GENESIS

Instructions For Use

UREA UV (UREASE GLUTAMATE DEHYDROGENASE) (4+1)

Cat no.	size
1109 201	5*10
1109 202	10*10
1109 203	5*20
1109 204	10*20
1109 205	2*25

INTENDED USE

The Urea UV Reagent is Intended for in vitro Quantitative diagnostic determination of UREA in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

Urea is synthesized in the liver as a by-product of the deamination of amino acids. Its elimination in the urine represents the major route for nitrogen excretion.

Elevated urea concentration in plasma is found as a result of a high-protein diet, increased protein catabolism, after a gastrointestinal hemorrhage, mild dehydration, shock and heart failure or treatment with glucocorticoids (pre-renal uremia).

Post-renal uremia is caused by conditions that obstruct urine outflow: nephrolithiasis, tumor or prostatic hypertrophy. The usefulness of urea as an indicator of renal function is limited by the variability of its plasma concentration as a result of non-renal factors

PRINCIPLE OF THE METHOD

Urea in the sample is hydrolyzed enzymatically into ammonia (NH3) and carbon dioxide (CO2). Ammonia ions formed react with -ketoglutarate in a reaction catalysed by glutamate dehydrogenase (GLDH) with simultaneous oxidation of NADH to NAD^+.

$$UREA + H_2O \xrightarrow{UREASE} 2NH^+_4 + CO_2$$

$$2NH^+_4 + NADH + H^+ + 2\text{-}OXOGLUTARATE \xrightarrow{GLDH} GLUTAMATE + NAD^+$$

COMPOSITION

R1	Tris Base	121 mmol/L
	urease	100 ku/L
	Glutamate dehydrogenase	>3000 U/L
	2-oxoglutarate	75 mmol/L
	Sodium Azide	9.5 g/L
R2	NADH	2.0 mmol/L
	Sodium Azide	9.5 g/L
STANDARD(S)		50 mg/dL

STORAGE

Store at 2 - 8°C

The reagent is stable until expiration date stated on vial label.

REAGENT PREPARATION

Working reagent: Mix (4) Parts of (R1) with (1) part of (R2).

Working reagent is stable for 3 weeks at 2 - 8 °C .

ADDITIONAL EQUIPMENT

− Thermostatic water bath at 37ºC

− Analyzer, spectrophotometer able to read at 340nm.

SPECIMEN

1.Serum, plasma or urine collected by standard procedures.

2.Dilute fresh urine 1/50 with distilled water before measurement.

3.Heparin is recommended as anticoagulant.

4.Urea in serum is reported stable for seventy-two (72) hours Refrigerated at 2 - 8°C.

5.Un-refrigerated serums should be used within eight (8) hours.

6.Urea in Urine is Stable For 3 Days at Room Temperature if microbial growth is prevented .

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by

PROCEDURE

1. Bring the Reagent to room temperature.
2. Assay parameters:

Mode:……Fixed Time

Wavelength……340 nm

Cuvette: ……1 cm light path Constant temperature ……..……37ºC

Delay time……....30 sec

Measuring time……..90 sec

3. Adjust the instrument to zero with distilled water or air.
4. Pipette into a cuvette:

Working reagent	1.0 ml
specimen	10 µL

5. Mix after 30 sec and read the absorbance (A1) of the standard or specimen. Exactly 90 sec Later , read the absorbance (A2) of the standard or specimen at 340nm.

CALCULATIONS

The UREA concentration in the sample is calculated using the following general formula:

A1-A2= Δ A for specimen or standard

$$\frac{(\Delta A)\text{Specimen}}{(\Delta A)\text{Standard}} \times C\ \text{Standard} = C\ \text{Specimen}$$

BUN= UREA/2.14

REFERENCE VALUES

Serum:	15 - 50 mg/dL
Urine:	20 - 35 g/24 h

QUALITY CONTROL

It is recommended to use the Control Serum level I and II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control

METROLOGICAL CHARACTERISTICS

− Detection limit: 4.0 mg/dL BUN= 1.87 mg/dL

− Linearity limit: 300 mg/dL BUN= 140 mg/dL

− For higher values dilute sample with **1/ 3** physiological saline and repeat measurement.

− Repeatability (within run):

Mean Concentration	CV	n
27 mg/dL = 4.5 mmol/L	4 %	20
142mg/dL = 23.6mmol/L	1.2 %	20

− Reproducibility (run to run):

Mean Concentration	CV	n
27 mg/dL = 4.5 mmol/L	4.7 %	25
142mg/dL = 23.6mmol/L	1.5 %	25

− INTERFERENCES:

− Bilirubin (20 mg/dL) does not interfere. Lipemia (triglycerides 2 g/L) and hemolysis may affect the results.

−Other drugs and substances may interfere.

BIBLIOGRAPHY

1. Talke H and Schubert GE. Enzymatische harnstoffbestimmung in blut und serm im optischentest nach Warburb. Klinische Wochenschrift 1965; 43: 174-175.

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CE

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