ISE S.r.l.
CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

Total Protein – Instructions for use

6 x 20 mL • REF A-R0000000019
6 x 50 mL • REF A-R0100000801

IVD CE

INTENDED USE
Product for use in the quantitative determination in vitro of the concentration of Total Proteins in human serum or plasma. The results of the test must always be interpreted in conjunction with the clinical picture.

PRINCIPLE
The Total Protein concentration can be determined by both physical and chemical methods. The I.S.E. S.r.l. test is based on the chemical biuret-tartrate method. In an alkaline ambient, copper ions react with substances containing two or more peptide groups, to form a violet coloured compound; this reaction is know as the biuret reaction (1). The intensity of the colour is directly proportional to the protein concentration in the sample.

REAGENTS
Kit 6 x 20 mL code A-R0000000019
Reagent: no. 6 vials x 19.5 mL code 184006
Kit 6 x 50 mL code A-R0100000801
Reagent: no. 6 vials x 48.5 mL code 184034

Concentrations

Reagent:			
	Conc.	**U.M.**	
Sodium hydroxide	0.5	M	
Potassium iodide	7.50	mM	
Copper sulphate	15.9	mM	
K-Na tartrate	46.8	mM	

Precautions
Reagent is harmful and must be used with caution. Refer to the appropriate Material Safety Data Sheet for the risk phrases and safety measures (**Identification of Risks: GHS05, H314 – H412**). In addition to any risk indications related to the active components, reagents may contain inactive components such as preservatives and detergents. The total concentrations of these components are lower than the limit reported in the EC directive 1272/2008 and subsequent amendments and additions. However, It is recommended to handle reagents according to the standards of good laboratory practice and adopt all adequate protective measures.

Storage and stability
Store at 15 - 25°C and protect from direct light. When correctly stored, the reagents are stable up the expiry date reported on the label. A slight variation in the composition of the reagent may occur between batches, but this has no effect on the test results. After opening, the vial R1 and R2 are stable 30 days if recapped immediately and protected from contamination, evaporation, direct light and stored at correct temperature

SAMPLE COLLECTION
Type of sample and storage
Serum or plasma samples can be used. The present method can be used to titrate sera with a high lipid content and sera with hemoglobin concentrations up to 250 mg/dL. When plasma samples are used, the results obtained are up to 0.4 g/dL higher than those found in serum samples. This difference is due to the presence of fibrinogen in plasma.

Precautions
All human samples must be handled and disposed of as potentially infectious materials.

PROCEDURE
Quality control
Human control serum with known levels of Total Protein is commercially available for quality control purposes. Data sheets are included, listing the values and the confidence limits. Normal and abnormal control sera are available from I.S.E. S.r.l. "Normal control serum" code R0400000006 and "Pathological control serum" code R0400000106. Obtained values must be within the range of acceptability. If erratic results occur, the following points should be checked:
- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation
This kit, though developed and manufactured to be used as manual assay and with I.S.E. S.r.l. analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions - Test procedure" Application sheets are available for automatic instruments.
All applications not explicitly approved by I.S.E. S.r.l. cannot be guaranteed in terms of performance, and must therefore be established by the operator.

Calibration
For calibration use the "Multicalibrator" I.S.E. S.r.l. code R0300000006.

Traceability
The Total Protein value is reported in the package insert supplied with the "Calibrator Serum".

Calibration Stability
For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

Method for automated instrumentation

Analyzer:	**I.S.E. Miura**		
Analyte Name :	**Total Protein**	Ref.:	A-R0100000801 A-R0000000019
Method Code:	**TP**		
Type:	**EndPoint**		
Unit:	**g/dL**		
Filter F1:	**546 nm**		
Blank in:	**Used**		
Step	**Reaction volume**		**U.M.**
Volume reagent R1:	**200**		µL
Sample volume:	**2**		µL
Final Incubation:	**600**		Sec.

Reagents included in the kit
The reagent is described above.

Materials required but not supplied in the kit
Calibrators and controls.

NORMAL VALUES (2)
Serum or plasma:
- 6.2 – 8.5 g/dL (62 - 85 g/L)

Each laboratory must establish its own normal values on the basis of its local population.

ANALYTICAL CHARACTERISTICS / PERFORMANCE
Linearity
The method is linear up to 12.94 g/dL.

Specificity
The I.S.E. S.r.l. method is specific, reducing to a minimum interference caused by lipemic sera or those with high bilirubin content or hemolysis.

Accuracy-Recovery
Accuracy studies were performed on normal samples to which known amounts of albumin had been added. The results indicate an accuracy of 97% with linear correlation.

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Revision E A-R0000000019/A-R0100000801-02-2016

Precision of the method

Within-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	g/dL	3.99	0.077	1.92%	20
High	g/dL	6.42	0.097	1.50%	20

Between-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	g/dL	3.99	0.104	2.61%	20
High	g/dL	6.42	0.276	4.30%	20

Sensitivity
At λ 546 nm, a concentration of 0.164 g/dL of Total Proteins.

Comparative method
The I.S.E. S.r.l. Total Proteins reagent was compared with the Sclavo Diagnostics Protein Test, giving the following results: Regression line Y = 1.009x - 0.36 ; r = 0.986; Sample tested No. = 71.

Disposal of reagents
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

The product is in conformity with D.L: 8 September 2000, no. 332 "Actuation of the directive 98/79/EC regarding in vitro medical diagnostic devices".

Symbols used on labels and packaging

IVD = In vitro diagnostic medical device

REF = Catalog Number

LOT = Lot Number

 = Manufacturer

 = Expiration date

 = Temperature limitation

 = Instruction for use

References
1. Kato M. Z Physik Chem (Frankfurt) 1960; 23: 375. In Chem Abstr 1960; 54:16128
2. Henry RJ. Clinical Chemistry: Principles and Technics 222-226. Harper & Row Publishers, New York 1968 .