PRE-ALBUMIN

Pre-albumin

Turbidimetry

Quantitative determination of Pre-albumin
IVD

Store 2 - 8ºC.

PRINCIPLE OF THE METHOD
PRE-ALBUMIN is a quantitative turbidimetric test for the measurement of prealbumin in human serum or plasma.
Anti-prealbumin antibodies when mixed with samples containing prealbumin, form insoluble complexes. These complexes cause an absorbance change, dependent upon the prealbumin concentration of the patient sample, that can be quantified by comparison from a calibrator of know prealbumin concentration.

CLINICAL SIGNIFICANCE
The prealbumin is a non-glycosilated protein synthesized mainly in the liver and choroid plexus of the brain. It binds and transport approximately 10% of serum thyroxin and triiodothyronine, and also plays a role in the transport of vitamin A in complex with retinal-binding protein.
Prealbumin is the earliest laboratory indicator of nutritional status and has emerged as the preferred marker for malnutrition because it correlates with patient outcomes in wide variety of clinical conditions. It is also a negative acute phase protein; serum levels falls in inflammation and malignancy, as well as cirrhosis, protein-losing enteropathy and zinc deficiency. However, the presence of a prealbumin producing tumor or Hodgkin's disease will increase serum concentrations.

REAGENTS

Diluent (R1)	Tris buffer 20 mmol/L, PEG 8000, pH 8,3. Sodium azide 0,95 g/L.
Antibody (R2)	Goat serum, anti-human prealbumin pH 7,5. Sodium azida 0,95 g/L.
Optional	Ref: 1102003 PROT CAL

CALIBRATION
The assay has been standardized against the Reference Material ERM-DA470k/IFCC. It is recommended the use of the PROT CAL for calibration. The reagent (both monoreagent and bireagent) should be recalibrated every three weeks, when the controls are out of specifications, and when changing the reagent lot or the instrument settings. For monoreagent, a reagent blank should be run daily before sample analysis.

PREPARATION
Reagents: Ready to use.
Calibration Curve: Prepare the following PROT CAL Calibrator dilutions in NaCl 9 g/L as diluent. Multiply the concentration of the pre-albumin calibrator by the corresponding factor stated in table bellow to obtain the prealbumin concentration of each dilution.

Calibrator dilution	1	2	3	4	5	6
Calibrator (µL)	--	10	25	50	75	100
NaCl 9 g/L (µL)	100	90	75	50	25	-
Factor	0	0,1	0,25	0,5	0,75	1,0

STORAGE AND STABILITY
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date.
Reagent deterioration: The presence of particles and turbidity.
Do not freeze; frozen Antibody or Diluent could change the functionality of the test.

ADDITIONAL EQUIPMENT
- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37ºC with a 340 nm filter (320 – 360 nm).

SAMPLES
Fresh serum or plasma. EDTA or heparin should be used as anticoagulant. Stable 7 days at 2-8ºC or 3 months at –20ºC.
The samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

PROCEDURE
1. Bring the reagents and the photometer (cuvette holder) to 37ºC.
2. Assay conditions:
   Wavelength: 340 nm
   Temperature: 37 ºC
   Cuvette ligth path: 1cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

Reagent R1 (µL)	800
Sample or Calibrator (µL)	10

5. Mix and read the absorbance (A_1) after the sample addition.
6. Immediately, pipette into de cuvette:

Reagent R2 (µL)	200

7. Mix and read the absorbance (A_2) of calibrators and sample exactly 2 minutes after the R2 addition.

Spinreact has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

CALCULATIONS
Calculate the absorbance difference (A_2-A_1) of each point of the calibration curve and plot the values obtained against the prealbumin concentration of each calibrator dilution. Pre-albumin concentration in the sample is calculated by interpolation of its (A_2-A_1) in the calibration curve.

QUALITY CONTROL
Control sera are recommended to monitor the performance of manual and automated assay procedures. It should be used the SPINREACT PROT CONTROL (Ref.:1102004). Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES[2]
Between 20 - 40 mg/dL. Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS
Measurement range: Up to 100 mg/dL, under the described assay conditions. Samples with higher concentrations, should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit depends on the sample /reagent ratio. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
Detection Limit: Values less than 0,69 mg/dL give non-reproducible results.
Sensitivity: 4,8 mA / mg/dL (50 mg/dL).
Prozone effect: No prozone effect was detected up to 230 mg/dL.
Precision:

EP5	CV (%)		
	20,04mg/dL	39,49 mg/dL	58,67 mg/dL
Total	4,9%	4,6%	4,9%
Within Run	1,8%	2,3%	1,4%
Between Run	2,4%	2,7%	2,4%
Between Day	3,9%	3,0%	4,0%

Accuracy: Results obtained using this reagent (y) were compared to those obtained using another immunoturbidimetric method. 60 samples ranging from 1 to 40 mg/dL of pre-albumin were assayed. The correlation coefficient (r) was 0,93 and the regression equation y = 1,031x – 4,617.
The results of the performance characteristics depend on the used analyzer.

INTERFERENCES
Hemoglobin (16 g/L), bilirubin (40 mg/dL), rheumatoid factors (200 IU/mL), do not interfere. Lipemia (≥ 8 g/L), interfere. Other substances may interfere [5,6].

NOTES
1. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

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4. Jayle MF et al. Progress in Hematology 1962; 3: 343-359.
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PACKAGING

Ref.: 1102124	Cont.	R1 Diluent: 1 x 40 mL R2 Antibody: 1 x 10 mL

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