Reactivos GPL

Barcelona, España

Store at: +2+8ºC.

- Total Protein -

TOTAL PROTEIN

Biuret. Colorimetric

Presentatión:
Cod. SU029 CONT: *R 2 x 125 mL.+ CAL 1 x 5 mL.*

Procedure

Quantitative determination of total protein.

Only for *in vitro use in clinical laboratory* (IVD)

TEST SUMMARY

Proteins give an intensive violet-blue complex with copper salts in an alkaline medium. Iodide is included as an antioxidant.
The intensity of the color formed is proportional to the total protein concentration in the sample[1,4].

REAGENTS COMPOSITION

R.1 BIURET	Sodium potassium tartrate	15 mmol/L
	Sodium iodide	100 mmol/L
	Potassium iodide	5 mmol/L
	Copper (II) sulphate	5 mmol/L
Calibrator	Bovine albumin primary standard	5 g/dL

REAGENT PREPARATION AND STABILITY

Reagent and standard are ready to use.
All the components of the kit are stable until the expiration date on the label when stored at 2-8ºC, protected from light and contamination prevented during their use.
Do not use reagents over the expiration date.
__Total Protein Calibrator__: Once open is stable up to 1 month when stored tightly closed at 2-8ºC, protected from light and contamination prevented during their use.
__Signs of Reagent deterioration__:

- Presence of particles and turbidity.
- Blank absorbance (A) at 540 nm. $\geq$ 0.22

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Stored at tightly closed at 2-8ºC,. Do not use reagents over the expiration date.

SPECIMEN

Serum or heparinized plasma[1]:
Stability of the sample: 1 month at refrigerator (2-8ºC).

MATERIAL REQUIRED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 540 nm.
- Matched cuvettes 1.0 cm. light path.

General laboratory equipment.

TEST PROCEDURE

1. Assay Conditions
- Wavelenght : .... 540 (530-550) nm.
- Cuvette: .... 1 cm light path.
- Temperature ....37ºC / 15-25ºC.

2. Adjust the instrument to zero with distilled water.

3. Pipette into a cuvette:

	Blank	Calibrator	Sample
R.1 (mL.)	1.0	1.0	1.0
Calibrator(Note 1-2) (μL.)	--	25	--
Sample (μL.)	--	--	25

4. Mix and incubate for 5 min at 30-37ºC or 10 min at room temperature (15-25ºC).

5. Read the absorbance (A) of the samples and calibrator, against the Blank. The colour is stable for at least 30 minutes.

CALCULATIONS

$$\text{Total Protein (g/dL.)} = \frac{(A)\text{Sample}}{(A)\text{Standard}} \times 5 \text{ (Calibrator conc.)}$$

Conversion Factor. g/dL. x 144,9 = μmol/L.

QUALITY CONTROL

Control sera are recommended to monitor the performance of the procedure, Control Normal Ref. QC001 and Control Pathological Ref. QC002. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions

REFERENCE VALUES

Adults	6.6 - 8.3 g/dL[1].
Newborn:	5,2 – 9,1 g/dL

(These values are for orientation purpose).
It is suggested that each laboratory establish its own reference range.

CLINICAL SIGNIFICANCE

The proteins are macromolecular organic compounds, widely distributed in the organism. They act like structural and transport elements. The proteins of the serum are divide in two fractions, albumin and globulins
The determination of total proteins is useful in the detection of:

- High protein levels caused by hemoconcentration like in the dehydrations or increase in the concentration of specific proteins.
- Low protein level caused by hemodilution by an impared synthesis or loss (as by hemorrhage) or excessive protein catabolism[4,5].

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE

– *Measuring Range*:
From detection limit 0f 0.20 g/dL. to linearity limit of 15 g/dL., under the described assay conditions.
If results obtained were greater than linearity limit, dilute the sample ½ with NaCl 9 g/L. and multiply result by 2.

– *Precision*:

	Intra-assay n= 20			Inter-assay n= 20	
Mean (g/dL)	5.07	9.64		5.15	9.74
SD	0.04	0.08		0.06	0.14
CV %	0.88	0.90		1.23	1.43

- Sensitivity:
  1 g/dL. = 0.07A
- Accuracy:
  Results obtained GPL reagents (y) did not show systematic differences when compared with other commercial reagents (x).
  The results obtained using 50 samples were the following:
  Correlation coefficient (r): 0.9918
  Regression Equation: y= 1.0164x – 0.1264
  The results of the performance characteristics depend on the analyzer used.

INTERFERING SUBSTANCES

– Interference:
Hemoglobin and lipemia[1,4].
Other substances may interfere. A list of drugs and other substances that could interfere has been reported by Young et. al[5,6].

NOTES

1. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
2. Use clean disposable pipette tips for its dispensation.

BIBLIOGRAPHY

1. Koller A. Total serum protein. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1316-1324 and 418.
2. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
3. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
4. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
5. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

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