Total Protein – Instructions for Use (IFU)

6 x 50 mL • REF A-R0100000801
3 x 18,5 mL • REF R3330000024

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

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. For professional use only.

CLINICAL SIGNIFICANCE
Proteinemia is a test useful to quantify the proteins present in the blood. Often, this parameter is measured as part of the panel of analyzes performed during routine check-ups, so it is frequently used in assessing the patient's general health status. The concentration of proteins in the blood can provide general information about nutritional status, useful, in particular, when the patient has inexplicably lost weight. Proteinemia can be prescribed together with other tests to understand the cause of an abnormal accumulation of fluid in the tissues (edema) and as a support to the diagnosis of certain liver and kidney diseases.

PRINCIPLE
The determination of Total Proteins can be performed both with physical and chemical methods. Its determination is based on the chemical method of biureto-tartrate. Copper ions in alkaline medium react with substances containing two or more peptide groups to form a violet complex, this reaction is referred to as the biuret reaction (1). The intensity of the colour is directly proportional to the concentration of proteins in the sample.

REAGENTS
A-R0100000801 - 6 x 50 mL
Reagent: n° 6 vials x 50,0 mL ready for use
R3330000024 - 3 x 18,5 mL
Reagent: n° 3 vials x 14,0 mL ready for use

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	* **GHS05**

***** _ Warning: **DANGER**
Contains Sodium hydroxide (CAS 1310-73-2)
H314 - Causes severe skin burns and eye damage.
H412 - Harmful to aquatic life with long lasting effects.
P101 - If medical advice is needed, have product container or label at hand.
P102 - Keep out of reach of children.
P103 - Read carefully and follow all instructions.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER/doctor.
P321 - Specific treatment (see on this label).
P501 - Dispose of contents/container in accordance with local / regional / national / international regulations.

Precautions
Kit for professional laboratory use, used only by qualified and properly trained technical personnel, under the supervision of a doctor in charge of the laboratory. In addition to risk indications related to the active components, reagents may contain inactive components such as preservatives and detergents. The total concentration of these components is lower than the limits reported in the EC 1272/2008 Regulation and subsequent amendments and additions. However, it is recommended to handle reagents according to the standards of good laboratory practice.

Reports of serious incidents
In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

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
Known Total Protein control sera are commercially available for quality control, including certificates of analysis showing values and confidence limits. Normal and pathological control sera "Normal control serum" cod. R0400000006 and "Pathological control serum" code R0400000106. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:
- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation
Although this device has been developed and manufactured to be used by manual method and instrumental systems, it can also be used in combination with other instrumental devices that are able to meet the requirements indicated in the paragraph "Reaction conditions / Technique".
All applications that are not explicitly approved cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user

Calibration
For calibration use the "Multicalibrator" code R0300000006. For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

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

Reaction conditions
Wavelength (primary): 540 nm
Temperature: 37°C

Technique – Procedure with Serum as starter
Bring the reagents to the reaction temperature.

	U.M.	**Calib.Serum**	**Sample**	**Blank**
Reagent	µL	1000	1000	1000
Calib.Serum	µL	10	-	-
Sample	µL	-	10	-
Blank	µL	-	-	10

Mix then wait 10 minutes before reading.
Read the absorbances of the sample and the Calibration Serum by subtracting the absorbance of the reagent white. The final color is stable 2 hours away from direct light.
The reaction volumes can be varied proportionately, the calculation remaining unchanged.

Results
The concentration of Total Protein is obtained through the following formula:

$$\frac{\text{O.D. Sample}}{\text{O.D. Calibration Serum}} \times \text{Calibrator Concentration} = \text{Total Protein (g/dL)}$$

Reagents included in the kit
The reagent is described above.

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

NORMAL VALUES
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.

Sclavo Diagnostics International
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Phone +39 0577 39041 - Fax +39 0577 390 444

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ANALYTICAL CHARACTERISTICS / PERFORMANCE

Linearity

The method is linear up to 12.94 g/dL.
The 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.

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 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.

Manufacturer:

Sclavo Diagnostics International
Via Po 26-28 – Loc. Pian dei Mori – 53018 Sovicille (SI) (Italy)
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Distributor:

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Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

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 .

REVISION	DATE	CHANGE
Rev.A	12/2022	New Issue for IVDR Regulation (UE) 2017/746 compliance