Reactivos GPL
Barcelona, España

CE

- Total Protein -

TOTAL PROTEIN
Biuret. Colorimetric

Store at: +2+8º C.

Presentation:
Cod. SU029-SP CONT: *R 2 x 50 mL.+ CAL 1 x 5 mL.*
Cod. SU029 CONT: *R 2 x 125 mL.+ CAL 1 x 5 mL.*
Cod. SU029-B CONT: *R 8 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 Sodium iodide Potassium iodide Copper (II) sulphate Sodium hydroxide	15 mmol/L 100 mmol/L 5 mmol/L 5 mmol/L 1000 mmol/L
Calibrator	Bovine albumin primary standard	5 g/dL

PRECAUTIONS
R: H314-Causes severe skin burns and eye damage. H412-Harmful to aquatic life with long lasting effects.
Follow the precautionary statements given in MSDS and label of the product.

REAGENT PREPARATION AND STABILITY
Reagent and standard are ready to use.
T. Protein CAL: Proceed carefully with this product because due its nature it can get contaminated easily.
Do not use reagents over the expiration date.
Signs of Reagent deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 540 nm. ≥ 0.22

All the components of the kit are stable until the expiration date on the label when stored at 2-8º C, protected from light and contamination prevented during their use.

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

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
   - Wavelength: ..... 540 (530-550) nm.
   - Cuvette: ..... 1 cm light path.
   - Temperature .....37º C / 15-25º C.
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 37º C or 10 min at room temperature (15-25º C).
5. Read the absorbance (A) of the samples and calibrator, against the Blank. The colour is stable for at least 30 minutes.

CALCULATIONS
$$\frac{(A)Sample - (A)Blank}{(A)Standard - (A)Blank} \times 5$$ (Std. Conc. = g/dL Total Protein in sample

QUALITY CONTROL
Control sera are recommended to monitor the performance of the procedure, Control H Normal Ref. QC003 and Control H Pathological Ref. QC004. 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[1]
Adults 6.6 - 8.3 g/dL.
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 divided 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 impaired 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 0.007 g/dL. to linearity limit of 14 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)	6.53	4.89	6.77	5.08
SD	0.01	0.01	0.07	0.05
CV %	0.21	0.24	1.05	0.94

- *Sensitivity:*
1 g/dL. = 0.0825A
- *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)[2]: 0.97002
Regression Equation: y= 0.954x + 0.511
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

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