

#### Order information:

Catalogue number	Size
9491C	10 x 65 ml
9492C	4 x 65 ml

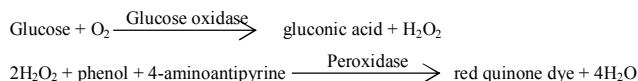
#### Reagent kit for quantitative in vitro determination of albumin in serum and plasma.

#### Summary

Determination of glucose concentration is important in the diagnosis and treatment of disorders of carbohydrate metabolism. Values higher or lower than the reference are of diagnostic significance. The levels are increased in diabetes mellitus, hyperthyroidism and in the hyperactivity of the pituitary gland. Decreased levels are observed in cases of overproduction of insulin by the pancreas, with tumors of the pancreas, as well as with hypofunction of the organs involved in the glucose synthesis and carbohydrate metabolism.

#### Method

Glucose oxidase/PAP method



#### Reagents

##### Composition and concentrations

Phosphate buffer, pH:7.4	100 mmol/l
Phenol	50 mmol/l
4-aminoantipyrine	1,5 mmol/l
Peroxidase	3500 U/l
Glucose oxidase	50000 U/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 72 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. The product contains sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. If disposal into a drain is in compliance with federal, state, and local requirements, flush reagents with a large amount of water to prevent the buildup of azides.

#### Preparation

The reagent is ready for use.

#### Sample

Serum, heparin, citrate or EDTA plasma.
Stability in serum: 72 hours at 4°C
8 hours at 25°C

#### Expected values and reference range

Serum:	3,87 – 5,81 mmol/l
CSF:	2,76 – 3,87 mmol/l

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

#### Assay procedure

Wavelength:	505 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 5 minutes and read the absorbance against reagent blank		

#### Calculation

Glucose[mmol/l]=ΔA sample/ΔA standard × standard concentration[mmol/l]

#### Conversion factor

[mmol/l]×17,97=[mg/dl]

#### Calibration and quality control

- S1: Distilled water  
S2: Glucose standard Cat.: 50411 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 0,1 – 50 mmol/l

##### Interferences

No significant interference was observed by bilirubin up to 1000 µmol/l bilirubin, triglycerides up to 4 mmol/l, hemoglobin up to 1 g/l and ascorbate up to 0,2 g/l. Significant interference: >10%.

##### Limit of detection

The limit of detection is 0,0037 mmol/l

##### Precision










Repeatability n = 20	mean	SD	CV
	[mmol/l]	[mmol/l]	[%]
normal sample	6,5	0,03	0,4
pathological sample	15,6	0,03	0,21
Reproduceability n = 10	mean	SD	CV
	[mmol/l]	[mmol/l]	[%]
normal sample	6,57	0,05	0,72
pathological sample	15,82	0,1	0,66

##### Method comparison

Comparison with the non-concentrated reagent.  
analyser: Advia 2400  
number of samples: 116  
range: 1,52 – 45,6 mmol/l  
correlation coefficient: 0,999  
regression line equation:  $y = 0,998x - 0,011$   
(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

Trinder P.: *Ann. Clin. Biochem.* 6, 24 (1969)  
Tietz *Clinical Guide To Laboratory Tests*, 4<sup>th</sup> edition, Elsevier, 2006