SIEMENS Healthineers

Dimension Vista®
System

MALB Flex® reagent cartridge

Microalbumin

Revision bar indicates update to previous version.

Intended Use

The MALB method is an *in vitro* diagnostic test for the quantitative measurement of albumin in human urine on the Dimension Vista® System. Measurement of albumin in urine aids in the diagnosis of kidney diseases.

Summary and Explanation

Albumin is the chief plasma protein in terms of quantity, normally accounting for more than half of the total serum protein. Albumin is formed exclusively in the liver and serves as a transport and binding protein for calcium, fatty acids, bilirubin, hormones, vitamins, trace elements and drugs. It contributes decisively towards maintaining the colloidal osmotic pressure. Due to defects in the glomerular filtration barrier urinary albumin levels will increase, leading to a condition designated as microalbuminuria if albumin excretion is within a range of 30 to 300 mg/24 h. Increased urinary excretion of albumin is an early indicator of renal and vascular complications, e. g., in diabetes mellitus[1].

Principles of the Procedure

Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Reagents

Wells[a,b]	Form	Ingredient	Concentration[c]	Source
1–8	Liquid	MALB Supplement Reagent: Phosphate buffer; Polyethylene glycol	 ~56 g/L	
9–12	Liquid	Antiserum to human Albumin	984 g/L	Rabbit

[a] Wells are numbered consecutively from the wide end of the cartridge.
[b] Contains Sodium azide (< 1 g/L) as a preservative.
[c] Nominal value per well in a cartridge.

Store at
2 to 8 °C.

Expiration
Refer to carton for expiration date of individual unopened reagent cartridges. Sealed wells on the instrument are stable for 90 days.

Open well stability
21 days for wells 1 - 12.

Warnings and Precautions

For *in-vitro* diagnostic use only.

For laboratory professional use.

Safety data sheets (MSDS/SDS) available on siemens-healthineers.com/sds.

CAUTION!
Federal (USA) law restricts this device to sale by or on the order of licensed healthcare professionals.

Caution
This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent the buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with all government requirements.

Reagent Preparation

All reagents are liquid and ready to use.

Specimen Collection and Handling[2,3,4,5,6]

Collecting the Specimen

Urine can be collected using recommended procedures.

The following samples are acceptable:

- Second morning urine
- First-morning sample for simultaneous albumin and creatinine measurement.
- 24-hour collection
- Overnight (8-12-hour) collection
- 1- to 2-hour collection

The use of frozen urine samples is not recommended. Each urine sample must be centrifuged (10 minutes at approximately 15 000 × g) prior to testing.

Samples should not be collected after exertion, in the presence of urinary tract infection, during acute illness, immediately after surgery, or after an acute fluid load. Specimens should be collected without preservatives. Specimens visibly contaminated with blood are not suitable for analysis of albumin concentration.

Procedure

Materials Provided

REF	Contents	Number of Tests
K7062	Dimension Vista® MALB Flex® reagent cartridge	2 × 200

Materials Required but not Provided

Item	Description
REF KC770	Dimension Vista® PROT3 CAL (Protein 3 Calibrator)
REF KS804	System Diluent
REF OUMT05	N DILUENT, N Diluent
REF KC775U	Dimension Vista® PROT3 CON (Protein 3 Control)
Instruments, such as:	• Dimension Vista® 500 System • Dimension Vista® 1000T System • Dimension Vista® 1500 System • Dimension Vista® 3000T System

Test Steps

Sampling, reagent delivery, mixing, and processing are automatically performed by the Dimension Vista® System. For details of this processing, refer to your Dimension Vista® Operator's Guide.

	Test Conditions
Initial Sample Dilution	1:1 (neat)
	Cuvette
Sample Volume (delivered to the cuvette)	10 µL
Diluent Volume	117.5 µL
Chase Volume	15 µL
Antiserum to human Albumin	20 µL
Temperature	37 °C
Reaction time	
Pre-reaction	122 seconds
Main reaction	6 minutes
Wavelength	840 nm
Type of Measurement	Nephelometric

