# Total Protein

DiaSystem Scandinavia AB

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

## Order Information

| Cat. No. | Kit size | | | | | | |
|---|---|---|---|---|---|---|---|
| 01 00042 70 04 0100 | R1 | 4 x | 20 mL | + | R2 | 1 x | 20 mL |
| 01 00042 70 04 0500 | R1 | 5 x | 80 mL | + | R2 | 1 x | 100 mL |
| CDT-TP | R1 | 4 x | 20 mL | + | R2 | 2 x | 10 mL |
| 01 00042 70 02 0180 | R1 | 4 x | 36 mL | + | R2 | 4 x | 9 mL |
| 06 00114 70 04 0018 | Total protein Standard 6x3 mL | | | | | | |

## 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.

## Method

Photometric test according to biuret method

## Principle

Proteins form a violet blue color complex with copper ions in alkaline solution. The absorbance of the color is directly proportional to the concentration.

## Reagents

**Components and Concentrations**

| | | |
|---|---|---|
| **R1:** | Sodium hydroxide | 100 mmol/L |
| | Potassium sodium tartrate | 17 mmol/L |
| **R2:** | Sodium hydroxide | 500 mmol/L |
| | Potassium sodium tartrate | 80 mmol/L |
| | Potassium iodide | 75 mmol/L |
| | Copper sulphate | 30 mmol/L |
| **Standard:** | | 5 g/dL |

Contains bovine serum albumin (< 5%)

**Storage Instructions and Reagent Stability**

The reagents and the Standard are stable up to the end of the indicated month of expiry, if stored at 2 – 25°C and contamination is avoided. Do not freeze the reagents and protect them from light!

**Warnings and Precautions**

1. Reagent 1: Warning. H290 May be corrosive to metals. P234 Keep only in original container. P390 Absorb spillage to prevent material damage.
2. Reagent 2: Warning. H290 May be corrosive to metals. H315 Causes skin irritation. H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effects. P234 Keep only in original container. P264 Wash hands and face thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection. P332+P313 If skin irritation occurs: Get medical advice/attention. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.
3. The reagents contain sodium hydroxide. Do not swallow! If the reagents get in contact with skin or mucous membranes rinse immediately with water!

***Continue Warnings and Precautions***

4. Total Protein Standard FS contains biological material. The standard should be handled as potentially infectious and with the same precautions used for patient specimens.
5. In serum or plasma of 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.
6. In very rare cases, samples of patients with gammopathy might give falsified results [5].
7. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. 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.

**Reagent Preparation**

The standard is ready to use.

***Substrate Start***

The reagents are ready to use.

***Sample Start***

Mix 4 parts of R1 with 1 part of R2
(e.g. 20 mL R1 + 5 mL R2) = mono reagent
Stability after mixing: 1 year at 2 - 25 °C

**Materials required but not provided**

NaCl solution 9 g/L
General laboratory equipment

## Specimen

Serum or plasma

| | | | |
|---|---|---|---|
| Stability [3]: | 6 days | at | 20 – 25 °C |
| | 4 weeks | at | 4 – 8 °C |
| | at least one year | at | -20 °C |

Freeze only once! Discard contaminated specimens!

## Assay Procedure

***Application sheets for automated systems are available on request.***

| | |
|---|---|
| Wavelength | 540 nm, Hg 546 nm |
| Optical path | 1 cm |
| Temperature | 20 - 25 °C/37 °C |
| Measurement | Against reagent blank |

***Substrate start***

| | Blank | Sample or standard |
|---|---|---|
| **Sample or standard** | - | 20 µL |
| **Dist. water** | 20 µL | - |
| **Reagent 1** | 1000 µL | 1000 µL |
| Mix, read absorbance A1 after 1 – 5 min at 20 – 25 °C/ 37 °C, then add: | | |
| **Reagent 2** | 250 µL | 250 µL |
| Mix, incubate for 5 min at 20 – 25 °C/37 °C and read absorbance A2 within 60 min. | | |

ΔA = (A2 – A1) sample or standard

# Total Protein

DiaSystem Scandinavia AB

***Sample start***

| | Blank | Sample or standard |
|---|---|---|
| **Sample or standard** | - | 20 µL |
| **Dist. water** | 20 µL | - |
| **Mono reagent** | 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. | | |

ΔA = A Sample/Standard

## Calculation

With standard or calibrator

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

## Calibrators and Controls

For the calibration of automated photometric systems, the DiaSystem UniCal CC is recommended. The assigned values of the calibrator are traceable to the biuret method. DiaSystem UniLab N and DiaSystem UniLab P should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery

| | Cat. No. | Kit size |
|---|---|---|
| UniCal CC | 06 00122 70 04 0018 | 6 x 3 mL |
| UniLab N | 07 00123 70 05 0030 | 6 x 5 mL |
| UniLab P | 07 00124 70 05 0030 | 6 x 5 mL |

## Performance Characteristics

**Measuring range**

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

**Specificity/Interferences**

No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 500 mg/dL, dextran up to 2000 mg/dL and lipemia up to 1000 mg/dL triglycerides. For further information on interfering substances refer to Young DS [4].

**Sensitivity/Limit of Detection**

The lower limit of detection is 0.05 g/dL.

**Precision (at 37 °C)**

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

**Method Comparison**

A comparison of DiaSytem 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.

## Reference Range [1]

| | [g/dL] | |
|---|---|---|
| Adults: | 6.6 – 8.8 | |
| Children | Female | Male |
| 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.

## Literature


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 ed. 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 Assocation 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.


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