respons®910

Prealbumin FS*

Order Information

Cat. No.	Kit size
1 0292 99 10 921	Σ 400 (4 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of prealbumin in human serum or heparin plasma on automated respons®910.

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. To avoid contamination and carryover, special care should be taken in combination with Ferritin SR reagent.
6. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
7. 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.
8. 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.
9. 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. The bottles are placed directly into the reagent rotor.

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

Performance Characteristics

Measuring range from 0.007 g/L up to 1.17 g/L, depending on the concentration of the highest calibrator. Linearity is given within ± 10%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.007 g/L
Limit of quantitation**	0.007 g/L
No prozone effect up to 2.9 g/L.	
Onboard stability	6 weeks
Calibration stability	5 days

Interference by	Interferences ≤ 10% up to	Analyte concentration [g/L]
Bilirubin (conjugated)	30 mg/dL	0.229
	45 mg/dL	0.526
Bilirubin (unconjugated)	40 mg/dL	0.248
	45 mg/dL	0.539
Hemolysis	250 mg/dL	0.245
	250 mg/dL	0.543
Lipemia (triglycerides)	2000 mg/dL	0.246
	2000 mg/dL	0.516
Rheumatoid factor	700 IU/mL	0.332

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]	0.157	0.233	0.458
CV [%]	2.64	3.51	1.46
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	0.199	0.292	0.492
CV [%]	3.28	2.24	2.59

Method comparison (n=136)	
Test x	DiaSys Prealbumin FS (Hitachi 911)
Test y	DiaSys Prealbumin FS (respons®910)
Slope	0.992
Intercept	-0.015 g/L
Coefficient of correlation	0.995

** according to CLSI document EP17-A, Vol. 24, No. 34

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.
2. Dati F, Metzmann E. Proteins Laboratory Testing and Clinical Use. Holzheim: DiaSys Diagnostic Systems GmbH; 2005. p. 42, 333-4.
3. Beck FK, Rosenthal TC. Prealbumin: A Marker for Nutritional Evaluation. American Family Physician. 2002;65:1575-8.
4. Zinellu A, Mangoni AA. Serum prealbumin concentrations, COVID-19 severity, and mortality: a systematic review and meta-analysis. Frontiers in medicine. 2021:14.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45()): 1240-1243.
6. Guder WG, da Fonseca-Wollheim F, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B. Quality of Diagnostic Samples. 3rd edition; 2010. p. 62-3
7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
8. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/ aaccweb/aacc/, accessed in May 2024. Published by AACC Press and John Wiley and Sons, Inc.
9. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001 Jul;38:376-85.
10. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2023 [cited 2024 06 03]. Available from: https:// www.clinical-laboratory-diagnostics.com

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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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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	PALB
Shortcut:	
Reagent barcode reference:	712
Host reference:	712

Technic	
Type:	End point
First reagent:[µL]	200
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	40
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	380
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	0.0070
Concentration technical limits-Upper	1.1700
SERUM	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6

Results	
Decimals	3
Units	g/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>=0.200 <=0.400
URINE	
PLASMA	>=0.200 <=0.400
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0100
Cal. 3	0.0100
Cal. 4	0.0100
Cal. 5	0.0100
Cal. 6	0.0100
Drift limit [%]	2.00

Calculations	
Model	Akima Spline
Degree	

* Enter calibrator value