respons®910

# Urea FS*

## Order Information

| Cat. No. | Kit size |
|---|---|
| 1 3101 99 10 920 | Σ 800 (4 x 200) |

## Intended Use

Diagnostic reagent for quantitative in vitro determination of urea in human serum, heparin plasma or urine on automated respons®910.

## Summary

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, for example 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. [1,2]

## Method

"Urease – GLDH": enzymatic UV test

$$\text{Urea} + 2\ H_2O \xrightarrow{\text{Urease}} 2\ NH_4^+ + 2\ HCO_3^-$$

$$2\text{-Oxoglutarate} + NH_4^+ + \text{NADH} \xrightarrow{\text{GLDH}} \text{L-Glutamate} + NAD^+ + H_2O$$

GLDH: Glutamate dehydrogenase

## Reagents

**Components and Concentrations**

| | | | |
|---|---|---|---|
| **R1:** | TRIS | pH 7.8 | 150 mmol/L |
| | 2-Oxoglutarate | | 9 mmol/L |
| | ADP | | 0.75 mmol/L |
| | Urease | | ≥ 7 kU/L |
| | GLDH (bovine) | | ≥ 1 kU/L |
| **R2:** | NADH | | 1.3 mmol/L |

## Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The in-use stability of the reagent is 18 months.

## Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 1 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [3].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. Please refer to the safety data sheets (SDS) 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.
7. For professional use only.

## Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

## Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

## Materials Required

General laboratory equipment

## Specimen

Human serum, heparin plasma (no ammonium heparin) or fresh urine

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability in serum/plasma [4]:

| | | |
|---|---|---|
| 7 days | at | 20 – 25°C |
| 7 days | at | 4 – 8°C |
| 1 year | at | –20°C |

Stability in urine [4]:

| | | |
|---|---|---|
| 2 days | at | 20 – 25°C |
| 7 days | at | 4 – 8°C |
| 4 weeks | at | –20°C |

Only freeze once. Discard contaminated specimens.

## Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to NIST- SRM 909b Level 1. Use DiaSys TruLab N and P or TruLab Urine Level 1 and Level 2 for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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 up to 300 mg/dL in serum.
Measuring range up to 7300 mg/dL in urine.
In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

| | |
|---|---|
| Limit of detection** | 3 mg/dL |
| Onboard stability | 4 weeks |
| Calibration stability | 7 days |

| Interfering substance | Interferences (serum) ≤ 10% up to | Analyte concentration [mg/dL] |
|---|---|---|
| **Ascorbic acid** | 30 mg/dL | 89.7 |
| **Bilirubin** (conjugated) | 65 mg/dL | 9.03 |
| | 70 mg/dL | 39.9 |
| **Bilirubin** (unconjugated) | 70 mg/dL | 9.28 |
| | 65 mg/dL | 42.2 |
| **Hemoglobin** | 500 mg/dL | 9.60 |
| | 550 mg/dL | 38.6 |
| **Lipemia** (triglycerides) | 1000 mg/dL | 10.5 |
| | 1900 mg/dL | 41.0 |
| **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 [5,6]. | | |

| **Precision (Serum)** | | | |
|---|---|---|---|
| **Within run (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/dL] | 18.8 | 38.8 | 154 |
| CV [%] | 2.96 | 2.48 | 2.11 |
| **Between day (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/dL] | 23.2 | 38.4 | 149 |
| CV [%] | 2.71 | 3.58 | 2.28 |

| **Method comparison (Serum; n=109)** | |
|---|---|
| Test x | DiaSys Urea FS (Hitachi 911) |
| Test y | DiaSys Urea FS (respons®910) |
| Slope | 1.02 |
| Intercept | –1.08 mg/dL |
| Coefficient of correlation | 0.999 |

| **Precision (Urine)** | | | |
|---|---|---|---|
| **Within run (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/dL] | 782 | 1726 | 3953 |
| CV [%] | 5.01 | 1.91 | 3.23 |
| **Between day (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/dL] | 791 | 1780 | 4033 |
| CV [%] | 4.44 | 2.94 | 3.74 |

| **Method comparison (Urine; n=94)** | |
|---|---|
| Test x | DiaSys Urea FS (BioMajesty® JCA-BM6010/C) |
| Test y | DiaSys Urea FS (respons®910) |
| Slope | 0.973 |
| Intercept | –18.4 mg/dL |
| Coefficient of correlation | 0.993 |

** according to CLSI document EP17-A, Vol. 24, No. 34

**Conversion Factor**
Urea [mg/dL] x 0.1665 = Urea [mmol/L]
Urea [mg/dL] x 0.467 = BUN [mg/dL]
BUN [mg/dL] x 2.14 = Urea [mg/dL]

(BUN: Blood urea nitrogen = Urea-N in blood)

## Reference Range

**Serum/Plasma** [1]

| | [mg/dL] | [mmol/L] |
|---|---|---|
| **Adults** | | |
| 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 |
| **Children** | | |
| 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**

| | | |
|---|---|---|
| **Adults** | | |
| 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 [(mmol/L)/(mmol/L)]
20 – 35 [(mg/dL)/(mg/dL)]

**Urea in urine** [2]
26 – 43 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


1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 374-7.
2. Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1838.3.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007;45(9):1240-1243.4.
4. Guder WG, da Fonseca-Wollheim F, Heil W, et al. The Quality of Diagnostic Samples. 3rd ed. Darmstadt: GIT Verlag; 2010. p. 62-3; 68-9.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.6.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in May 2022. Published by AACC Press and John Wiley and Sons, Inc.


