type="text" value="15 μL"/>	<input type="text" value="135 μL"/>	Stirring Speed		R1 <input type="text" value="high"/>	R2 <input type="text" value="high"/>	
Rerun (Low)	<input type="text" value="20 μL"/>						

Calibration Checks

** Duplicate Limit	<input type="text"/>	** mAbs/10	Sampling Method for Standards			
** Sensitivity Limit	<input type="text"/>	** mAbs/10	<input checked="" type="checkbox"/> Duplicate			
			<input type="checkbox"/> Triplicate			
** Linearity Limit	<input type="text"/>	** %	Blank measurement			
** Prozone Limit	<input type="text" value="upper"/>		<input checked="" type="checkbox"/> Enable Reagent blank			
SL1-S	** <input type="text" value="SL1-F"/>	**	<input type="text" value="None"/>			
SL2-S	** <input type="text" value="SL2-F"/>	**	Reagent blank measurement at calibration			
Sens	<input type="text" value="mAbs/10"/>		<input checked="" type="checkbox"/> Reagent blank (system water)			
x Absorbance Limit			Multiplex measurement is the same as standards			
Reaction Limit	<input type="text" value="Increase"/>		Reagent Blank Limit Checks			
	<input type="text" value="25000"/>	mAbs/10	** Duplicate limit	<input type="text" value="50"/>	mAbs/10	

Calibration

Method	<input type="text"/>	Name	<input type="text" value="MALB"/>	Interval	<input type="text" value="90"/>	days
Calculation	<input type="text" value="Point to Point"/>					
	Conc	WORK	MASTER	Lot No		
S1	<input type="text" value="0"/>	<input type="text" value="-11"/>			K	<input type="text" value="N/A"/>
S2	<input type="text" value="25"/>	<input type="text" value="550"/>				
S3	<input type="text" value="50"/>	<input type="text" value="790"/>				
S4	<input type="text" value="100"/>	<input type="text" value="1986"/>				
S5	<input type="text" value="250"/>	<input type="text" value="4501"/>				
S6	<input type="text" value="500"/>	<input type="text" value="9120"/>				

Reagent Registration

Reagent Code	<input type="text" value="0184"/>											
Reagent Name	<input type="text" value="MALB"/>											
R1	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text" value="**"/>	mL	Volume (S)	<input type="text" value="**"/>	mL	Stability Check	<input checked="" type="checkbox"/> enable	Term	<input type="text" value="**"/>	days
R2	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text" value="**"/>	mL	Volume (S)	<input type="text" value="**"/>	mL	Stability Check	<input checked="" type="checkbox"/> enable	Term	<input type="text" value="**"/>	days

** Operator definable N/A not applicable to this test Calibration curve is only as example