UREA Color

Berthelot modidied method - Endpoint

2 x 50 ml **CP06-100**
2 x 100 ml **CP06-200**

INTENDED USE

Kit for quantitative determination of Urea in serum, plasma and urine according to Berthelot modified reaction.

CLINICAL MEANING

Urea derives from protein catabolism, more than 90% is excreted through the kidney. The increase in plasma urea can occur from kidney or heart failure, loss of water and salts, obstruction of the urinary tract, or increased protein breakdown. A decrease can be found in cases of hyperhydration, severe hepatic insufficiency, increased protein synthesis, deficient protein intake in the diet.

PRINCIPLE

Urease catalyzes urea hydrolysis into carbon dioxide and ammonia which, in presence of sodium nitroprussiate, reacts with sodium hypochlorite and sodium salicylate to form 2,2 dicarboxy-indophenol. This green colored compound is colorimetric defined and is proportional to the urea concentration in the sample.

SAMPLE

Serum, plasma.
Avoid anticoagulants containing fluoride or ammonium salts.
Urea in serum or plasma, avoiding bacterial contamination, is stable up to 3 days at 2-8°C.
Diluted urine 1:100 with distilled water..

REAGENTS

Only for in Vitro diagnostics.
Dangerous reagents are marked by an asterisk. Refer to safety data sheet

Pack Contents:	**CP06-100 Quantity**	**CP06-200 Quantity**
***REAGENT 1A** (powder) Phosphate buffer (pH 7,0) 75 mmol/L Sodium salicylate 40 mmo/L Sodium nitroprussiate 5 mmol/L, EDTA 5 mmol/L, urease > 7000 U/L	CP06-100R1 2 x 1 gr	CP06-200R1 2 x 2 gr
REAGENT 1B Phosphate buffer (pH 7,0) 75 mmol/L EDTA 5 mmol/L	CP06-100R2 2 x50 ml	CP06-200R2 2 x 100 ml
***REAGENT 2** Sodium hydroxide 1,5 mol/L Sodium hypochlorite 60 mmol/L	CP06-100R3 1 x 11 ml	CP06-200R3 1 x 22 ml
STANDARD (Std) Urea 40 mg/dl (6,65 mmol/L) Benzoic acid 15 mmol/L	CP06-100S 1 x 4 ml	CP06-200S 1 x 4 ml

STABILITY:: store at 2-8°C and protect from light to keep the reagents stable up to the expiration date on the label. Do not freeze. Keep bottles closed when not in use. Do not use turbid reagents.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

Preparation of working reagent 1

Dissolve 1 vial of Reagent 1A with 1 vial of Reagent 1B. Mix gently until complete powder dissolution (about 5 minutes).
STABILITY: 30 days at 2-8°C if stored in a closed bottle protected from light.

Preparation of working reagent 2

Dilute 1 volume of Reagent 2 with 10 volumes of distilled water.
STABILITY: 6 months at 2-8°C if stored in a closed bottle protected from light.

PROCEDIMENTO

Analysis:	increasing endpoint
Wavelength:	600 nm (580 - 620)
Cuvette:	1 cm optical path
Temperature:	37°C
Reaction time:	5 + 5 minutes
Reading:	against blank reagent
Sample/Reagents:	1/125/125

Let the reagent required to perform the test reach the chosen temperature for the analysis.

Pipette in cuvette:

	Blank Reagent	Standard	Sample
Distilled water	10 µl	-	-
Standard	-	10 µl	-
Sample	-	-	10 µl
Working reagent 1	1,25 ml	1,25 ml	1,25 ml

Mix. Incubate for 5 minutes at 37°C. Than add:

Working reagent 2	1,25 ml	1,25 ml	1,25 ml

Mix. Incubate for 5 minutes at 37°C. Then read the absorbencies of the standard (AbsStd) and the sample (AbsS) against the blank reagent.

Reaction volumes can be proportionally varied without any change in calculation.

CALCULATION

Calculate the concentration in the sample using the following formula:

Serum / plasma: [mg/dl] urea = AbsS / AbsStd x 40

[mmol/L] urea = AbsS / AbsStd x 6,65

Urine: [gr/24h] urea = AbsS / AbsStd x 40 x L 24h

[mmol/24h] urea = AbsS / AbsStd x 665 x L 24h

REFERENCE VALUES

Serum / plasma: 10 ÷ 50 mg/dl (1,79 ÷ 8,3 mmol/L)
Urine: 20 ÷ 35 gr/24h (330 ÷ 580 mmol/24h)

Each laboratory should define its own reference values for this method.

QUALITY CONTROL

A quality control program is recommended for all clinical laboratories.
Control serums of human origin are available for this purpose on request:
PRE-NORM serums with normal values
PRE-PATH serums with pathological values
If the method requires it, a multi-parameter calibrator of human origin is available.

PERFORMANCE CHARACTERISTICS

Sensitivity: the sensitivity of the method is 3 mg/dl.

Linearity: up to 300 mg/dl.
For higher values, dilute the samples 1:10 with saline solution and multiply the result by 10.

Precision:

Within-run(n= 10)	Average [mg/dl]	SD	CV %
Sample 1	28,5	1,10	3,85
Sample 2	146,9	5,6	3,81

Between-run (n=20)	Average [mg/dl]	SD	CV %
Sample 1	28,8	1,3	4,5
Sample 2	151,3	6,3	4,2

Interferences:up to 30 mg/dl of bilirubin does not interfere. Up to 500 mg/dl of hemoglobin does not interfere.

Correlation: the correlation of the method (Y) against a reference method (X) gives this equation:
Y = 1,1153X – 0,5649 r = 0,9993

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

REAGENT1A and REAGENT 2 **WARNING:** ***H319*** *causes severe eye irritation.* ***H315*** Causes skin irritation.
REAGENT 1B and STANDARD: not classified as dangerous.

REFERENCES

1. J.P. Bretandiere et All, Clin. Chem. 22, 164 (1976)
2. Hallet and Cook, Clin. Chem. Acta 35, 33 (1971)
3. Fawcett J.K., Scott J.E., J. Clin. Path. 13, 156 (1960)
4. Kaplan LA, Pesce AJ: “Clinical Chemistry”, Mosby Ed. 1989

MANUFACTURER

FAR
Via Fermi, 12 - 37026 Pescantina - VERONA - ITALY
tel +39 045 6700870
website http://www.fardiag.com
e-mail: order@fardiag.com e-mail: fardiag@fardiag.com

KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalogue number
	temperature limits
	use by
	caution
	consult accompanying documents

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