

#### Order information:

Catalogue number	Size
9441C	10 x 65 ml
9442C	4 x 65 ml

#### Reagent kit for quantitative in vitro determination of albumin in serum and plasma.

#### Summary

Albumin is a protein that is formed in the liver. Approximately 50-60 % of total protein is albumin, the rest is globulin. The albumin helps to maintain normal distribution of water in the body (colloidal osmotic pressure), and also helps in the transport of blood constituents such as ions, pigments, bilirubin, hormones, enzymes, and drugs. The ratio of albumin to globulin is an important indicator of certain disease states. Albumin level is decreased in several liver diseases, malabsorption, diarrhoea, eclampsia and nephrosis. The level is increased in dehydration.

#### Method

Photometric bromocresolgreen method. At acidic pH albumin binds with bromocresol green to produce a blue-green complex. The change in absorbance correlates with the concentration of albumin

#### Reagents

##### Composition and concentrations

Bromocresolgreen	3,75 mmol/l
Succinate buffer (pH: 4,2)	300 mmol/l
Brij 35	35 ml/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 60 days.

##### Warnings and precautions

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

##### Chemical safety

This product is not classified as dangerous. Safety data sheet is available upon request.

##### Preparation

The reagent is ready for use.

##### Sample

Serum, heparin, citrate or EDTA plasma.
Stability in serum:
1 month at 2 – 8°C
1 week at 15 – 25°C
3 months at -20°C

##### Expected values and reference range

Serum 36 – 52 g/l

It is recommended that each laboratory should assign its own normal range.

#### Assay procedure

Wavelength:	600 nm / 700 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 3 minutes and read the absorbance against reagent blank		

#### Calculation

Albumin[g/l]= $\Delta A$  sample/ $\Delta A$  standard  $\times$  standard concentration[g/l]

#### Conversion factor

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

#### Calibration and quality control

S1: Distilled water

S2: Albumin standard Cat.: 52301 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 10,2 – 52,8 g/l.

##### Interferences

No significant interference was observed by bilirubin up to 1000 µmol/l bilirubin, triglycerides up to 8 mmol/l, hemoglobin up to 0,4 g/l and ascorbate up to 4 g/l. Significant interference: >10%.

##### Limit of detection

The limit of detection is 0,187 g/l

##### Precision

Repeatability	mean	SD	CV
n = 20	[g/l]	[g/l]	[%]
normal sample	40,1	0,12	0,31
pathological sample	29,0	0,09	0,3
Reproduceability	mean	SD	CV
n = 10	[g/l]	[g/l]	[%]
normal sample	39,19	0,27	0,7
pathological sample	28,26	0,22	0,77

##### Method comparison

Comparison with the non-concentrated reagent.

analyser: Advia 2400

number of samples: 178

range: 20,6 – 53,1 g/l










correlation coefficient: 0,9993

regression line equation:  $y = 0,955x + 0,089$

(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

Doumas B. et al.: *Clin.Chem.Acta* 31; 87 (1971)

Doumas B. et al.: *In Standard Methods of Clinical Chemistry, Acad. Press N.Y.7,175 (1972)*

Drupt F.: *Pharm. Biol.* 9,777 (1977)

*Tietz Clinical Guide To Laboratory Tests, 4<sup>th</sup> edition, Elsevier, 2006*