BIOLABO
www.biolabo.fr
FABRICANT :
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UREA U.V.

High Linearity Kinetic Method

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

REF LP99532	**R1** 4 x 30 mL	**R2** 1 x 30 mL	**R3** 1 x 10 mL
REF LP99632	**R1** 4 x 100 mL	**R2** 1 x 100 mL	**R3** 1 x 10 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IN VITRO DIAGNOSTIC USE

CLINICAL SIGNIFICANCE (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 COMPOSITION

R1 BUFFER ENZYME BUF ENZ **UREA**

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 COENZYME COENZ **UREA**

NADH	≥ 1.5	mmol/L
Preservative		

R3 STANDARD STD

Urea	40	mg/dL

According to 1272/2008 regulation, these reagents are not classified as dangerous

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use (Do not pipette by mouth).

- Verify the integrity of the contents before use.
- Material Safety Data Sheet (MSDS) is available on request or on www.biolabo.fr
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

REAGENTS PREPARATION

REF LP99532: Mix 4 volumes of R1 (Buffer-Enzymes) with 1 volume of R2 (Coenzyme).

REF LP99632: Add exactly 25 mL of the contents of vial R2 into vial R1. Well recap and mix gently.

STABILITY AND STORAGE

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

Unopened:

- Until expiry date stated on the label of the kit.

Once opened:

- Working reagent (R1+R2) is stable for 1 month when free from contamination.
- Discard any cloudy reagent or if reagent blank is < 1.100 at 340 nm.
- Don't use working reagent after expiry date stated on the label.

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.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Thermostated Spectrophotometer or Biochemistry Analyzer

CALIBRATION (7)

- BIOLABO Multicalibrator REF 95015 traceable to SRM 909c

Or

- Standard (vial R3)

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

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | sufficient for | → dilute with | H2O Demineralized water | Biological hazard

Made in France
Latest revision : www.biolabo.fr
Revision : 13/02/2019

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. Repeat the test with the same control
2. If control is still out of range, prepare a fresh control and repeat the test
3. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test
4. If control is still out of range, calibrate with a new vial of reagent
5. If control is still out of range, please contact BIOLABO technical support or your local Agent

EXPECTED VALUES (2)

In serum and plasma	UREA (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]
In urines	26-43 g/24 h	[0.43-0.71 mol/24 h]

To calculate blood urea nitrogen (BUN): multiply the value of urea (mg/dL) by 0.467.

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

PERFORMANCES at 37°C on KENZA 240TX

Linearity Range: between 11 and 250 mg/dL

Detection limit: approx. 1.7 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	14.0	40.8	123.9
S.D. mg/dL	0.5	0.6	2.1
C.V. %	3.5	1.5	1.7

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	15.1	43.4	132.2
S.D. mg/dL	0.5	1.1	2.8
C.V. %	3.3	2.6	2.1

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 = 0.9990

Analytical Sensitivity: approx. 0.0014 abs/min for 1 mg/dL

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.

PROCEDURE

Detailed Kenza 240TX procedure is available on request

Wavelength: 340 nm

Temperature: 37°C

Let stand reagents and specimen at room temperature

	Automated analyzer	Manual procedure
Working Reagent	300 µL	1000 µL
Specimen (1) or Standard/Controls	3 µL	100 µL
Mix. After 30 seconds, record initial absorbance A1 at 340 nm against distilled water. Record the absorbance A2 after 90 seconds.		

Notes:

1- For urines prediluted (1+19) use standard (vial R3) to calibrate (do not dilute) and controls REF 95012 (to be treated as patient's urines)

2- Performances and stability data's have been validated on KENZA 240TX and KENZA 450TX

3- With Manual Procedure on Spectrophotometer and on other biochemistry analyzers, performances and stability data should be validated by user

4- Applications proposal are available on request

CALCULATION

Calculate the result as follows:

Serum and plasma:

$$\text{Result} = \frac{\text{Abs (A1 – A2) Assay}}{\text{Abs (A1 – A2) Standard}} \times \text{Standard concentration}$$

Urines:

Multiply the result by dilution factor 20.

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).*

(4) *SRM: Standard Reference Material* ®