

Quantitative determination of Prealbumin IVD

Store 2 - 8°C.

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 known prealbumin concentration.

CLINICAL SIGNIFICANCE

The prealbumin is a non-glycosylated 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

| | |
|------------------------|--|
| R1 | Tris buffer 20 mmol/L, PEG 8000, pH 8.2. Sodium azide 0.95 g/L. |
| R2 | Goat serum, anti-human prealbumin pH 7.5. Sodium azide 0.95 g/L. |
| Saline Solution | NaCl 9% (for samples predilution) |

CALIBRATION

The assay has been standardized against the Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM).

PREPARATION

Reagents: Ready to use.

Samples and Controls Pre-Dilution: Before the use, samples and/or controls must be diluted in this way:

- 50 µL sample or control + 450 µL NaCl 9 g/L (1:10)

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contamination is 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

- Pipette 100 - 1000 µL
- Pipette 10 - 100 µL
- Cuvettes and microstirrers (ref. code ACC16-037)

SAMPLES

Fresh serum or plasma. EDTA or heparin should be used as anticoagulant. Stable 7 days at 2-8°C or 3 months at -20°C.

The samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolyzed or lipemic samples.

TEST PARAMETERS

Filter: set filter on position B

Reading time: 120 seconds

PROCEDURE

1. Pipette into an appropriate number of cuvettes:

| kind of reagent | µL |
|------------------------------|-----|
| R1 | 500 |
| Prediluted sample or control | 50 |

2. Incubate the cuvettes in positions 1-4 for at least 1 minute
3. Transfer each cuvette in the reading channel and, when requested on the display, add 25 µL of R2.
4. Read the result which will appear automatically on the reader's display after 120 sec.

QUALITY CONTROL

Control sera are recommended to monitor the performance of manual and automated assay procedures. Vital Diagnostics SERUM PROT CONTROL BILEVEL (Cod.: ACC16-038) is available. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES²

Between 20 - 40 mg/dL. Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. Linearity: Up to 50 mg/dL (Nota 1), 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.
2. Detection Limit: Values less than 3 mg/dL give non-reproducible results.
3. Prozone effect: No prozone effect was detected upon 1000 mg/dL.
4. Sensitivity: Δ 4.8 mA / mg/dL (50 mg/dL).
5. Precision:

| | Mean | SD | CV% |
|--------------------|------|------|-----|
| Intra-assay (n=10) | 12.8 | 0.67 | 5.3 |
| Inter-assay (n=10) | 12.8 | 0.60 | 4.7 |

6. Accuracy: Results obtained using this reagent (y) were compared to those obtained using the method Elecsys from Roche. 64 samples ranging from 1 to 60 mg/dL of prealbumin were assayed. The correlation coefficient (r) was 0.93 and the regression equation $y = 1.095x + 0.024$.

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. Linearity depends on the calibrator concentration.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

1. Clinical Guide to Laboratory Tests, Edited by NW Tietz W B Saunders Co., Philadelphia, 483, 1983.
2. Dati F et al. Eur J Clin Chem Clin Biochem 1996; 34:517-520.
3. Pesce AJ and Kaplan, LA. Methods in Clinical Chemistry. The CV Mosby Company, St. Louis MO, 1987.
4. Jayle MF et al. Progress in Hematology 1962; 3: 343-359.
5. Young DS. Effects of drugs on clinical laboratory tests, 4th ed. AACC Pres, 1995.
6. Friedman and Young. Effects of disease on clinical laboratory tests, 3th ed. AACC Pres, 1997.

PACKAGING

| | | |
|-----------------|-------|-----------------------------|
| Ref.: ACC16-012 | Cont. | : 1 x 50 mL R1. Diluent |
| | | : 1 x 2 mL R2. Antibody |
| | | : 1 x 50 ml Saline solution |