

Prealbumin FS *

Reagent for quantitative in vitro determination of prealbumin in serum or plasma on photometric systems

Order Information

| Cat. No. | Kit size |
|------------------|--|
| 1 0292 99 10 935 | R1 2 x 20 mL + R2 1 x 8 mL |
| 5 9200 99 10 037 | 3 x 1 mL TruCal Protein high |
| 5 9200 99 10 039 | 5 x 1 mL TruCal Protein: Calibrator set with 5 different levels |

Summary [1,2,3]

Prealbumin or transthyretin is a protein synthesized mainly by the liver with a molecular mass of 55 kDa. The name prealbumin is derived from its electrophoretic mobility, as it migrates ahead of albumin on electrophoresis. Prealbumin acts as transport protein for the hormone thyroxine. It also transports vitamin A in the presence of retinol-binding protein, thereby preventing its loss through the kidneys. It has an abundance of the amino acid tryptophane and one of the highest ratios of essential-to-nonessential amino acids of any protein in the body making it a distinct marker for protein synthesis. Due to its short half-life of 1 to 2 days, measurement of the serum level may provide a more timely and sensitive assessment of protein malnutrition or liver dysfunction than transferrin or albumin.

Serum prealbumin concentration is affected by various conditions: Prealbumin is a negative acute phase reactant whose concentration decreases in the presence of inflammation as well as in the immediate postsurgical period. Serum levels also decline in patients with conditions associated with protein malnutrition, such as malignancy, cirrhosis, protein-losing enteropathy and zinc deficiency. Serum levels are also depressed by estrogens. Serum prealbumin levels may rise as a result of glucocorticoid, anabolic steroid and androgen use as well as in case of acute alcohol intoxication.

Method

Immunoturbidimetric test

Principle

Fixed time determination of the 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 Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. Reagent 1: Warning. H319 Causes serious eye irritation. P280 Wear protective gloves/protective clothing/eye protection/face 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 animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
4. In very rare cases, samples of patients with gammopathy might give falsified results [7].
5. Please refer to the safety data sheets 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.
6. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin or EDTA plasma
Stability [4]: 3 days at 2 – 8°C
6 months at –20°C

Freeze only once!

Discard contaminated specimens!

Assay Procedure for Analyzers

Application sheets for automated systems are available on request.

Wavelength 415 nm
Optical path 1 cm
Temperature 37°C
Measurement Against reagent blank

| Sample or calibrator | Blank | Sample or calibrator |
|--|---------|----------------------|
| Sample or calibrator | - | 12 µL |
| Dist. water | 12 µL | - |
| Reagent 1 | 1000 µL | 1000 µL |
| Mix, incubate for 5 min. and read absorbance A1, then add: | | |
| Reagent 2 | 200 µL | 200 µL |
| Mix, incubate for 5 min. and read absorbance again (A2). | | |

$\Delta A = (A2 - A1)$ sample or calibrator

Calculation

The prealbumin concentration of unknown samples is derived from the calibration curve using an appropriate mathematical model such as 4-parameter Logit-log. The calibration curve is obtained with five calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.

Stability of calibration: 6 weeks.

Calibrator and controls

For the calibration of automated photometric systems, DiaSys TruCal Protein calibrator set or the calibrator TruCal Protein high is recommended.

The assigned values of the calibrators have been made traceable to the reference material ERM[®]-DA470k/IFCC.

For internal quality control, DiaSys TruLab Protein controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

| | Cat. No. | Kit size |
|------------------------|------------------|----------|
| 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

The test has been developed to determine prealbumin concentrations from 0.04 – 1.5 g/L, at least up to the concentration of the highest calibrator. When values exceed this range samples should be diluted 1 + 3 with NaCl solution (9 g/L) and the result multiplied by 4.

Prozone Limit

No prozone effect was observed up to prealbumin values of 2.6 g/L.

Specificity/Interferences

DiaSys Prealbumin FS is specific for human prealbumin given by the antibodies chosen. No significant interference was observed by conjugated bilirubin up to 40 mg/dL, unconjugated bilirubin up to 35 mg/dL, hemoglobin up to 150 mg/dL, lipemia up to 2000 mg/dL triglycerides and RF up to 500 IU/mL. For further information on interfering substances refer to Young DS [6].

Sensitivity/Limit of Detection

The lower limit of detection is 0.01 g/L.

Precision

| Intra-assay n = 20 | Mean [g/L] | SD [g/L] | CV [%] |
|-----------------------|---------------|-------------|-----------|
| Sample 1 | 0.198 | 0.002 | 1.12 |
| Sample 2 | 0.341 | 0.005 | 1.41 |
| Sample 3 | 0.520 | 0.008 | 1.52 |

| Inter-assay n = 20 | Mean [g/L] | SD [g/L] | CV [%] |
|-----------------------|---------------|-------------|-----------|
| Sample 1 | 0.213 | 0.011 | 4.99 |
| Sample 2 | 0.353 | 0.013 | 3.74 |
| Sample 3 | 0.533 | 0.014 | 2.58 |

Method comparison

A comparison of DiaSys Prealbumin FS (y) with an immunoturbidimetric test (x) using 100 samples gave following results:

$$y=0.954 x + 0.011 \text{ g/L}; r=0.994$$

A comparison of DiaSys Prealbumin FS (y) with a nephelometric test (x) using 100 samples gave following results:

$$y= 0.983 x + 0.013 \text{ g/L}; r= 0.990$$

Reference range [5]

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. Dati F, Metzmann E. Proteins Laboratory Testing and Clinical Use. Holzheim: DiaSys; 2005. p. 42, 333-4.
2. Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W. B. Saunders Company; 1999. p. 500, 1144, 1384-5.
3. Beck FK, Rosenthal TC. Prealbumin: A Marker for Nutritional Evaluation. American Family Physician 2002; 65 (8): 1575-8.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 40-1.
5. Dati F et al. Consensus of a Group of Professional Societies and Diagnostic Companies on Guidelines for Interim Reference Ranges for 14 Proteins in Serum Based on the Standardization Against the IFCC/BCR/CAP Reference Material (CRM 470). Eur J Clin Chem Clin Biochem 1996; 34: 517-20.
6. 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.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(1): 1240–1243.

Manufacturer



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