

# Urea FS\*

Diagnostic reagent for quantitative in vitro determination of urea in serum, plasma or urine on photometric systems

## Order Information

Cat. No.	Kit size					
1 3101 99 10 021	R1 4 x	20 mL	+	R2 1 x	20 mL	
		3 mL		Standard		
1 3101 99 10 026	R1 5 x	80 mL	+	R2 1 x	100 mL	
1 3101 99 10 023	R1 1 x	800 mL	+	R2 1 x	200 mL	
1 3101 99 10 704	R1 8 x	50 mL	+	R2 8 x	12.5 mL	
1 3101 99 10 917	R1 8 x	60 mL	+	R2 8 x	15 mL	
1 3101 99 90 314	R1 10 x	20 mL	+	R2 2 x	30 mL	
1 3100 99 10 030	6 x	3 mL		Standard		

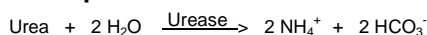
## Summary [1,2]

Urea is the nitrogen-containing end product of protein catabolism. States associated with elevated levels of urea in blood are referred to as hyperuremia or azotemia. Parallel determination of urea and creatinine is performed to differentiate between pre-renal and post-renal azotemia. Pre-renal azotemia, caused by e.g. dehydration, increased protein catabolism, cortisol treatment or decreased renal perfusion, leads to increased urea levels, while creatinine values remain within the reference range. In post-renal azotemias, caused by the obstruction of the urinary tract, both urea and creatinine levels rise, but creatinine in a smaller extent. In renal diseases urea concentrations are elevated when the glomerular filtration rate is markedly reduced and when the protein intake is higher than 200 g/day.

## Method

"Urease – GLDH": enzymatic UV test

## Principle



GLDH: Glutamate dehydrogenase

## Reagents

### Components and Concentrations

<b>R1:</b>	TRIS	pH 7.8	150 mmol/L
	2-Oxoglutarate		9 mmol/L
	ADP		0.75 mmol/L
	Urease		≥ 7 kU/L
	GLDH (Glutamate dehydrogenase, bovine)		≥ 1 kU/L
<b>R2:</b>	NADH		1.3 mmol/L
<b>Standard:</b>			50 mg/dL (8.33 mmol/L)

### Storage Instructions and Reagent Stability

Reagents and standard are stable up to the end of the indicated month of expiry, if stored at 2–8°C, protected from light and contamination is avoided. Do not freeze the reagents!

### Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [6].
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
- For professional use only!

## Waste Management

Please refer to local legal requirements.

## Reagent Preparation

### Substrate Start

The standard and the reagents are ready to use.

### Sample Start

Mix 4 parts of R1 with 1 part of R2

(e.g. 20 mL R1 + 5 mL R2) = mono reagent

Leave the mono reagent for at least 30 min. at 15 – 25°C before use.

Stability: 4 weeks at 2 – 8°C  
5 days at 15 – 25°C

Protect mono reagent from light!

## Materials required but not provided

NaCl solution 9 g/L

General laboratory equipment

## Specimen

Serum, plasma (no ammonium heparin!), fresh urine

Dilute urine 1 + 50 with dist. water and multiply results by 51.

TruLab Urine controls must be prediluted the same way as patient samples.

### Stability [4]

in serum or plasma:

7 days at 20 – 25°C

7 days at 4 – 8°C

1 year at –20°C

in urine:

2 days at 20 – 25°C

7 days at 4 – 8°C

1 month at –20°C

Freeze only once! Discard contaminated specimens.

## Assay Procedure

**Application sheets for automated systems are available on request.**

Wavelength	340 nm, Hg 334 nm, Hg 365 nm
Optical path	1 cm
Temperature	25°C/30°C/37°C
Measurement	Against reagent blank 2-point kinetic

### Substrate start

	Blank	Sample or standard
<b>Sample or standard</b>	-	10 µL
<b>Reagent 1</b>	1000 µL	1000 µL
Mix, incubate 0 – 5 min., then add:		
<b>Reagent 2</b>	250 µL	250 µL
Mix, incubate for approx. 60 sec. at 25°C/30°C or approx. 30 – 40 sec at 37°C, then read absorbance A1. Read absorbance A2 exactly after another 60 seconds.		

$\Delta A = (A1 - A2)$  sample or standard

### Sample start

	Blank	Sample or standard
<b>Sample or standard</b>	-	10 µL
<b>Mono reagent</b>	1000 µL	1000 µL
Mix, incubate for approx. 60 sec. at 25°C/30°C or approx. 30 – 40 sec at 37°C, then read absorbance A1. Read absorbance A2 exactly after another 60 seconds.		

