



Instructions For Use

GENESIS

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⁺.



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 37°C

– 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 inhale. 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
IVD	For in-vitro diagnostic use
REF	Catalogue number
LOT	Lot number
	Expiration date
	CAUTION, consult instructions for use
	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

.....37°C

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

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

$$\text{BUN} = \text{UREA} / 2.14$$

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 serum im optischentest nach Warbur. Klinische Wochenschrift 1965; 43: 174-175.

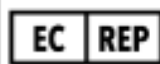
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