Instructions For Use

GENESIS

Total Protein (BIURET Method)

Cat no.	size
1107 101	2*100
1107 102	4*100

INTENDED USE
The Total Protein Reagent is intended for in vitro Quantitative diagnostic determination of total protein in human serum and plasma .

DIAGNOSTIC CHARACTERISTICS
Most of the plasma proteins are synthesized by the liver. The major exception to this is the immunoglobulins which are produced by plasma cells found in the spleen, lymph nodes and bone marrow.
The two general causes of alterations of serum total protein are a change in the volume of plasma water and a change in the concentration of one or more of the serum proteins.
Hyperproteinemia can be caused by dehydration (inadequate water intake, severe vomiting, diarrhea, Addison's disease, diabetic acidosis) or as a result of an increase in the concentration of specific proteins (immunoglobulins in chronic infections, multiple myeloma).
Hypoproteinemia may be caused by hemodilution (salt retention syndromes, massive intravenous infusions), by an impaired synthesis (severe malnutrition, chronic liver disease, intestinal malabsorptivedisease), or by an excessive protein loss due to a chronic kidney disease or severe burns.

PRINCIPLE OF THE METHOD
Protein in the sample reacts with copper (II) ion in alkaline medium forming a colored complex that can be measured by spectrophotometry

$$\text{Protein} + Cu^{2+} \xrightarrow{\text{alkaline pH}} \text{Cu-protein complex}$$

COMPOSITION

REAGENT(R)	
Copper sulphate	30 mmoll/L
Pot iodide	0.25 mmol/L
Sod hydroxide	15 mmol/L
STANDARD(S)	6.0 g/dL

STORAGE
Store at 2-8°C
Reagent and Standard are stable until the expiry date shown on the label Vial when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION
Reagent and Standard are provided ready to use.

ADDITIONAL EQUIPMENT
− Analyzer, spectrophotometer able to read at 546 nm.

SPECIMEN
1.Serum or heparinized plasma collected by standard procedures.
2.Anticoagulants other than heparin should not be used.
3.The serum or plasma should be separated from the cells within 4 hours.
4.Stability: 1 day at 15 – 25 °C
4 weeks at 2 – 8 °C
1 year at -20 °C

Precautions and Warnings
Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by

PROCEDURE
1. Bring the Reagent to room temperature.
2. Pipette into labeled test tubes:

	Blank	Standard	Sample
Reagent (R)	1.0 mL	1.0 mL	1.0 mL
Standard (S)	-	20 µL	-
Sample	-	-	20 µL

3. Mix thoroughly and incubate the tubes for **10 minutes** at room temperature (16-25ºC).
4. Measure the absorbance (A) of the Standard and Sample at 546 nm against the Blank. The color is stable for at least 1 hour.

CALCULATIONS
The Total protein concentration in the sample is calculated using the following general formula:

$$\frac{A\ Sample}{A\ Standard} \times 6.0 = g/dL\ Total\ protein$$

REFERENCE VALUES

Adults	6.6 – 8.7 g/dL
Children (> 1 year)	6.0 – 8.0 g/dL
(< 1 year)	4.8 – 7.6 g/dL

QUALITY CONTROL
It is recommended to use the Control Serum level I and II to verify the performance of the measurement procedure.
Each laboratory should establish its own internal Quality Control.

METROLOGICAL CHARACTERISTICS

− Detection limit: 0.46 g/dL

− Linearity limit: 15.0 g/dL

For higher values dilute sample 1/2 with physiological saline and repeat measurement.

− Repeatability (within run):

Mean Concentration	cv	n
4.4 g/dL	1.1 %	20
5.7 g/dL	0.9 %	20

− **Reproducibility (run to run):**

Mean Concentration	cv	n
4.4 g/dL	1.8 %	25
5.7 g/dL	1.9 %	25

− INTERFERENCES
- Hemoglobin (0.25 g/dL) and lipemia interfere
- Bilirubin (20 mg/dL) does not affect the results
- Other drugs and substances may interfere

BIBLIOGRAPHY
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CE

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