$\Delta A = (A1 - A2)$  sample or standard

**Notes**

- The method is optimized for 2-point kinetic measurement. It is recommended to perform the method only on mechanized equipment because it is difficult to incubate **all** samples and the reagent blank **strictly** for the same time intervals. The assay scheme may be used for adaptation purposes for instruments with no specific adaptation sheet. The volumes may be proportionally smaller.
- The statement "approx. 60 sec. or approx. 30 - 40 sec" means that the time period chosen does not need to be exactly 60 resp. 30 - 40 sec. A time period once chosen (e.g. 55 sec.) has to be respected **exactly** for all samples, standards and the reagent blank.

**Calculation**

With standard or calibrator

$$\text{Urea [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. Std/Cal [mg/dL]}$$

**Conversion factor**

$$\text{Urea [mg/dL]} \times 0.1665 = \text{Urea [mmol/L]}$$

$$\text{Urea [mg/dL]} \times 0.467 = \text{BUN [mg/dL]}$$

$$\text{BUN [mg/dL]} \times 2.14 = \text{Urea [mg/dL]}$$

(BUN: Blood urea nitrogen)

**Calibrators and Controls**

For the calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. The assigned values of the calibrators have been made traceable to NIST SRM®-909 Level 1. DiaSys TruLab N, P and TruLab Urine controls should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
TruLab Urine Level 1	5 9170 99 10 062	20 x 5 mL
	5 9170 99 10 061	6 x 5 mL
TruLab Urine Level 2	5 9180 99 10 062	20 x 5 mL
	5 9180 99 10 061	6 x 5 mL

**Performance Characteristics****Measuring range**

The test has been developed to determine urea concentrations within a measuring range from 2 – 300 mg/dL (0.3 – 50 mmol/L) in serum/plasma respectively up to 30 g/dL (5 mol/L) in urine. When values exceed this range the samples should be diluted 1 + 2 with NaCl solution (9 g/L) and the result multiplied by 3.

**Specificity/Interferences**

No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 500 mg/dL and lipemia up to 2000 mg/dL triglycerides. Ammonium ions interfere; therefore, do not use ammonium heparin as anticoagulant for collection of plasma! For further information on interfering substances refer to Young DS [5].

**Sensitivity/Limit of Detection**

The lower limit of detection is 2 mg/dL.

**Precision (at 37°C)**

Intra-assay precision n = 20	Mean [mg/dL]	SD [.mg/dL]	CV [%]
Sample 1	21.3	0.50	2.33
Sample 2	35.3	0.82	2.33
Sample 3	141	1.52	1.08

Inter-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	20.3	0.58	2.88
Sample 2	48.3	1.12	2.32
Sample 3	152	1.38	0.91

**Method Comparison**

A comparison of DiaSys Urea FS (y) with a commercially available test (x) using 68 samples gave following results:

$$y = 0.99 x + 1.06 \text{ mg/dL}; r = 0.999$$

**Reference Range****In Serum/Plasma [1]**

	[mg/dL]	[mmol/L]
<b>Adults</b>		
Global	17 – 43	2.8 – 7.2
Women < 50 years	15 – 40	2.6 – 6.7
Women > 50 years	21 – 43	3.5 – 7.2
Men < 50 years	19 – 44	3.2 – 7.3
Men > 50 years	18 – 55	3.0 – 9.2
<b>Children</b>		
1 – 3 year(s)	11 – 36	1.8 – 6.0
4 – 13 years	15 – 36	2.5 – 6.0
14 – 19 years	18 – 45	2.9 – 7.5

**BUN in Serum/plasma**

	[mg/dL]	[mmol/L]
<b>Adults</b>		
Global	7.94 – 20.1	2.8 – 7.2
Women < 50 years	7.01 – 18.7	2.6 – 6.7
Women > 50 years	9.81 – 20.1	3.5 – 7.2
Men < 50 years	8.87 – 20.5	3.2 – 7.3
Men > 50 years	8.41 – 25.7	3.0 – 9.2

**Children**

1 – 3 year(s)	5.14 – 16.8	1.8 – 6.0
4 – 13 years	7.01 – 16.8	2.5 – 6.0
14 – 19 years	8.41 – 21.0	2.9 – 7.5

**Urea/Creatinine ratio in serum [1]**

$$25 - 40 \text{ [(mmol/L)/(mmol/L)]}$$

$$20 - 35 \text{ [(mg/dL)/(mg/dL)]}$$

**Urea in Urine [2]**

$$26 - 43 \text{ g/24h (0.43 - 0.72 mol/24h)}$$

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

**Literature**

- Thomas L. Clinical Laboratory Diagnostics. 1<sup>st</sup> ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 374-7.
- Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3<sup>rd</sup> ed. Philadelphia: W.B Saunders Company; 1999. p. 1838.
- Talke H, Schubert GE. Enzymatische Harnstoffbestimmung in Blut und Serum im optischen Test nach Warburg (Enzymatic determination of urea in blood and serum with the optical test according to Warburg). Klin Wschr 1965; 43: 174-5.
- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1<sup>st</sup> ed. Darmstadt: GIT Verlag; 2001; p. 48-9, 52-3.
- Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240-1243.

**Manufacturer**

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