Calibration

Calibration Material	PROT3 CAL, REF KC770
Calibration Scheme	7 levels, n = 3
Units	mg/dL [mg/L][d] (mg/dL x 10) = [mg/L]
Typical Calibration Levels	0.44, 0.88, 1.80, 3.50, 7.00, 14.0, 41.2 mg/dL [4.4, 8.8, 18, 35, 70, 140, 412 mg/L] Multiply calibrator levels by the sample dilution to obtain the analytical measurement range. To obtain calibrator levels that span the measuring range, PROT3 CAL is diluted automatically with System Diluent by the instrument to the following dilutions: Level 1: 1:160 dilution Level 2: 1:80 dilution Level 3: 1:40 dilution Level 4: 1:20 dilution Level 5: 1:10 dilution Level 6: 1:5 dilution Level 7: 1:1.7 dilution
Calibration Frequency	Every 45 days for any one lot

Calibration interval may be extended based on acceptable verification of calibration.

A new calibration is required:
- For each new lot of Flex® reagent cartridges
- After major maintenance or service, if indicated by quality control results
- As indicated in laboratory quality control procedures
- When required by government regulations

[d] Système International d'Unités [SI Units] are in brackets.

Quality Control

Follow government regulations or accreditation requirements for quality control frequency. If not otherwise specified, analyze a minimum of two levels of a Quality Control (QC) material with known albumin concentrations, e. g., PROT3 CON at least once each day of use.

Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Matrix effects may be observed in Quality Control materials that contain bovine serum albumin.

Analytical Measurement Range (AMR)

0.50 to 34.0 mg/dL [5.00 to 340 mg/L]

This is the measuring range for undiluted samples that are automatically processed by the instrument. If the readings obtained are outside the initial measuring range, the method can be repeated using a higher dilution of the sample.

Refer to your Dimension Vista® Operator's Guide for information on repeat measurements using other dilutions.

- Samples with results in excess of 34.0 mg/dL [340 mg/L] can be repeated on a higher dilution.
- Samples with results less than 0.50 mg/dL [5.00 mg/L] will be reported as "less than 0.50 mg/dL" by the instrument.

Results

The instrument calculates the concentration of albumin in mg/dL [mg/L] using the calculation scheme described in your Dimension Vista® Operator's Guide.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Limitations

Turbidity and particles in the samples may interfere with the determination. Therefore, all urine samples must be centrifuged prior to testing.

Due to matrix effects, inter-laboratory survey samples and control samples may yield results that differ from those obtained with other methods. It may therefore be necessary to assess these results in relation to method-specific target values.

The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in albumin results. Refer to your Dimension Vista® Operator's Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed according to your laboratory's procedure manual and not reported.

If a result exceeds the upper limit of the extended measuring range, it can be repeated by manual dilution.

Manual Dilution: Dilute with N DILUENT to obtain results within the analytical measurement range. Enter dilution factor on the instrument. Reassay. Results are multiplied by the dilution factor.

Expected Values[2,3]

Excretion rate: Less than 20 µg/min[e]
Less than 30 mg/24 hours[6]
Less than 30 mg albumin/g creatinine[f]

[e] Albumin (mg/L) x [Urine Volume (mL) / Time (minutes)] = µg Albumin/min.
[f] [Albumin (mg/L) / Urine creatinine (mg/dL)] x 100 = mg Albumin/g creatinine.

To minimize intra-individual variation, analysis of three random urine samples collected over the course of a week has also been recommended[2]. Calculation of an excretion rate requires a timed specimen collection and accurate volume measurement.

Each laboratory should establish its own expected values for microalbumin as performed on the Dimension Vista® System.

Performance Characteristics

The following data represent typical performance for the Dimension Vista® System.

Specificity

HIL Interference

The MALB method was evaluated for interference according to CLSI EP7-A2[9]. Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10 % is considered interference.

Substance Tested	Substance concentration		Albumin mg/dL [g/L]	Bias[g] (%)
Hemoglobin (hemolysate)	115 mg/dL	[17.8 µmol/L]	2.205 [22.05]	-1
Bilirubin (unconjugated)	2 mg/dL	[34.2 µmol/L]	1.763 [17.63]	-6
Bilirubin (conjugated)	2 mg/dL	[34.2 µmol/L]	1.763 [17.63]	+8
Lipemia	(not applicable for urine methods)			

[g] Analyte results should not be corrected based on this bias.

Maximum Observed Repeatability

The expected maximum observed standard deviations (SD) for repeatability (within-run precision) using n = 5 replicates at the following nominal albumin concentrations are:

Albumin Concentration	Acceptable SD Maximum
16.5 mg/dL [165 mg/L]	1.47 mg/dL [14.7 mg/L]

A system malfunction may exist if the acceptable SD maximum is exceeded.