Additions and/or changes in the document are highlighted in grey. For deletions, please refer to the customer information for the corresponding edition number of the package inserts.

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Fluid Stable

respons®910

# Urea FS

## Application for serum, plasma or urine samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

| Identification | |
|---|---|
| This method is usable for analysis: | Yes |
| Twin reaction: | No |
| Name: | UREA |
| Shortcut: | |
| Reagent barcode reference: | 054 |
| Host reference: | 054 |

| Technic | |
|---|---|
| Type: | Linear kinetic |
| First reagent:[µL] | 160 |
| Blank reagent | Yes |
| Sensitive to light | |
| Second reagent:[µL] | 40 |
| Blank reagent | No |
| Sensitive to light | |
| Main wavelength:[nm] | 340 |
| Secondary wavelength:[nm] | 405 |
| Polychromatic factor: | 1.0000 |
| 1 st reading time [min:sec] | 05:48 |
| Last reading time [min:sec] | 07:00 |
| Reaction way: | Decreasing |
| Linear Kinetics<br>Substrate depletion: Absorbance limit | 0.4500 |
| Linearity: Maximum deviation [%] | 100.0000 |
| Fixed Time Kinetics<br>Substrate depletion: Absorbance limit | |
| Endpoint<br>Stability: Largest remaining slope | |
| Prozone Limit [%] | |

| Reagents | |
|---|---|
| Decimals | |
| Units | |

| Sample | |
|---|---|
| Diluent | DIL A (NaCl) |
| Hemolysis: | |
| Agent [µL] | 0 (no hemolysis) |
| Cleaner | |
| Sample [µL] | 0 |
| Technical limits | |
| Concentration technical limits-Lower | 3.0000 |
| Concentration technical limits-Upper | 300.0000 |
| SERUM | |
| Normal volume [µL] | 2.0 |
| Normal dilution (factor) | 1 |
| Below normal volume [µL] | |
| Below normal dilution (factor) | |
| Above normal volume [µL] | 2.0 |
| Above normal dilution (factor) | 6 |
| URINE | |
| Normal volume [µL] | 2.0 |
| Normal dilution (factor) | 26 |
| Below normal volume [µL] | |
| Below normal dilution (factor) | |
| Above normal volume [µL] | 2.0 |
| Above normal dilution (factor) | 26 |
| PLASMA | |
| Normal volume [µL] | 2.0 |
| Normal dilution (factor) | 1 |
| Below normal volume [µL] | |
| Below normal dilution (factor) | |
| Above normal volume [µL] | 2.0 |
| Above normal dilution (factor) | 6 |
| CSF | |
| Normal volume [µL] | 2.0 |
| Normal dilution (factor) | 1 |
| Below normal volume[ µL] | |
| Below normal dilution (factor) | |
| Above normal volume [µL] | 2.0 |
| Above normal dilution (factor) | 6 |
| Whole blood | |
| Normal volume [µL] | 2.0 |
| Normal dilution (factor) | 1 |
| Below normal volume[ µL] | |
| Below normal dilution (factor) | |
| Above normal volume [µL] | 2.0 |
| Above normal dilution (factor) | 6 |

| Results | |
|---|---|
| Decimals | 1 |
| Units | mg/dL |
| Correlation factor-Offset | 0.0000 |
| Correlation factor-Slope | 1.0000 |

| Range | |
|---|---|
| Gender | All |
| Age | |
| SERUM | >=17.0 <=43.0 |
| URINE | >=2000.0 <=3307.0 |
| PLASMA | >=17.0 <=43.0 |
| CSF | |
| Whole blood | |
| Gender | |
| Age | |
| SERUM | |
| URINE | |
| PLASMA | |
| CSF | |
| Whole blood | |

| Contaminants |
|---|
| Please refer to r910 Carryover Pair Table |

| Calibrators details | |
|---|---|
| **Calibrator list** | **Concentration** |
| Cal. 1/Blank | 0 |
| Cal. 2 | * |
| Cal. 3 | |
| Cal. 4 | |
| Cal. 5 | |
| Cal. 6 | |
| | **Max delta abs.** |
| Cal. 1 | 0.002 |
| Cal. 2 | 0.005 |
| Cal. 3 | |
| Cal. 4 | |
| Cal. 5 | |
| Cal. 6 | |
| Drift limit [%] | 0.80 |

| Calculations | |
|---|---|
| Model | X |
| Degree | 1 |

* Enter calibrator value