



TOTAL PROTEIN LR liquid reagent

REF C4500650 1309 Test
CE C4500650A 1309 Test
IVD For in vitro medical device

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Kit for measurement of total protein in serum or plasma. Biuret method

Summary

Changes in serum total protein concentration are generally caused by a change in the volume of plasma water or changes in the concentration of one or more of the specific proteins in the plasma. Total proteins measurements are used in the diagnosis and treatment of a variety of liver and kidney diseases as well as metabolic and nutritional disorders.

Principle

End point analysis, biuretic method. In alkaline environment proteins react with bivalent ions of copper giving a coloured complex. The increase in absorbance due to the complex is proportional to the protein concentration in the sample. Absorbance measurements are taken at 540 nm.

Reagent

| | |
|---------------------------|--------------|
| R1 Sodium hydroxide | 350,0 mmol/l |
| Sodium potassium tartrate | 20,0 mmol/l |
| Iodide potassium | 5,2 mmol/l |
| Sulphate copper | 4,8 mmol/l |

Reagent Preparation

The reagent is ready to use.

Storage and stability

- The reagent R1 can be stored at 15 - 25°C.
- After opening, the vials R1 is stable up to the expiry date if recapped immediately

Precaution in use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with caution, according to good laboratory practice.

Waste management

Please refer to the local legal requirements.

Specimen collection and preparation

- Serum or heparinized plasma.
- Do not use sample with haemolysis.
- The proteins are stable in the samples up to 7 days at 15-25°C and 30 days at 2-8°C.

Note

- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package other lot number or the singles vials.

Procedure

Wavelength λ : 540 (530-570) nm
 Working temperature 37°C
 Optical path 1 cm
 Reaction "end point"

| | Blank | STD | Sample |
|-----------------|--------------|--------------|--------------|
| Reagent R1 | 1000 μ l | 1000 μ l | 1000 μ l |
| Distilled water | 10 μ l | -- | -- |
| Sample | -- | -- | 10 μ l |
| Standard | -- | 10 μ l | -- |

Mix, then incubate 10' at 37°C (15-25°C). Measure the absorbance of sample (EC) and standard. (ES) against the reagent blank.

Calculation

$$\text{Total Proteins [g/dl]} = \text{EC} / \text{ES} \times \text{Conc. STD}$$

The reagent performances are related to 37°C, 1 cm and 540 nm.

Reference Values

| | |
|----------------|----------------|
| Serum - plasma | 6.6 - 8.3 g/dl |
|----------------|----------------|

Reference values are considered indicatives since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity

Reaction is linear up to a concentration of 10 g/dl with a range of 0.3-10 g/dl. Samples with values exceeding 10 g/dl must be diluted with saline solution. Multiply, then, the result for diluting factor.

"Intra-Assay" Precision (Within - Run)

Determined on 20 samples for each control (N-H) (Normal-High). Results:

| | | |
|--------------|----------|----------|
| MEAN [mg/dl] | N = 5.05 | H = 5.23 |
| S.D. | N = 0.15 | H = 0.16 |
| C.V.% | N = 2.97 | H = 3.08 |

"inter-Assay" Precision (Between -Run)

Determined on 20 samples for each control (N-H) (Normal-High). Results:

| | | |
|--------------|----------|----------|
| MEAN [mg/dl] | N = 5.15 | P = 5.24 |
| S.D. | N = 0.18 | P = 0.21 |
| C.V.% | N = 3.41 | P = 3.92 |

Analytical sensitivity

The test sensitivity in terms of detection limit is: 0.5 g/dl.

Correlation

A study based comparing this method with a similar method on 21 samples has given a correlating factor: $r = 0.94$

$$y = 0.9445x + 0.755$$

Interferences

No interference was observed by the presence of:
 Bilirubin ≤ 30 mg/dl.
 Hemoglobin ≤ 500 m g/dl.
 Lipemic specimens should not be used for analysis. For a comprehensive review of interfering substances, refer to the publication by Young.

Quality Controls

It's necessary, each time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing

Bibliography

- Henry, R.J.: Clinical Chemistry, Hoeber, N.Y. 413, (1976)
 Tietz, N.W.: Fundamentals of Clinical Chemistry, Saunders Co., Philadelphia, PA 302 (1970)
 Kaplan LA, Pesce AJ: "Clinical Chemistry", Mosby Ed. (1996).
 Young D.S., Effects of Drugs on clinical laboratory Test, AACC Press, Washington, DC 5th ed. 2000.

Symbols

| | |
|-----|-------------------------------|
| CE | CE Mark (98/79 CE regulation) |
| IVD | in vitro medical device |
| LOT | Batch Code |
| | Use by |
| | Storage temperature limits |
| | Read instruction for use |
| | Producer |

Total Protein LR
MOD. 7.3.5 Rev. 0 del 2005-07

Gesam Production s.r.l.

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