Precision[7,h]

	Mean		Repeatability			Within-Lab		
Material	(mg/dL)	(mg/L)	SD (mg/dL)	SD (mg/L)	CV (%)	SD (mg/dL)	SD (mg/L)	CV (%)
PROT3 CAL	14.6	146	0.35	3.5	2.4	0.58	5.8	4.0
Urine pool	1.00	10	0.06	0.6	6.4	0.08	0.8	7.6
Urine pool	24.5	245	0.69	6.9	2.8	1.09	10.9	4.5

[h] CLSI EP5-A2 was used. During each day of testing, two separate runs, with two test samples, for each test material, were analyzed for 20 days.

Method Comparison[8]

Regression Statistics[i]

Comparative Method	Slope	Intercept mg/dL [mg/L]	Correlation Coefficient	n
Albumin on the BN ProSpec® System	0.988	–0.0936 [–0.936]	0.996	74[j]

[i] CLSI EP9-A2 was used. The method used to fit the linear regression line was Passing Bablok.

[j] The range of albumin values in the correlation study was 0.587 mg/dL to 33.274 mg/dL [5.87 mg/L to 332.74 mg/L].

Non-Interfering Substances

The following substances do not interfere with the MALB method when present in serum and plasma at the concentrations indicated. Inaccuracies (biases) due to these substances are less than 10 % at albumin concentrations of 2.138 to 3.141 mg/dL [21.38 to 31.41 mg/L].

Substance	Test Concentration	SI Units
Acetone	1 000 mg/dL	217.1 mmol/L
Ascorbic acid	1 500 mg/dL	68.1 mmol/L
Boric acid	1 000 mg/dL	161.7 mmol/L
Creatinine	500 mg/dL	44.2 mmol/L
Ethanol	1 000 mg/dL	217 mmol/L
Glucose	2 000 mg/dL	111 mmol/L
Immunoglobulin G (IgG)	400 mg/dL	4 000 mg/L
Oxalic acid	64 mg/dL	5.1 mmol/L
Riboflavin	7.5 mg/dL	200 µmol/L
Sodium azide	1 000 mg/dL	153.8 mmol/L
Sodium chloride	6 000 mg/dL	1 027 mmol/L
Sodium fluoride	1 000 mg/dL	238.2 mmol/L
Urea	6 000 mg/dL	1 mol/L

Hook Effect

The MALB method shows no hook effect up to 1 269.3 mg/dL [12 693 mg/L].

Recovery

Recovery of protein reference material ERM-DA470 (CRM 470) ranged from 100.6 to 108.7 % with a mean recovery of 105.3 %.

Limit of Quantitation

The limit of detection represents the lower limit of the reportable range for MALB.

0.50 mg/dL [5.00 mg/L]

Technical Assistance

For customer support, contact your local technical support provider or distributor.

siemens-healthineers.com

Applicable Version of electronic Instructions for Use

As Siemens Healthineers continuously monitors the product performance and safety, the users are required to ensure that they work with the correct revision of the instructions for the product lots in use. Please periodically review the availability of new electronic labeling revisions to ensure safe use of the product.

The IFU version number is visible on each product box label. Siemens Healthineers ensures that all products lots bearing the same IFU version number are compatible with the electronic labeling provided via siemens-healthineers.com/eIFU.

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Definition of Symbols

The following symbols may appear on the product labeling:

	Do not reuse		Use By
LOT	Batch Code	REF	Catalogue Number
	Caution		Manufacturer
EC REP	Authorized representative in the European Community		Contains sufficient for <n> tests
	Biological Risks	IVD	*In Vitro* Diagnostic Medical Device
	Temperature Limitation		Consult instruction for Use
NON STERILE	Non-sterile	CE	CE marking of conformity
CE 0197	CE marking of conformity with notified body ID number. Notified body ID number can vary.	CONTENTS	Contents
	Reconstitution volume	LEVEL	Level
	Keep away from sunlight and heat	WARNING	Warning
DANGER	Danger	RxOnly	Prescription device (US only)
UDI	Device Identification (UDI) barcode	REACH xx/xx/xx	REACH Authorization Number

Legal Information

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