BioMajesty®

Prealbumin FS*

Order Information

Cat. No.
1 0292 99 10 966

Kit size
Σ 200 (R1: 2 x 100, R2: 2 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of prealbumin in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

Summary

Prealbumin or transthyretin is a protein synthesized mainly by the liver with a molecular mass of 55 kDa. It is a transport protein for the thyroid hormones thyroxine or triiodothyronine. A further function of prealbumin is transporting vitamin A in the presence of retinol-binding protein, thereby preventing its loss through the kidneys [1]. Furthermore, prealbumin exhibits a tryptophane abundance and one of the highest essential-to nonessential amino acids ratios of any protein in the body, making it a distinct marker for protein synthesis [1-3]. Due to its short half-life of 1 to 2 days, measurement of prealbumin serum levels may provide a timelier and sensitive assessment of protein malnutrition or liver dysfunction than transferrin or albumin [1]. Various pathological conditions affect serum prealbumin concentrations: As a negative acute phase reactant, prealbumin concentration decreases in the presence of inflammation as well as in the immediate postsurgical period [1,2]. Serum levels also decline in patients with conditions associated with protein malnutrition, such as malignancy, cirrhosis, protein-losing enteropathy and zinc deficiency [1-3]. An elevation of serum prealbumin levels is associated with prednisone and progestational therapy, usage of anabolic steroids, and acute alcohol intoxication [2,3]. Moreover, lowered prealbumin levels in serum are significantly associated with disease severity and mortality in COVID-19 patients. Prealbumin determination might support early risk assessment and disease monitoring in COVID-19 patients with malnutrition [4].

Method

Immunoturbidimetric test

Determination of prealbumin concentration by photometric measurement of antigen antibody reaction between antibodies against prealbumin and prealbumin present in the sample.

Reagents

Components and Concentrations

R1:	TRIS	pH 7.5	100 mmol/L
	NaCl		50 mmol/L
R2:	TRIS	pH 7.8	150 mmol/L
	NaCl		450 mmol/L
	Antibodies (goat) against human prealbumin		< 1%

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

1. Components contained in Prealbumin FS are classified according to EC regulation 1272/2008 (CLP) as follows:

⚠ Reagent 1: Warning. H319 Causes serious eye irritation. P280 Wear protective gloves/protective clothing/eye protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.

2. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Reagent 2 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
4. In very rare cases, samples of patients with gammopathy might give falsified results [5].
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. 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.
7. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
8. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [6]:

3 days	at	20 – 25°C
6 months	at	4 – 8°C
1 year	at	-20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal Protein is recommended for calibration. Calibrator values have been made traceable to the reference material ERM®-DA470k/IFCC. Use DiaSys TruLab Protein Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Protein	5 9200 99 10 039	5 x 1 mL
TruLab Protein Level 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein Level 2	5 9510 99 10 046	3 x 1 mL

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Performance Characteristics

Measuring range from 0.14 g/L up to 1.42 g/L, depending on the concentration of the highest calibrator. Linearity is given within ± 5%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.01 g/L
No prozone effect up to 2.6 g/L.	
Onboard stability	6 weeks
Calibration stability	6 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [g/L]
Bilirubin (conjugated)	20 mg/dL	0.236
Bilirubin (unconjugated)	30 mg/dL	0.242
Hemolysis	200 mg/dL	0.210
Lipemia (triglycerides)	2000 mg/dL	0.220

For further information on interfering substances, refer to the literature [7-9].

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	0.255	0.141	0.472
CV [%]	1.13	1.29	1.20
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	0.142	0.213	0.477
CV [%]	1.71	2.46	0.907

Method comparison (n=100)	
Test x	Competitor Prealbumin (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Prealbumin FS (BioMajesty® JCA-BM6010/C)
Slope	1.00
Intercept	0.004 g/L
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Conversion Factor
Prealbumin [g/L] x 18.2 = Prealbumin [µmol/L]

Reference Range [10]

Serum/Plasma 0.2 – 0.4 g/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Ranasinghe RN, Biswas M, Vincent RP. Prealbumin: The clinical utility and analytical methodologies. Annals of Clinical Biochemistry. 2022;59:7-14.
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5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45()): 1240-1243.
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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

IVD CE

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* Fluid Stable

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Prealbumin FS

Chemistry code 10 029

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	16
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.0
Sample vol (U)	1.0
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	PALB
Digits	2
M-wave L.	410
S-wave.L	805
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1.0	1.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting

Formula	Logit Log 2	**Axis Conv**	No conv
Blank	Blank is 0	**Points**	6

	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	1.0	No dil	0	0	0	9.999	-9.999
1	#	1.0	No dil	0	0	0	9.999	-9.999
2	#	1.0	No dil	0	0	0	9.999	-9.999
3	#	1.0	No dil	0	0	0	9.999	-9.999
4	#	1.0	No dil	0	0	0	9.999	-9.999
5	#	1.0	No dil	0	0	0	9.999	-9.999

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