BIOBASE

Urea (UREA) Test Kit

(Urease-GLDH)

【NAME】

Urea (UREA) Test Kit (Urease-GLDH)

【INTEND USE】

The reagent is intended for the in vitro quantitative determination of Urea (UREA) in human serum,plasma . UREA increased: common in kidney disease: such as acute renal failure, chronic nephritis, renal arteriosclerosis, chronic pyelonephritis, renal tuberculosis, kidney advanced tumors. According UREA measurement results can be used to determine the degree of renal failure. UREA decreased: mainly seen in liver damage, decreased production. Such as acute yellow atrophy of the liver, liver cirrhosis, toxic hepatitis, severe anemia.

【METHODOLOGY】

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

$$\alpha\text{-ketoglutaric acid} + NH_4^+ + \text{NADH} \xrightarrow{\text{GLDH}} \text{L- glutamic acid} + NAD^+ + H_2O$$

【STABILITY AND STORAGE】

Unopened, avoid light preservation in 2 ~ 8 ℃, valid for 12 months;

Opened, avoid light preservation in 2 ~ 8 ℃, valid for 1 month.

Reagent is not allowed frozen.

【SPECIMEN COLLECTION AND HANDLING】

Serum, plasma (do not use heparin ammonium).

Urine diluted with distilled water, and the detection value multiplied by the dilution ratio .

Stability of sample: Serum or plasma stability: 4 ~ 25℃ preservation stability in 7 days,- 20℃ preservation can be stable for 12 months.

Urine stability: 20~ 25℃keep stable 2 days; 4 ~ 8℃ keep stable 6 days; - 20℃ can be stable for 1 months.

【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer.

【SYSTEM PARAMETERS】

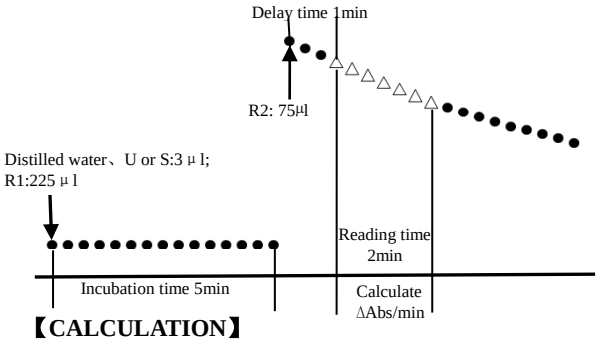
The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group.

Temperature	37° C
Cuvette light path	1.0cm
Primary Wavelength	405 nm
Secondary Wavelength	600nm
Assay Type	Fixed time method
Direction	Increase
Sample : Reagent Ratio	1:75:25
eg : Sample Vol	3 μL
Reagent1 Vol	225 μL
Reagent2 Vol	75 μL
Linearity	0～35.7 mmol /L
Testing	Deducting the reagent blank

【OPERATION STEPS】

Double reagent operation:

R1：Reagent 1 R2：Reagent 2 S：Calibrator U：Sample



【CALCULATION】

$$\text{TBA（u mol/L）} = \frac{\text{Sample } \Delta A/\text{mın}}{\text{Calibrator } \Delta A/\text{min}} \times \text{Calibrator concentration}$$

【REFERENCE RANGE】

Serum/Plasma:1.7～8.3mmol/L

Urine:15-35g/24h

By clinical trials, choose no less than 100 women or men blood specimens, tested by automatic biochemical analyzer, and then processing the testing value with statistical method, calculating out the reference range.

Recommendation: The laboratory set up its own reference range!

【THE LIMITATION OF TEST RESULTS】

UREA testing is just one of the standard that clinicist diagnose the patient. Clinical physicians should according to patients' bodies, history and other diagnostic program, to get comprehensive judgment.

【THE INTERPRETATION OF TEST RESULTS】

Human error, the processing of specimen, analysis instrument deviation, etc. all can affect the measurement result；When one sample deviates from the expected value too far, need to be tested again.

【PERFORMANCE INDEX】

1.Reagent blank absorbance≥1.2, (340nm，lcm optical path).

2.Precision: repeatability CV≤5%; batch variations R≤5%.

3.Accuracy: relative deviation ≤10%.

4.Linearity range: 0～35.7mmol /L,r≥0.990.

【ATTENTION】

1.Reagent contains sodium azide (toxic) preservatives, avoid contact with skin and mucous membrane.If necessary preventive measures should be taken use of reagents, reagent contact with skin and mucous membrane, please rinse with water, please go to a doctor if necessary.

2.The maximum linearity is 35.7mmol/L.If testing results is upper limit,dilute with 0.9% sodium chloride solution before test, results multiplied by the dilution ratio.

3.Liquid waste disposal: Suggest follow local regulations

4.Different batches reagents cannot mix, when replacing reagents batch number, please calibration again.

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