UREA

Urease-GLDH. Kinetic. Liquid

Product information

24UREA01-UN	**Meditest Urea**	**4 x 40 mL 2x20 mL**
24UREA01-AU	**Meditest Urea**	**4 x 40 mL 2x20 mL**
24UREA01-AB	**Meditest Urea**	**4 x 40 mL 2x20 mL**
24UREA01-ER	**Meditest Urea**	**4 x 40 mL 2x20 mL**
24UREA01-AR	**Meditest Urea**	**4 x 40 mL 2x20 mL**

Purpose

In vitro assay for the quantitative determination of urea/urea nitrogen in human serum, plasma and urine.

Summary

Urea is the end result of the metabolism of proteins; It consists of their destruction in the liver. High urea in the blood (uremia) can occur in the following cases: diets with an excess of protein, kidney diseases, heart failure, gastrointestinal bleeding, dehydration or kidney obstruction[1,4,5]. Clinical diagnosis should not be made based on a single test result; integrate clinical and other laboratory data.

Test principle

The urea in the sample is enzymatically hydrolyzed to ammonia (NH4+) and carbon dioxide (CO2). The ammonia ions formed react with alpha-ketoglutarate in a reaction catalyzed by glutamate dehydrogenase (GLDH), and at the same time, oxidation of NADH to NAD^+ takes place:

$$Urea + H_2O + 2\,H^+ \xrightarrow{UREASE} (NH_4^+)_2 + CO_2$$

$$NH_4^+ + \alpha\text{-Ketoglutarate} + NADH \xrightarrow{GLDH} H_20 + NAD^+ + \text{L-Glutamate}$$

The decrease in NADH concentration is proportional to the concentration of urea in the sample1

Reagents - working solutions

R 1 Buffer	TRIS pH 7.8	<80 mmol/L
	α-Ketoglutarate	>6 mmol/L
	Urease	>75000 U/L
R 2 Enzymes	GLDH	<60000 U/L
	NADH	<0.32 mmol/L

Precautions warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.
Infectious or microbial waste:
Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.
Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users.
Inhibit foam formation in all reagents and sample types (sample, calibrator and control).
If there is any damage on the package, do not use it Read the user manual carefully before use, do not use the expired assay kit Do not mix different lot reagents.
All samples should be considered epidemic material, please dispose of them in accordance with the laboratory working standard of infectious diseases.
Take the necessary protective measures to prevent users from becoming infected during operation.

Use of reagents

Ready to use.

Storage and stability

All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contamination is avoided during their use.
Do not use reagents after the expiration date. Signs of reactive decay: Presence of particles and turbidity at 340 nm empty absorbance (A) < 1.00.

Sample collection and preparation

- Serum or heparinized plasma: Do not use ammonium salts or fluoride as anticoagulants
- Urine: Dilute the sample with 1/50 distilled water. Mix. Multiply the results by 50 (dilution factor).

Maintain urine specimens at pH<4.
Urea is stable at 2-8ºC for 5 days.

Required Materials (not included in the kit)

1. Cat# 24BIO01-DC Meditest Diachem Calibrator
2. Cat# 24BIO01-DQ Meditest Diacheck Control L1
3. Cat# 24BIO02-DQ Meditest Diacheck Control L2
4. General laboratory equipment
5. Distilled or deionized water

Working Procedure

If you are using a spectrophotometer to perform this test, work with the following procedure. Ask your representative for the application data for fully automatic devices.

1.Test Conditions:
Wavelength: . 340 nm
Cuvette: . . . . . 1 cm light path
Temperature: . 37ºC / 15 25ºC 2.Set the appliance to zero with distilled water.
3.Place the pipettes in a cuvette.

	Blank	Standard	Sample
WR (mL)	1,0	1,0	1,0
Standard(Note 2,3) (µL)	--	10	--
Sample (µL)	--	--	10

4. Stir and read the absorbance after 30 seconds (A1) and 90 seconds (A2).
5. Calculation: ΔA= A1 – A2

$$\frac{(A1-A2)\ Sample-(A1-A2)Blank}{(A1-A2)\ S\ tan\ dard-(A1-A2)Blank\ \text{the sample}} \times 50\ (\text{Standard conc}) = \text{mg/dL}$$

mg/dL urea x 0.466 = mg/dL urea BUN (Blood Urea Nitrogen)[1].

Conversion factor: mg/dL x 0.1665 = mmol/L

Expected values

Serum or plasma: 15-45 mg/dL 2.5-7.5 mmol/L
24-hour urine: 25,742.9 g/24 h, corresponding: 1,713.57 g/dL

These values are for orientation purposes; Each laboratory should establish its own reference range

Limitations
Criterion: Recovery within 10% of base±line at urea concentrations of 8.3 mmol/L (49.8 mg/dL urea, 23.2 mg/dL urea nitrogen) in serum/plasma and 150 mmol/L (901 mg/dL urea, 421 mg/dL urea nitrogen) in urine. Recovery within 10% of ± for drug interaction.
Serum/plasma Icterus: No apparent interactions for conjugated and unconjugated bilirubin until the I index is 60 (approximate concentration of conjugated and unconjugated bilirubin: 1026 µmol/L or 60 mg/dL).
Hemolysis: No apparent interaction until the H index is 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL). Lipemia (Intralipid): No obvious interaction until the L index is 1000. There is a weak correlation between the L index (which corresponds to turbidity) and the concentration of triglycerides. Ammonium ions can cause falsely elevated results.
Drugs: No interactions were found at therapeutic concentrations when common drug panels were used. In very rare cases, gammopathy, especially type IgM (Waldenström macroglobulinemia), can cause unreliable results.
Urinary Hemolysis: No apparent interaction until the H index is 750 (approximate hemoglobin concentration: 466 µmol/L or 750 mg/dL).
Drugs: No interactions were found at therapeutic concentrations when common drug panels were used. When making a diagnosis, the results must be evaluated together with the patient's medical history, clinical examination and other findings.

Performance characteristics
Measuring range: 1.24 - 530 mg/dL. If the concentration is greater than the linearity limit, dilute the sample with NaCL 9 g/L in a ratio of 1:2 and multiply the result by 2.

Precision

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (mg/dL)	40.7	130	40,5	128
SD	0.88	1.02	1,19	2,07
CV (%)	2,16	0,78	2,94	1,61

Sensitivity: 1 mg/dL = 0.00080 A.
Accuracy: Results obtained using Meditest reagents (y) showed no systematic differences when compared to other commercial reagents (x). The results obtained using 50 samples are as follows:
Correlation coefficient (r)²: 0.998.
Regression equation y= 1.5759x - 1.1577

The results of the performance characteristics depend on the analyzer used.

References

1. Tiger A. Urea. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1257-1260 and 437 and 418.
2. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
3. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
4. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
5. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

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