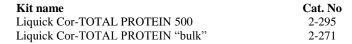
Liquick Cor-TOTAL PROTEIN

DIAGNOSTIC KIT FOR DETERMINATION OF TOTAL PROTEIN CONCENTRATION



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-	Liquick Cor-
TOTAL PROTEIN	TOTAL PROTEIN
500	"bulk"
4 x 500 ml	*

1-TOTAL PROTEIN

*reagent volume is printed on the label.

Working reagent preparation and stability The reagent is ready to use.

The reagent when stored at $2-8^{\circ}C$ is stable up to expiry date printed on the package. The reagents are stable for 8 weeks on board the analyser at $2-10^{\circ}C$.

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

- Product for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- 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 37°C;
- 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 2-8°C or 6 months at -20°C

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

546 nm
37°C
1 cm

Pipette into the cuvettes:

	reagent blank (RB)	test (T)	standard (S)
1-TOTAL PROTEIN	1000 μ1	1000 μ1	1000 μl
Pring up to the temperature		· · · · · ·	

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

protein	_ <u>A(T)</u>	standard / calibrator
concentration	- A(S)	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).

For calibration of the <u>automatic analysers systems</u> the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174, 5-176) is recommended.

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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)	Mean	SD	CV
n = 10	[g/dl]	[g/dl]	[%]
level 1	4.29	0.02	0.52
level 2	6.69	0.03	0.46
Reproducibility (day to day)	Mean	SD	CV
n = 10	[g/dl]	[g/dl]	[%]
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 reference material.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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