SIEMENS Healthineers

Dimension Vista®
System

PREALB Flex® reagent cartridge

Prealbumin

Revision bar indicates update to previous version.

Intended Use

The PREALB method is an *in vitro* diagnostic test for the quantitative measurement of prealbumin (transthyretin) in human serum and heparinized plasma on the Dimension Vista® System. Prealbumin levels are useful in the monitoring of nutritional status and/or nutritional support.

Summary and Explanation

Prealbumin is synthesized in the liver and acts as a binding protein for thyroxin and retinol-binding protein. The serum concentration reflects the synthesis capacity of the liver and is markedly diminished in malnutrition and other conditions.

Due to the short half life of approximately two days, prealbumin may be suitable for monitoring the nutritional status and efficacy of parenteral nutrition[1,2].

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
1–4	Liquid	PREALB Supplement Reagent: Phosphate buffer; Polyethylene glycol	 ~47 g/L	
11–12	Liquid	Antiserum to human Prealbumin	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

Collecting the Specimen

Recommended specimen types: serum or heparinized plasma.

Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture[3].

Follow the instructions provided with your specimen collection device for use and processing[4].

For serum, complete clot formation should take place before centrifugation. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection[5].

Storing the Specimen

Samples should be as fresh as possible (stored for no more than seven days at 2 to 8 °C) or stored frozen. Samples can be stored at below –20 °C for up to three months[10], if they are frozen within 24 hours after collection and if repeated freeze-thaw cycles are avoided. Lipemic or frozen samples, which become turbid after thawing, must be clarified by centrifugation (10 minutes at approximately 15 000 × g) prior to testing. Specimens should be free of particulate matter.

Procedure

Materials Provided

REF	Contents	Number of Tests
K7064	Dimension Vista® PREALB Flex® reagent cartridge	2 × 100

Materials Required but not Provided

Item	Description
REF KC710U	Dimension Vista® PROT1 CAL (Protein 1 Calibrator)
REF KS804	System Diluent
REF OUMT05	N DILUENT, N Diluent

Item	Description
REF KC715	Dimension Vista® PROT1 CON L (Protein 1 Control L (low))
REF KC716	Dimension Vista® PROT1 CON M (Protein 1 Control M (medium))
REF KC717	Dimension Vista® PROT1 CON H (Protein 1 Control H (high))
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	1:5
	Cuvette
Diluted Sample Volume (delivered to the cuvette)	26.9 µL
Diluent Volume	102.2 µL
Chase Volume	15 µL
Antiserum to human Prealbumin	21.5 µL
Temperature	37 °C
Reaction time	6 minutes
Wavelength	840 nm
Type of Measurement	Nephelometric

Calibration

Calibration Material	PROT1 CAL, REF KC710U
Calibration Scheme	6 levels, n = 3
Units	mg/dL [g/L][d] (mg/dL x 0.01) = [g/L]
Typical Calibration Levels	0.50, 1.00, 1.90, 3.80, 7.60, 15.3 mg/dL [0.005, 0.010, 0.019, 0.038, 0.076, 0.153 g/L] Multiply calibrator levels by the sample dilution to obtain the analytical measurement range. To obtain calibrator levels that span the measuring range, PROT1 CAL is diluted automatically with System Diluent by the instrument to the following dilutions: Level 1: 1:64 dilution Level 2: 1:32 dilution Level 3: 1:16 dilution Level 4: 1:8 dilution Level 5: 1:4 dilution Level 6: 1:2 dilution
Calibration Frequency	Every 30 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 prealbumin concentrations, e. g. PROT1 CON L, M or H 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)

3.00 to 60.0 mg/dL [0.03 to 0.60 g/L]

This is the measuring range for the initial 1:5 dilution of 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 60.0 mg/dL [0.60 g/L] can be repeated on a higher dilution.
- Samples with results less than 3.00 mg/dL [0.03 g/L] will be reported as "less than 3.00 mg/dL" by the instrument.

Results

The instrument calculates the concentration of prealbumin in mg/dL [g/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 sample may interfere with the determination. Therefore, samples containing particles must be centrifuged prior to testing. Lipemic or turbid samples, which cannot be clarified by centrifugation (10 minutes at approximately 15 000 × g), must not be used.

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 prealbumin 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

20.0 to 40.0 mg/dL [0.20 to 0.40 g/L]

This reference interval applies for serum samples from healthy adults[6].

