

#### Order information:

Catalogue number	Size
9461C	10 x 65 + 10 x 13 ml
9462C	4 x 65 + 4 x 13 ml

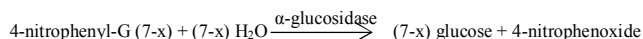
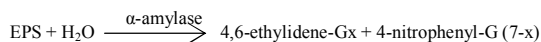
#### Reagent kit for quantitative in vitro determination of alpha-amylase in serum and plasma.

#### Summary

Measurements of amylase are used primarily in the diagnosis and treatment of the diseases of the pancreas. Amylase is found primarily in the pancreas and salivary glands. When released in the digestive tract, the enzyme hydrolyzes starch. Amylase determinations are useful in the diagnosis of diseases of the pancreas and parotids. Elevated serum levels are associated with acute pancreatitis and other pancreatic disorders as well as mumps and bacterial parotitis.

#### Method

Optimized IFCC method



#### Reagents

##### Composition and concentrations

##### Reagent 1

HEPES buffer, pH=7.15	50 mmol/l
NaCl	70 mmol/l
MgCl <sub>2</sub>	10 mmol/l
α-Glucosidase	≥16 kU/l

##### Reagent 2

HEPES buffer, pH=7.15	50 mmol/l
EPS	9 mmol/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.

The absorbance at 410 nm should not be higher than 0,5.

#### 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 and urine.

Stability in serum:	1 month 2 at – 8°C
	7 days 15 at – 25°C
	1 year at -20°C

#### Expected values and reference range

Serum: <99 U/l

Urine: 32 – 641 U/l

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

#### Assay procedure

Wavelength:	410 nm / 505 nm (primary/secondary)
Optical path:	1 cm
Temperature:	37°C
Measurement:	against water blank
Reaction:	kinetic, increasing

	blank	sample or standard
reagent 1	300 µl	300 µl
dist. water (diluent)	600 µl	600 µl
dist. water (blank)	14,4 µl	-
sample or standard	-	14,4 µl
Mix and incubate for 3 minutes		
reagent 2	60 µl	60 µl
dist. water (diluent)	120 µl	120 µl
Mix and incubate for 3 minutes then continuously read the absorbances for 3 minutes		

#### Calculation

amylase[U/l]=ΔA sample/ΔA standard × standard concentration[U/l]

#### Conversion factor

[U/l]=[µkat/l]×60

#### Calibration and quality control

S1: Distilled water

S2: 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 – 1800 U/l

##### Interferences

No significant interference was observed by bilirubin up to 1000 µmol/l bilirubin, triglycerides up to 12 mmol/l, hemoglobin up to 7,0 g/l and ascorbate up to 2 g/l. Significant interference: >10%.

##### Limit of detection

The limit of detection is 0,69 U/l

##### Precision

Repeatability n = 20	mean	SD	CV
	[U/l]	[U/l]	[%]
	normal sample	87	0,86
pathological sample	284	1,88	0,66
Reproduceability n = 10	mean	SD	CV
	[U/l]	[U/l]	[%]
	normal sample	87,4	0,96
pathological sample	284	2,13	0,75

##### Method comparison

Comparison with the non-concentrated reagent.

analyser: Advia 2400

number of samples: 141

range: 10 – 1721 U/l










correlation coefficient: 0,9996

regression line equation:  $y = 0,96x + 2,986$

(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

A. Kurrie-Weittenhiller, W.Hölzel, D.Engel, J.Finke, G. Klein: Clin. Chem. 42, 598 (1996)  
Tietz Clinical Guide To Laboratory Tests, 4<sup>th</sup> edition, Elsevier, 2006