UREA UV (BUN)-Kinetic
Urease / GLDH

Diagnostic reagent for determination of Urea concentration.

Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2330	5 x 100 mL	R2230	1705 Tests	N2230	800 Tests	M2231	1591 Tests
A2331	5 x 50 mL	R2231	568 Tests	N2231	400 Tests	L2230	3750 Tests
A2332	5 x 25 mL	S2230	2727 Tests	K2230	3750 Tests	L2231	2000 Tests
T2230	3474 Tests	S2231	1309 Tests	K2231	2500 Tests	BY2330	5579 Tests
T2231	1795 Tests	DM2230	840 Tests	M2230	2386 Tests	BY2331	4091 Tests

INTENDED USE

The test is applied for the quantitative determination of urea in serum, plasma or urine.

TEST PRINCIPLE

The urease hydrolizes urea in sample to release ammonium ions, which react with 2-oxoglutarate and nadh in presence of glutamate dehydrogenase to form glutamate and NAD+ the decrease of absorbance is measured at 340 nm.

TEST PARAMETERS

Method	: UV, Two Point Kinetic (fixed time), Decreasing Reaction, GLDH
Wavelength	: 340 nm
Temperature	: 37°C
Sample	: Serum, Plasma, Urine (dilute urine with 1:100 with distilled water)
Linearity	: 2 mg/dL - 300 mg/dL (50 mmol/L) of urea

REAGENT COMPOSITION

Tris buffer	≤ 120 mM pH 7.60,
2-Oxoglutarate	≤ 8 mM,
ADP	≤ 1.6 mM,
Urease	> 8 KU/L,
GLDH	> 800 U/L,
NADH	≤ 0.60 mM,
Stabilizers	

REAGENT PREPARATION

Working reagent

Mix 4 parts of Reagent 1 with 1 part of Reagent 2. For example: 4 ml Reagent 1 and 1 ml Reagent 2. The reagents are stable up to the expiration date on the label. Store reagents at 2-8°C, protected from direct light.

Stability of working reagent is minimum 60 days at 2-8°C, away from light sources. Avoid contamination of the opened reagents.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum, plasma (avoid ammonium heparinate) and urine are collected by standard procedures. Dilute urine sample 1:100 with deionized water.

Urea is stable 3 days at 2-8°C, 3 days at 20 - 25°C and 1 year at -20°C.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

$$\frac{\Delta A/min\ Sample}{\Delta A/min\ Standard} \times \text{Concentration of Standard(50)}$$

= mg/dL (mmol/L) urea in sample.

For urea concentration in urine, multiply the result by 100.

To convert mg of Urea into mg of Urea nitrogen, use the ratio between the molecular weights of Nitrogen and urea. 28.1/60.06 = 0.467 multiply this factor by the mg/dl of urea.

Unit Conversion

mg/dL x 0.1665 = mmol/L Urea
mg/dL x 0.356= mmol/L Urea Nitrogen

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Serum/Plasma	10 - 50 mg/dL (1.7 to 8.3 mmol/L) urea
Urine/24h:	20- 35 g/24h (330-580 mmol/L) urea

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

All control sera with Urea UV values determined by this method can be used. We recommend:

A3910 ARCON N Assayed Control Serum Normal
A3920 ARCON P Assayed Control Serum Abnormal

This assay requires the use of a Urea UV Standard or a Urea UV Calibrator. We recommend

A2330S Standard 50 mg/dL
A39050 Calibrator (ARCAL AUTO)

Any commercially available Standard or Calibrator suitable for this method may be used.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 7 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 2 mg/dL

High Linearity: The assay is linear up to 300 mg/dl (50 mmol/L). Above this concentration, dilute the sample with physiological NaCl (150 mmol/L) and rerun multiplying the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatability (within run) (Intra-assay)

Mean conc.	SD	CV	n
46.19 mg/dL	0.65	1.40%	10
140.89 mg/dL	2.72	1.90%	10

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD	CV	n
42.77 mg/dL	1.91	4.50%	20
144.29 mg/dL	6.72	4.70%	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 1 mg/dL.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Interferences: No interference was observed by the presence of:

Hemoglobin	≤ 500 mg/dL
Bilirubin	≤ 28 mg/dL
Lipids	≤ 600 mg/dL

Methods comparison: A comparison between Archem and a commercially available product gave the following results:

Urea UV FL Archem = x
Urea competitor = y
n = 100
$y = 0.9746x + 3.03$ mg/dl $r^2 = 0.986$

These performance characteristics have been obtained using an analyzer. Results may vary, if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.

7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NAD : Nicotinamide Adenine Dinucleotide
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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