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UREA UV

CONCENTRATED LIQUID REAGENT

CE

Order information:

Catalogue number	Size
9581C	10 x 60 + 10 x 20 ml
9582C	4 x 60 + 4 x 20 ml

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

Summary

The detoxification of $NH4^+$ formed in the catabolism of amino acids takes place in the urea cycle. Enzymes catalyzing these reactions are synthesized in the liver. The end product is Carbamide (Urea) which is a nontoxic, nonpolar, small molecule. It is eliminated by the kidney. Increased levels are associated with renal diseases, as well as dehydration, circulatory collapse gose, gastrointestinal hemorrhage and diabetic coma. Decreased values are observed in some cases of severe liver disease.

Method

Enzymatic UV

$$\text{Urea} + H_2O \xrightarrow{\text{urease}} 2NH_4^+ + CO_2$$

$$2NH_4^+ + 2\ \alpha\text{-ketoglutarate} + 2NADH \xrightarrow{\text{glutamate dehydrogenase}} \text{2-L-glutamate} + 2NAD^+ + 2H_2O$$

Reagents

Composition and concentrations

Reagent 1	
NADH	900 µmol/l
Reagent 2	
Tris buffer, pH: 7.60	100 mmol/l
α-ketoglutarate	27 mmol/l
Urease	18000 U/l
GLDH	3200 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 frequeny of calibration is 72 days.
The absorbance at 340 nm should not be lower than 1,4

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. Avoid ammonium-heparin and NaF!
Dilute urine to 1:99

Stabiliy in serum:	7 days at 20 – 25°C
	7 days at 4 – 8°C
	1 year at -20°C
Stability in urine:	2 days at 20 – 25°C
	7 days at 4 – 8°C
	1 month at -20°C

Expected values and reference range

Serum: 2,44 – 7,51 mmol/l
Urine: 338 – 592 mmol/l
It is recommended that each laboratory should assign its own normal range.

Assay procedure

Wavelength:	340 nm / 410 nm (primary/secondary)
Optical path:	1 cm
Temperature:	37°C
Measurement:	against water blank
Reaction:	kinetic, decreasing

	blank	sample or standard
reagent 1	300 µl	300 µl
dist. water (diluent)	600 µl	600 µl
dist. water (blank)	12 µl	-
sample or standard	-	12 µl
Mix and incubate for 1 minute		
reagent 2	100 µl	100 µl
dist. water (diluent)	200 µl	200 µl
Mix and incubate for 30 secundum then continuously read the absorbances for 1 minutes		

Calculation

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

Conversion factor

[mmol/l]×6=[mg/dl]

Urea[mg/dl]×0,467=BUN[mg/dl]

Calibration and quality control

S1: Distilled water
S2: Urea standard Kat.: 50811 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 maitenance 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.

Preformance characteristics

Measuring range

The method is linear in the range 0,5 – 60 mmol/l

Interferences

No significant intereference was observed by bilirubin up to 1000 µmol/l bilirubin, triglycerides up to 12 mmol/l, hemoglobin up to 7 g/l and ascorbate up to 4 g/l. Significant interference: >10%.

Limit of detection

The limit of detection is 0,093 mmol/l

Precision

Repeatability	mean	SD	CV
n = 20	[mmol/l]	[mmol/l]	[%]
normal sample	7,7	0,1	1,33
pathological sample	19,6	0,17	0,88
Reproduceability	**mean**	**SD**	**CV**
n = 10	[mmol/l]	[mmol/l]	[%]
normal sample	7,59	0,14	1,89
pathological sample	19,24	0,36	1,87

Method comparison

Comparison with the non-concentrated reagent.
analyser: Advia 2400
number of samples: 108
range: 1,2 – 52,3 mmoll
correlation coefficient: 0,999
regression line equation: y = 1,016x – 0,096
(x= normal reagent, y= concentrated reagent)

For in vitro diagnostic use only!

The following symbols can be used on the labels

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

Literature

Talke H,. Schubert G.E. Klin.1965, 43:174.
Tietz Clinical Guide To Laboratory Tests, 4th edition, Elsevier, 2006