PZ CORMAY S.A.
ul. Wiosenna 22,
05-092 Łomianki, POLSKA
tel.: +48 (0) 81 749 44 00
fax: +48 (0) 81 749 44 34
http://www.cormay.pl

Liquick Cor-TOTAL PROTEIN

Kit name	(EN) Cat. No
Liquick Cor-TOTAL PROTEIN mini	2-221
Liquick Cor-TOTAL PROTEIN 30	2-240
Liquick Cor-TOTAL PROTEIN 60	2-236
Liquick Cor-TOTAL PROTEIN 120	2-237

INTENDED USE
Diagnostic kit for determination of total protein concentration intended to use for manual assay and in several automatic analyzers.
The reagents must be used only for *in vitro* diagnostic, by suitably qualified laboratory personnel, only for the intended purpose, under appropriate laboratory conditions.

INTRODUCTION
Most serum proteins except gamma globulins and hemoglobin are synthesized in the liver. Proteins participate in transport, catalysis and coagulation, act as hormones and receptors, antigens and antibodies, regulate osmotic pressure and play structural functions. Correct serum level of total protein depends mainly on balance between synthesis and degradation of albumin and immunoglobulins. Total protein level abnormalities are caused usually by dehydration, liver or kidney disease and starvation.

METHOD PRINCIPLE
The method is based on the biuret reaction. Protein forms the coloured complex with cupric ions in alkaline medium. The colour intensity is proportional to the protein concentration.

REAGENTS
Package

	Liquick Cor-TOTAL PROTEIN mini	Liquick Cor-TOTAL PROTEIN 30	Liquick Cor-TOTAL PROTEIN 60	Liquick Cor-TOTAL PROTEIN 120
1-TOTAL PROTEIN	2 x 30 ml	6 x 30 ml	6 x 60 ml	6 x 120 ml
2-STANDARD	1 x 1 ml	1 x 2 ml	1 x 2 ml	-

2-STANDARD is albumin standard solution: 4.0 g/dl (40 g/l).

Working reagent preparation and stability
The reagent is ready to use.
The reagent when stored at 2-8°C is stable up to expiry date printed on the package. The reagents are stable for 8 weeks on board the analyser at 2-10°C.

Concentrations in the test

copper sulfate	12 mmol/l
sodium-potassium tartrate	30 mmol/l
potassium iodide	30 mmol/l
sodium hydroxide	480 mmol/l

Warnings and notes
- Protect from light and avoid contamination!
- 1-TOTAL PROTEIN meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.

Ingredients:
1-TOTAL PROTEIN contains sodium hydroxide and copper (II) sulfate pentahydrate.

Danger

H314 Causes severe skin burns and eye damage.
H411 Toxic to aquatic life with long lasting effects.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P273 Avoid release to the environment.

ADDITIONAL EQUIPMENT
- automatic analyzer or photometer able to read at 546 nm;
- thermostat at 37ºC;
- general laboratory equipment;

SPECIMEN
Nonhemolyzed, nonlipaemic, fresh serum is recommended. Results obtained from plasma analysis might be slightly elevated due to fibrinogen presence.
Recommended anticoagulants: EDTA, heparine lithium, sodium or ammonium salt.
Serum should be separated from red blood cells as soon as possible after blood collection.
Serum and plasma can be stored up to 3 days at 2-8ºC or 6 months at -20ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE
These reagents may be used both for manual assay and in several automatic analysers. Applications for them are available on request.

Manual procedure

wavelength	546 nm
temperature	37°C
cuvette	1 cm

Pipette into the cuvettes:

	reagent blank (RB)	test (T)	standard (S)
1-TOTAL PROTEIN	1000 µl	1000 µl	1000 µl

Bring up to the temperature of determination. Then add:

standard / calibrator	-	-	20 µl
sample	-	20 µl	-

Mix well, incubate for 5 min. at the temperature of determination. Read the absorbance of the test A(T) and standard A(S) against reagent blank (RB). The intensity of colour is stable for 30 min.

Calculation

$$\text{protein concentration} = \frac{A(T)}{A(S)} \times \text{standard / calibrator concentration}$$

REFERENCE VALUES [7]

serum		g/dl	g/l
premature	1 d	3.4 – 5.0	34 – 50
children	1d – 4 wk	4.6 – 6.8	46 – 68
	2 – 12 mo	4.8 – 7.6	48 – 76
	≥1 y	6.0 – 8.0	60 – 80
adults		6.6 – 8.7	66 – 87

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL
For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.
For calibration when using the manual methods the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) or PROTEIN STANDARD 4 (Cat. No 5-116) or 2-STANDARD attached to the kit is recommended.
For calibration of the automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174, 5-176) is recommended.
The calibration curve should be prepared every 8 week, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS
These metrological characteristics have been obtained using automatic analyser Biolis 24i Premium. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity**

0.13 g/dl (1.3 g/l)

- **Linearity:**

up to 16.50 g/dl (165 g/l) using automatic analyser;
up to 16.90 g/dl (169 g/l) for manual procedure.

For higher concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**

Haemoglobin up to 0.31 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 950 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [g/dl]	SD [g/dl]	CV [%]
level 1	4.29	0.02	0.52
level 2	6.69	0.03	0.46
Reproducibility (day to day) n = 10	**Mean [g/dl]**	**SD [g/dl]**	**CV [%]**
level 1	4.33	0.07	1.61
level 2	6.85	0.12	1.72

- **Method comparison**

A comparison between total protein values determined at **Biolis 24i Premium** (y) and at **ADVIA 1650** (x) using 21 samples gave following results:
y = 1.014 x + 0.018 g/dl;
R = 0.976 (R – correlation coefficient)

TRACEABILITY
PROTEIN STANDARD 4 is traceable to the SRM 927D/1950 reference material.

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE
1. Koller A., Kaplan L.A.: Methods in Clinical Chemistry. C. V. Mosby Company, 1134 (1987).
2. Gornall A.G. Barswill C.J. David M.M.: J. Biol. Chem. 177, 751-766 (1949).
3. Doumas B.T.: Clin. Chem. 21, 1159-1166 (1975).
4. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia, PA: WB Saunders, 696-7 (1994).
5. Tietz N.W., ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: WB Saunders, 518 (1995).
6. Kaplan A., Jack R., Opheim K.E., Toivola B., and Lyon A.W., ed. Clinical Chemistry, Interpretation and Techniques, 4th ed. Malvern PA: Williams & Wilkins, 265 (1995).
7. Dembińska-Kieć A., Naskalski J.W.: Diagnostyka laboratoryjna z elementami biochemii klinicznej, Volumed, 142-144, 778, (1998).

Date of issue: 06. 2018.