ISE S.r.l.

CUSTOMISED SOLUTIONS
FOR YOUR LABORATORY

Total Protein – Instructions for use

CE IVD

R1: 4x 10 mL **R3330000024** REF

Diagnostic reagent for quantitative in vitro determination of total protein in human serum or plasma on photometric systems

TEST PARAMETERS

Method:	Colorimetric, Endpoint, Increasing Reaction, Biuret
Wavelength:	540 nm, Hg 546 nm
Temperature:	20 – 25 °C, 37 °C
Sample:	Serum or plasma
Linearity:	up to 15 g/dL (150 g/L)
Sensitivity:	Lower limit of detection: 0.05 g/dL (0.5 g/L)

SUMMARY [1,2]

Measurement of total protein is a useful test in a variety of disorders. Decreased total protein concentrations can be detected in defective protein synthesis in the liver, protein loss due to impaired kidney function, intestinal malabsorption or nutritional deficiency. Elevated protein levels occur in chronic inflammatory disorders, liver cirrhosis and dehydration.

TEST PRINCIPLE

Photometric test according to the Biuret method.
Proteins form a violet blue colour complex with copper ions in alkaline solution.
The absorbance of this colored complex is directly proportional to the protein concentration in the sample.

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Sodium hydroxide	180 mmol/L
Potassium sodium tartrate	30 mmol/L
Potassium iodide	15 mmol/L
Copper sulphate	6 mmol/L

REAGENT PREPARATION

The reagent is ready to use.

REAGENT STABILITY AND STORAGE

Conditions: Protect from light.
Close immediately after use.
Do not freeze the reagents.
Avoid contamination.
Storage: at 2 – 25 °C
Stability: up to the expiration date

SAMPLE STABILITY AND STORAGE

Stability [3]: at 20 – 25 °C 6 days
at 4 - 8 °C 4 weeks
at -20° C at least 1 year
Discard contaminated specimens.
Freeze only once!

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

STANDARD

(not included in the kit – has to be ordered separately)
Concentration 5 g/dL (50 g/L)
Storage: 2 – 8 °C
Stability: up to the expiration date
Close immediately after use! Avoid contamination!

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std./Cal.	Sample
Sample	-	-	20 µl
Standard/Calibrator	-	20 µl	-
Dist. water	20 µl	-	-
Reagent	1000 µl	1000 µl	1000 µl
Mix, incubate for 5 min. at 20-25 °C / 37 °C and read absorbance against the reagent blank within 60 min.			

CALCULATION

$$\text{Total protein [g/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. Std/Cal [g/dL]}$$

UNIT CONVERSION

g/dL x 10 = g/L

REFERENCE RANGE [1] * [g/dL]

	Females	Males
Adults:	6.6 - 8.8	6.6 - 8.8

Children:	**Females**	**Males**
1 - 30 day(s)	4.2 - 6.2	4.1 - 6.3
1 – 6 month(s)	4.4 - 6.6	4.7 - 6.7
6 months – 1 year	5.6 - 7.9	5.5 - 7.0
1 – 18 year(s)	5.7 - 8.0	5.7 - 8.0

*Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Linearity, measuring range

The test has been developed to determine total protein concentrations within a measuring range from 0.05 – 15 g/dL (0.5 – 150 g/L).
If values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 0.05 g/dL (0.5 g/L).

PRECISION (at 37 °C)

Intra-assay n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	5.27	0.05	0.91
Sample 2	7.05	0.07	1.01
Sample 3	10.4	0.08	0.80

Inter-assay n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	5.24	0.06	1.06
Sample 2	7.07	0.11	1.53
Sample 3	10.4	0.14	1.32

SPECIFICITY/INTERFERENCES

no interference up to:

Ascorbic acid	30 mg/dL
Bilirubin	40 mg/dL
Hemoglobin	500 mg/dL
Triglycerides	1000 mg/dL
Dextran	2000 mg/dL

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For further information on interfering substances refer to Young DS

[4].

METHOD COMPARISON

A comparison between this Total protein (y) with a commercially available test (x) using 68 samples gave following results: y = 1.00 x – 0.07 g/dL; r= 0.997.

CALIBRATION

The assay requires the use of a protein total standard or calibrator.

QUALITY CONTROL

All control sera with protein total values determined by this method can be used.
Each laboratory should establish corrective action in case of deviations in control recovery.

WARNINGS AND PRECAUTIONS

1. Reagent: Warning.
   H290: May be corrosive to metals.
   H315: Causes skin irritation.
   H319: Causes serious eye irritation.
   P234: Keep only in original container.
   P280: Wear protective gloves/protective clothing/eye protection/face protection.
   P302+P352: If on skin: Wash with plenty of water/soap.
   P305+P351+P338: In in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Contrinue rinsing.
   P309+P311: If exposed or if you feel unwell: call a poison center or doctor/physician.
   P390: Absorb spillage to prevent material damage.
2. The reagents contain sodium hydroxide. Do not swallow! If the reagents come in contact with skin or mucous membranes rinse immediately with water!
3. The Protein Total Standard contains biological material. The standard should be handled as potentially infectious and with the same precautions used for patient specimens.
4. In serum or plasma from patients who have received large intravenous amounts of polydextrans too high values can be measured with the biuret method. In such cases an alternative method (e.g. Kjeldahl) has to be used.
5. In very rare cases, samples of patients with gammopathy might give falsified results [5].
6. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
7. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
8. For professional use only!

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 644-7.
2. Johnson Am, Rohlfs EM, Silverman LM. Proteins. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 477-540.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st e. Darmstadt: GIT Verlag; 2001; p.42-3.
4. Young DS. Effects of Drugs on Clinical laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007; 45(9): 1240-1243.

Symbols on labels and packaging

IVD = In vitro diagnostic medical device

REF = Catalog Number

LOT = Lot Number

= Manufacturer

= Expiration date

= Temperature limitation

= Instruction for use

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