

## Prealbumin FS\*

### Order Information

**Cat. No.**

1 0292 99 10 921

**Kit size**



400 (4 x 100)

### Intended Use

Diagnostic reagent for quantitative in vitro determination of prealbumin in human serum or heparin plasma on automated respons<sup>®</sup>940.

### 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

<b>R1:</b>	TRIS	pH 7.5	100 mmol/L
	NaCl		50 mmol/L
<b>R2:</b>	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

- 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.

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 2 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [5].

- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- 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.
- 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.
- 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<sup>®</sup>-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 0.01 g/L up to 1.19 g/L, depending on the concentration of the highest calibrator. Linearity < 0.06 g/L is given with ± 0.006 g/L, between 0.06 g/L to 0.2 g/L within ± 10%, at > 0.2 g/L 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**	0.004 g/L
Limit of quantitation**	0.01 g/L
No prozone effect up to 2.6 g/L.	
Onboard stability	5 weeks
Calibration stability	1 week

Interference by	Interferences ≤ 10% up to	Analyte concentration [g/L]
<b>Bilirubin</b> (conjugated)	15 mg/dL	0.241
	20 mg/dL	0.407
<b>Bilirubin</b> (unconjugated)	10 mg/dL	0.216
	15 mg/dL	0.413
<b>Hemolysis</b>	250 mg/dL	0.214
	340 mg/dL	0.424
<b>Lipemia</b> (triglycerides)	2381 mg/dL	0.240
	2381 mg/dL	0.414
<b>Rheumatoid factor</b>	800 IU/mL	0.334
	800 IU/mL	0.538

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

<b>Precision</b>			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/L]	0.152	0.221	0.414
CV [%]	1.61	0.839	2.33
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [g/L]	0.152	0.302	0.837
CV [%]	2.42	3.22	2.70
Reproducibility (n=75, no. of instruments=3)	Sample 1	Sample 2	Sample 3
Mean [g/L]	0.140	0.301	0.736
CV [%]	5.50	5.29	6.17

<b>Method comparison (n=135)</b>	
Test x	Competitor Prealbumin (cobas c 501)
Test y	DiaSys Prealbumin FS (respons <sup>®</sup> 940)
Slope	1.09
Intercept	-0.004 g/L
Coefficient of correlation	0.992

\*\* according to CLSI document EP17-A2, Vol. 32, No. 8

### 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

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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.



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\* Fluid Stable

## Prealbumin FS

Application for serum and plasma

Test Details		Test Volumes		Reference Ranges	
Test	: PALB			Auto Rerun	<input type="checkbox"/>
Report Name	: Prealbumin			Online Calibration	<input type="checkbox"/>
Unit	: g/L	Decimal Places	: 3	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 415	Secondary	: 700	Special Diluent	<input type="checkbox"/>
Assay Type	: 2-Point	Curve Type	: Cubic Spline	Warn after	: 20
M1 Start	: 24	M1 End	: 24	Reagents Used	: 2
M2 Start	: 57	M2 End	: 57	Reagent R1	: PALB R1
Sample Replicates	: 1	Standard Replicates	: 2	Reagent R2	: PALB R2
Control Replicates	: 1	Control Interval	: 0	<b>Consumables/Calibrators:</b>	
Reaction Direction	: Increasing	React. Abs. Limit	: 0.0000	Blank /Level 0	: 0
Prozone Limit %	: 97	Prozone Check	: Lower	Calibrator 1	: *
Linearity Limit %	: 0	Delta Abs./Min.	: 0.0000	Calibrator 2	: *
Technical Minimum	: **	Technical Maximum	: **	Calibrator 3	: *
Y = aX + b    a=	: 1.0000	b=	: 0.0000	Calibrator 4	: *
Reagent Abs Min	: 0.0000	Reagent Abs Max	: 0.0000	Calibrator 5	: *

Test Details		Test Volumes		Reference Ranges	
Test	: PALB				
Sample Type	: Serum				
<b>Sample Volumes</b>				<b>Sample Types</b>	
Normal	: 2.00 $\mu$ L	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other	
Increase	: 6.00 $\mu$ L	Dilution Ratio	: 1 X		
Decrease	: 2.00 $\mu$ L	Dilution Ratio	: 2 X		
Standard Volume	: 2.00 $\mu$ L				
<b>Reagent Volumes and Stirrer Speed</b>					
RGT-1 Volume	: 200.00 $\mu$ L	R1 Stirrer Speed	: High		
RGT-2 Volume	: 40.00 $\mu$ L	R2 Stirrer Speed	: High		

Test Details		Test Volumes		Reference Ranges	
Test	: PALB				
Sample Type	: Serum				
Reference Range	: DEFAULT				
Category	: Male				
<b>Reference Range</b>				<b>Sample Types</b>	
	Lower Limit (g/L)	Upper Limit (g/L)		<input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other	
Normal	: #	: #			
Panic	: #	: #			

\* Enter calibrator value

\*\* Technical limits are automatically defined by the software via the upper and lower calibrator level

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