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

Performance Characteristics

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

Specificity

HIL Interference

The PREALB 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		Prealbumin mg/dL [g/L]	Bias[e] (%)
Hemoglobin (hemolysate)	1 000 mg/dL	[0.155 mmol/L]	25.0 [0.25]	-4
Bilirubin (unconjugated)	60 mg/dL	[1026 µmol/L]	26.0 [0.26]	1
Bilirubin (conjugated)	60 mg/dL	[1026 µmol/L]	26.0 [0.26]	4
Lipemia	Refer to "Specimen Collection and Handling", page 2 section			

[e] **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 prealbumin concentrations are:

Prealbumin Concentration	Acceptable SD Maximum
18.5 mg/dL [0.185 g/L]	2.8 mg/dL [0.028 g/L]
36.3 mg/dL [0.363 g/L]	7.8 mg/dL [0.078 g/L]

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

Precision[7,f]

	Mean		Repeatability			Within-Lab		
Material	(mg/dL)	(g/L)	SD (mg/dL)	SD (g/L)	CV (%)	SD (mg/dL)	SD (g/L)	CV (%)
PROT1 CON L	20.4	0.204	0.70	0.007	3.3	0.70	0.007	3.4
PROT1 CON M	33.8	0.338	1.40	0.014	4.0	1.40	0.014	4.2
PROT1 CON H	46.1	0.461	1.90	0.019	4.0	1.90	0.019	4.1
Serum pool	3.40	0.034	0.10	0.001	3.1	0.20	0.002	5.5
Serum pool	5.20	0.052	0.20	0.002	3.9	0.20	0.002	4.2
Serum pool	26.7	0.267	1.30	0.013	5.0	1.80	0.018	6.7
Serum pool	34.4	0.344	1.20	0.012	3.3	1.70	0.017	4.8
Serum pool	46.2	0.462	1.80	0.018	4.0	2.70	0.027	5.7

[f] 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[g]

Comparative Method	Slope	Intercept mg/dL [g/L]	Correlation Coefficient	n
Prealbumin on the BN ProSpec® System	0.962	0.30 [0.003]	0.988	115[h]

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

[h] The range of prealbumin values in the correlation study was 3.00 mg/dL to 59.6 mg/dL [0.030 g/L to 0.596 g/L].

Non-Interfering Substances

The following substances do not interfere with the PREALB method when present in serum and plasma at the concentrations indicated. Inaccuracies (biases) due to these substances are less than 10 % at prealbumin concentrations of 3.70 mg/dL to 65 mg/dL [0.037 g/L to 0.65 g/L].

Substance	Test Concentration	SI Units
Acetaminophen	0.025 mg/dL	1.66 µmol/L
Amikacin	15 mg/dL	256 µmol/L
Ammonium heparin	3 U/mL	3 000 U/L
Ampicillin	5.3 mg/dL	152 µmol/L
Ascorbic acid	5 mg/dL	227 µmol/L
Caffeine	6 mg/dL	308 µmol/L
Carbamazepine	3 mg/dL	127 µmol/L
Chloramphenicol	5 mg/dL	155 µmol/L
Chlordiazepoxide	1 mg/dL	33.3 µmol/L
Chlorpromazine	0.2 mg/dL	6.27 µmol/L
Cholesterol	500 mg/dL	12.9 mmol/L
Cimetidine	2 mg/dL	79.2 µmol/L
Creatinine	30 mg/dL	2 652 µmol/L
Dextran 40	6 000 mg/dL	1 500 µmol/L
Diazepam	0.5 mg/dL	17.6 µmol/L
Digoxin	5 ng/mL	6.15 nmol/L
Erythromycin	6 mg/dL	81.6 µmol/L
Ethanol	400 mg/dL	86.8 mmol/L
Ethosuximide	25 mg/dL	1 770 µmol/L
Furosemide	6 mg/dL	181 µmol/L
Gentamicin	12 mg/dL	251 µmol/L
Ibuprofen	50 mg/dL	2 425 µmol/L
Immunoglobulin G (IgG)	5 g/dL	50 g/L
Lidocaine	1.2 mg/dL	51.2 µmol/L
Lithium chloride	2.3 mg/dL	3.2 mmol/L
Lithium heparin	3 U/mL	3 000 U/L
Nicotine	0.1 mg/dL	6.2 µmol/L
Penicillin G	25 U/mL	25 000 U/L
Pentobarbital	8 mg/dL	354 µmol/L
Phenobarbital	10 mg/dL	431 µmol/L
Phenytoin	5 mg/dL	198 µmol/L
Primidone	4 mg/dL	183 µmol/L
Propoxyphene	0.2 mg/dL	4.91 µmol/L
Protein, Albumin	6 g/dL	60 g/L
Rheumatoid Factors	450 IU/mL	450 IU/mL
Salicylic acid	60 mg/dL	4.34 mmol/L
Sodium heparin	3 U/mL	3 000 U/L

Substance	Test Concentration	SI Units
Theophylline	4 mg/dL	222 µmol/L
Urea	500 mg/dL	83.3 mmol/L
Uric acid	20 mg/dL	1 190 µmol/L
Valproic acid	50 mg/dL	3 467 µmol/L

Recovery

Recovery of protein reference material ERM-DA470 (CRM 470) ranged from 90.0 to 93.7 % with a mean recovery of 91.9 %.

Limit of Detection

The limit of detection represents the lower limit of the reportable range for PREALB:

3.00 mg/dL [0.03 g/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	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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