UREA UV (BR-120/BR-160)

IVD

UREASE –GLDH, KINETIC METHOD

PRODUCT
CODE CS027

INTENDED USE
This reagent is intended for *in vitro* quantitative determination of Urea in serum, plasma or urine.

CLINICAL SIGNIFICANCE
Urea is the end product of protein metabolism. It is synthesized in the liver from the ammonia produced by the catabolism of amino acids. It is transported by the blood to kidneys from where it is excreted. Increased level associated in renal disease, urinary obstruction, shock, congestive heart failure and burns. Decreased levels are found in liver failure and pregnancy.

PRINCIPLE
Urea in the sample hydrolyzed enzymatically into ammonia (NH_4) and carbon dioxide (CO_2). The ammonia formed further combined with α-ketoglutarate in a reaction catalyzed by glutamate dehydrogenase (GLDH) with simultaneous oxidation of NADH to NAD+

$$\text{Urea} + H_2O + 2H^+ \xrightarrow{\textit{Urease}} (NH_4^+)_2 + CO_2$$

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

The decrease in concentration of NADH, is proportional to urea concentration in the sample[1].

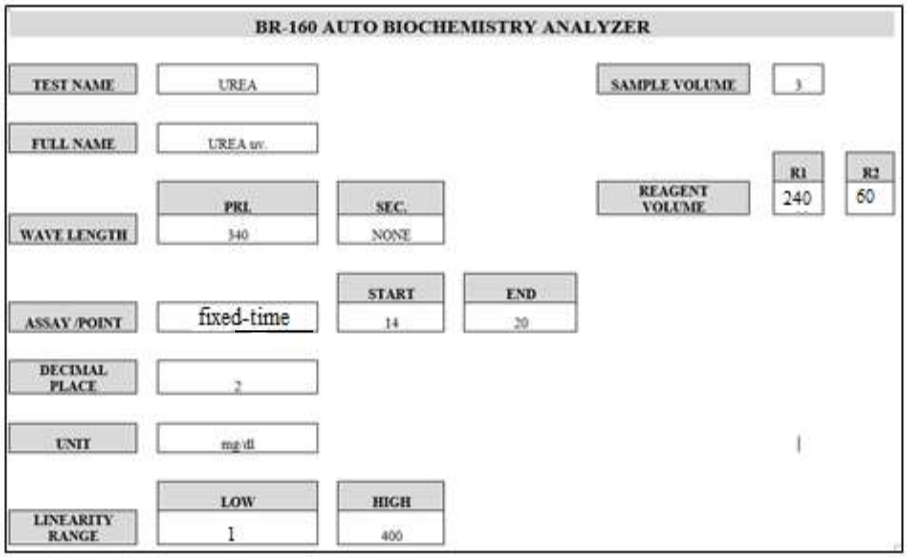
REAGENT COMPOSITION

REAGENT 1, Buffer	
TRIS pH 7.8	80 mmol/L
α-Ketoglutarate	6 mmol/L
Urease	75000 U/L
REAGENT 2	
(Enzymes) GLDH	60000 U/L
NADH	0.32 mmol/L

REAGENT PREPARATION
R1 and R2, ready-to-use and stable upto the expiry date if contamination is avoided and stored at 2-8°C and protect from light. **Signs of reagent deterioration**
Presence of turbidity
Blank absorbance (A) at 340 nm < 1.00

SPECIMEN
Serum, heparinized plasma; don't use ammonium salts or fluoride as anti coagulants.
Urine: dilute sample 1+49 with distilled water before the assay, multiply the results by 50. Preserve urine sample at pH<4.
Urea is stable for 5 days when stored at 2-8ºC.

PROCEDURE
APPLICATION ON AUTO BIOCHEMISTRY ANALYSERS



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BR-120 AUTO BIOCHEMISTRY ANALYZER						
TEST NAME	UREA			SAMPLE VOLUME	3	
FULL NAME	UREA uv.					
					R1	R2
	PRI.	SEC.		REAGENT VOLUME	240	60
WAVE LENGTH	340	NONE				
		START	END			
ASSAY /POINT	fixed-time	22	31			
DECIMAL PLACE	2					
UNIT	mg/dl					
	LOW	HIGH				
LINEARITY RANGE	2	400				

QUALITY CONTROL

Control Sera are recommended to monitor the performance of assay procedure. If control values are found out of the range, check the instrument, reagent, and standard for problems. Each laboratory should establish its own Quality Control scheme and corrective actions if the controls don't meet the acceptable tolerances.

REFERENCE VALUES [4.]

Serum or plasma: 15 – 45 mg/dL = 2.5 – 7.5 mmol/L

Urine: 26 – 43g/24 h = 428 – 714 mmol/24 h

These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring Range: From detection limit 1 mg/dL to linearity limit 400 mg/dL.

If the concentration is greater than linearity limit dilutes 1: 2 the sample with normal saline and multiply the result by 2. **Precision**

Intra-assay n=20	Mean (mg/dL)	SD	% CV
Level I	40.70	0.88	2.16
Level II	130	1.02	0.78

Inter-assay n=20	Mean (mg/dL)	SD	% CV
Level I	40.50	1.19	2.94
Level II	128	2.07	1.61

Sensitivity/Limit of Detection

The lower limit of detection is 1 mg/dL.

Accuracy

Results obtained using Bio Research reagent (y) didn't show any systematic differences when compared with other commercial reagent (x). The results obtained using 50 samples was the following,

Correlation coefficient: $(r)^2$:0.998

Regression equation y= 1.5759x – 1.1577

The results of performance characteristics depend on the analyzer used.

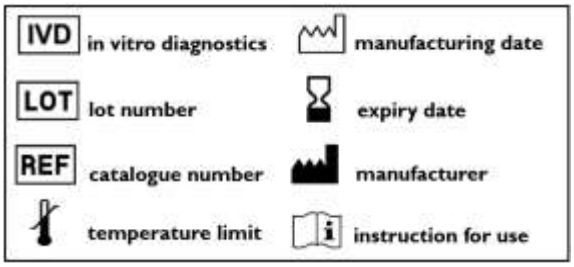
INTERFERENCES

It is recommended to use heparin as anticoagulant. Do not use ammonium salts or fluorides[1].

A list of drugs and other interfering substances with urea determination has been reported by Young et [al2, 3]. **NOTES**

1. Glassware and distilled water must be free from ammonia and ammonium salt.
2. Calibration with aqueous standard may cause a systematic error in automatic procedure. In these cases, it is recommended to use a serum calibrator.
3. Use clean disposable pipette tips for dispensing.
4. Bio Research has instruction sheets for several automated analyzers. Instructions for many of them are available on request.

SYMBOL ON LABELS



BIBILOGRAPHY

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Bio Research For Medical Diagnostics
Muslim Al Attar Street,P.O.Box:1235,
Amman-11953,Jordan
Tel:+962 64892525, Fax: +962 64892526 www.bioresearch.com.jo