respons®910

Urea FS*

Diagnostic reagent for quantitative in vitro determination of urea in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 3101 99 10 920
4 twin containers for 200 tests each

Method

"Urease - GLDH": enzymatic UV test

Principle

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

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

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 (Glutamate dehydrogenase)		≥ 1 kU/L
R2:	NADH		1.3 mmol/L

Storage Instructions and Reagent Stability

The reagents 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. DiaSys respons containers provide protection from light. Do not freeze the reagents!

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. In very rare cases, samples of patients with gammopathy might give falsified results.
3. 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.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

Specimen

Serum or plasma (no ammonium heparin!)

Stability [1]:

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

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration, the DiaSys TruCal U calibrator is recommended. The assigned values of the calibrator have been made traceable to the reference material NIST SRM-909 level 1. For internal quality control DiaSys TruLab N and P controls should be assayed. 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

Performance Characteristics

Measuring range up to 300 mg/dL urea (in case of higher concentrations re-measure samples after manual dilution or use rerun function).	
Limit of detection**	3 mg/dL urea
On-board stability	4 weeks
Calibration stability	7 days

Interfering substance	**Interferences < 10%**	**Urea [mg/dL]**
Ascorbate	up to 30 mg/dL	89.7
Hemoglobin	up to 500 mg/dL	9.60
	up to 550 mg/dL	38.6
Bilirubin, conjugated	up to 65 mg/dL	9.03
	up to 70 mg/dL	39.9
Bilirubin, unconjugated	up to 70 mg/dL	9.28
	up to 65 mg/dL	42.2
Lipemia (triglycerides)	up to 1000 mg/dL	10.5
	up to 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 [2].		

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

Method comparison (n=109)	
Test x	DiaSys Urea FS (Hitachi 911)
Test y	DiaSys Urea FS (respons®910)
Slope	1.019
Intercept	-1.08 mg/dL
Coefficient of correlation	0.999

** according to NCCLS 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)

Reference Range [3]

	[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

Urea/Creatinine ratio

25 – 40 [(mmol/L)/(mmol/L)]
20 – 35 [(mg/dL)/(mg/dL)]

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

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 48-9.
2. 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.
3. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 374-7.
4. Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1838.
5. 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.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
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respons®910

Urea FS

Application for serum and plasma 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
Name:	UREA
Shortcut:	
Reagent barcode reference:	054
Host reference:	

Technic	
Type:	Linear Kinetic
First reagent:[µL]	160
Blanc correction	Yes
Second reagent:[µL]	40
Blanc correction	Yes
Main wavelength:[nm]	340
Secondary wavelength:[nm]	405
Polychromatic factor:	1.000
1 st reading time [min:sec]	05:48
Last reading time [min:sec]	07:00
Reaction way:	Decreasing
Linear Kinetics Substrate deplation: absorbance limit	0.45
Linearity: Maximum deviation [%]	100
Fixed Time Kinetics Substrate deplation: absorbance limit	
Endpoint Stability: largest remaining slope	
Prozone Limit [%]	

Sample	
Diluent	NaCl
Concentration technical limits-Lower	15
Concentration technical limits-Upper	300
SERUM	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume[µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6

Results	
Decimals	1
Units	mg/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	All
Age	
SERUM	>=17 <=43
URINE	
PLASMA	>=17 <=43
CSF	
Genre	
Age	
SERUM	
URINE	
PLASMA	
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	

Calibrators details	
Calibrator list	**Concentration**
Cal. 1	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*

	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0100
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X degree
Degree	1

* Enter calibrator value