BIOLABO
www.biolabo.fr
FABRICANT :
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

UREA U.V. High Linearity Kinetic Method

Reagent for quantitative determination of urea (UREA) in human serum and plasma or urines.

I REF K1532	**R1** 2 x 16 mL	**R2** 1 x 8 mL
I REF K2532	**R1** 2 x 32 mL	**R2** 2 x 8 mL
I REF K4532	**R1** 2 x 40 mL	**R2** 1 x 20 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

I INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantitative determination of urea (UREA) in human serum and plasma or urines.

I GENERALITIES (1) (6)

More than 90% of urea is excreted through the kidneys in urines. Measurement of the plasma or serum urea concentration is widely regarded as a test of renal function. However, a number of non-renal factors also influence the circulating urea concentration: Urea increased level occurs when proteins catabolism is accelerated, burns, stress, myocardial infarction... Urea is decreased in acute liver destruction and is accompanied with increased ammonium level. Urea level is generally studied in conjunction with creatinine level (urea/creatinine ratio) to refine the diagnosis of post-renal or pre-renal azotemia.

PRINCIPLE (4) (5)

Enzymatic method based on Talke and Schubert reaction, simplified by Tiffany and al. who demonstrated that urea concentration is proportional to absorbance change at 340 nm over a fixed time interval. Reaction scheme is as follows:

$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

$$NH_3 + \text{oxoglutarate} + \text{NADH} + H^+ \xrightarrow{\text{GLDH}} \text{Glutamate} + NAD^+ + H_2O$$

REAGENTS

R1	**UR3**	Buffer Enzymes	
Tris pH 7.9 ± 0.1 at 30°C		100	mmol/L
Urease		≥ 17000	IU/L
GLDH		≥ 700	IU/L
Oxoglutarate		6.5	mmol/L
Preservative			
R2	**UR3**	Coenzyme	
NADH		≥ 1.5	mmol/L
Preservative			

According to 1272/2008/EC Regulation, these reagents are not classified as dangerous.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, reagents are stable when stored and used as described in the insert:

Unopened:
- Until expiry date stated on the label of the kit

Once opened:
- 2 separate reagents are stable at least 60 days
- Discard any cloudy reagent or if reagent blank is < 1.100 at 340 nm

SPECIMEN COLLECTION AND HANDLING (2)

Unhemolysed serum or heparinised plasma. Avoid fluoride or ammonium as anticoagulants which interfere with the assay.

- Stable for 24 h at room temperature
- several days at 2-8°C
- at least 2-3 months frozen

24h Urines:

- Stable for 4 days at 2-8°C
- Add antibacterial agent as Thymol to improve the stability
- Dilute (1+19) with demineralised water before assay

LIMITES (3)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

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EXPECTED VALUES (2)

Serum or plasma	(mg/dL)	[mmol/L]
In cord	45-86	[7.5-14.3]
Premature	6-54	[1.1-8.9]
< 1 year	9-41	[1.4-6.8]
Children	11-39	[1.8-6.4]
18-60 years	13-43	[2.1-7.1]
60-90 years	17-49	[2.9-8.2]
> 90 years	21-66	[3.6-11.1]

Urines	26-43 g/24 h	[0.43-0.71 mol/24 h]

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On Kenza 240TX, at 37°C, 340 nm:

Linearity Range: between 16 and 272 mg/dL

Detection limit: approx. 12 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	26	48	135
S.D. mg/dL	1.1	1.2	1.8
C.V. %	4.3	2.5	1.3

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	27	51	138
S.D. mg/dL	1.2	2.0	3.1
C.V. %	4.3	4.0	2.3

Analytical Sensitivity: approx. 0.0012 abs/min for 1 mg/dL

Comparison studies with commercially available reagent:
Realised on human specimens (n=100) between 12 and 300 mg/dL

y = 1.0249 x – 1.0527 r = 0.999

Interferences:

Total bilirubin	No interference up to 502 µmol/L
Direct bilirubin	No interference up to 403 µmol/L
Ascorbic acid	No interference up to 2500 mg/dL
Glucose	No interference up to 1064 mg/dL
Turbidity	Positive interference from 0.143 OD
Haemoglobin	No interference up to 379 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 7 days

Calibration Stability: 7 days

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

Performances and stability data on Kenza 450TX/ISE and Kenza One are available on request.

CALIBRATION (7)

- BIOLABO Multicalibrator REF 95015 traceable *to SRM 909*

The calibration frequency depends on proper instrument functions and on the preservation of reagent

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

QUALITY CONTROL

- REF 95010 BIOLABO EXATROL-N Level I
- REF 95011BIOLABO EXATROL-P Level II
- REF 95012 Urinary Controls
- External quality control program

It is recommended to control in the following cases:

- At least once a run
- At least once within 24 hours
- When changing vial of reagent
- After maintenance operations on the instrument

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly final result.
Refer to the instruction of use of Kenza analyzer.

REFERENCES

(1) TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 1239-1241.
(2) Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 1096-1099.
(3) YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1990) p. 3-599 to 3-609
(4) Talke H., Schubert G. E., Klin. Wochschr., 19, (1965), 43, p.174
(5) Tiffany T. O., and al., Clin. Chem., 18, (1972) p.829-840
(6) Bernard S. Bioch. clin. Diagnostics médicaux chirurgicaux 2ème éd. p.143-144. Ed. Maloine PARIS (1989).
(7) SRM: Standard Reference Material ®

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with