

Order information:

Catalogue number	Size
9811C	10 x 65 ml
9812C	4 x 65 ml

Reagent kit for quantitative in vitro determination of total protein in serum and plasma.

Summary

The human body contains countless different protein (50% in cells). Not only is the variety of proteins seemingly infinite, so are their variations of concentration in health and disease, their distribution within the body, their functions, their compositions and their structures. Most plasma proteins with the exception of immunoglobulins and hormonal proteins are synthesized in liver. They function as major components of cells, are involved in transport, enzyme catalysis, homeostatic control, hormonal regulation, blood coagulation, immunity, growth and repair, and heredity.

Method

Photometric, Biuret.
Cupric ions in an alkaline solution react with the peptide bonds of proteins colored complex. The absorbance is directly proportional to the concentration of protein in the sample.

Reagents

Composition and concentrations

Potassium-iodide	150 mmol/l
Potassium-sodium-tartrate	500 mmol/l
Copper-sulfate	150 mmol/l
Sodium-hydroxide	0,1 mol/l

Storage and stability

The reagent is stable up to the end of the indicated month of expiry without opening, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze!
Onboard stability after opening and the frequency of calibration is 30 days.

Warnings and precautions

Do not use reagents after the expiry date stated on each reagent container label.

Chemical safety

C, Corrosive
R34 Causes burns
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S37/39 Wear suitable gloves and eye/face protection
S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)
Safety data sheet is available upon request.

Preparation

The reagent is ready for use.

Sample

Serum, heparin, citrate or EDTA plasma.
Stability in serum: 4 weeks at 4 – 8°C
6 days at 20 – 25°C
1 year at -20°C

Expected values and reference range

Serum 63 – 80 g/l
It is recommended that each laboratory should assign its own normal range.

Assay procedure

Wavelength: 545 nm / 658 nm (primary/secondary)
Optical path: 1 cm
Temperature: 37°C
Measurement: against reagent blank
Reaction: endpoint, increasing

	blank	sample or standard
reagent	200 µl	200 µl
dist. water (diluent)	800 µl	800 µl
dist. water (blank)	10 µl	-
sample or standard	-	10 µl
Mix and incubate for 10 minutes and read the absorbance against reagent blank		

Calculation

Total protein[g/l]= ΔA sample/ ΔA standard \times standard concentration[g/l]

Conversion factor

[g/l]=10 \times [g/dl]

Calibration and quality control

S1: Distilled water

S2: Total protein standard Cat.: 51911 or

Roche C.F.A.S. (Calibrator for automated system) or
Randox Calibration Serum Level I or
Randox Calibration Serum Level II

Calibration is recommended:

- after opening new reagent batch
- after system maintenance or troubleshooting

For internal quality control, two levels controls are recommended (normal and pathological) at least once a day. The measured values must in the range which was given by the control's manufacturer. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics

Measuring range

The method is linear in the range 8 – 166 g/l

Interferences

No significant interference was observed by bilirubin up to 1000 µmol/l bilirubin, triglycerides up to 2 mmol/l, hemoglobin up to 0,2 g/l and ascorbate up to 4 g/l. Significant interference: >10%.

Limit of detection

The limit of detection is 1,66 g/l

Precision

Repeatability n = 20	mean	SD	CV
	[g/l]	[g/l]	[%]
	normal sample	59,3	0,80
pathological sample	47,1	0,64	1,36
Reproduceability n = 10	mean	SD	CV
	[g/l]	[g/l]	[%]
	normal sample	57,9	0,50
pathological sample	46,1	0,60	1,30

Method comparison

Comparison with the non-concentrated reagent.

analyser: Advia 1650

number of samples: 178

range: 40 – 112 g/l










correlation coefficient: 0,975

regression line equation: $y = 0,948x + 4,221$

(x= normal reagent, y= concentrated reagent)

For in vitro diagnostic use only!

The following symbols can be used on the labels

	In vitro diagnostic device
	Manufacturer
	CE-marking
	Temperature limitations
	Use by (year/month)
	Batch code
	Catalogue number
	This way up
	Biological risk

Literature

Gornal A. et al.: *J. Biol. Chem.* 117, 751 (1949)

Weichselbaum P.E.: *Am. J. Path.* 16, 40 (1946)

Tietz *Clinical Guide To Laboratory Tests*, 4th edition, Elsevier, 2006