Urea, creatinine, uric acid test card (dry chemical method)
Instructions for Use

Product Name

Common name: Urea, creatinine, uric acid test card (dry chemical method)

Package Specification

Model	DiaCard-4
Specification	10 pcs/box, 20 pcs/box, 50 pcs/box

Intended Use

It is intended to be used for in vitro quantitative detection of uric acid, creatinine, and urea in human whole blood or serum samples.

Test Principle

After adding appropriate amount of blood specimen to the test card, the uric acid and creatinine in the specimen react with the enzymes and chemicals in the reaction layer through the diffusion layer and produce color changes. The urea produces ammonia and carbon dioxide under the action of urease. And the ammonia causes the color change of agent. The color changes produced is proportional to the concentration. Then the analyzer uses the reflection method to read the results and calculates the content of the substance to be measured. The reaction equation is as follows:

Urea:

$$(NH_2)_2CO + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

$$NH_3 + \text{ indicator (yellow)} \longrightarrow NH_4^+ + \text{ indicator (green)}$$

Creatinine:

$$C_4H_7N_3O + H_2O \xrightarrow{\text{Creatinine aminohydrolase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatinine hydrolase}} C_3H_7NO_2 + C_4H_7N_3O$$

$$C_3H_7NO_2 + H_2O + O_2 \xrightarrow{\text{Sarcosine oxidase}} C_2H_5NO_2 + HCHO + H_2O_2$$

$$H_2O_2 + \text{4-AAP} + \text{ Aniline} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine dye} + H_2O$$

Uric acid:

$$C_5H_4N_4O_3 + O_2 + H_2O \xrightarrow{\text{Uricase}} C_4H_6O_3N_4 + CO_2 + H_2O_2$$

$$H_2O_2 + \text{4-AAP} + \text{ Aniline} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine dye} + H_2O$$

Main Composition

1. The urea, creatinine, uric acid test card contains the following active ingredients:

Uricase	4.0U
Peroxidase	21U
4-aminoantipyrine	150μg
TOOS	136μg
Urease	4.0U
Creatinine amidohydrolase	2.5U
Amidinohydrolase Creatine	2.5U
Sarcosine oxidase	2.5U

2. *code chip*

   Code chip contains specific batch number of test card.

Storage Conditions and Expiry Date

1. The test card should be sealed and stored at 2～30°C, and its period of validity is 12 months.
2. Test card must be stored in the original packaging. Use the test card immediately after taking out from package.
3. Refer to the packaging or label for the manufacture date and expiration date.

Applicable Analyzer

The test card is applicable to Compass2000-1, Compass2000-2, Compass2000-3 dry biochemical analyzer produced by Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.

Specimen Requirements

1. Applicable blood samples include whole blood and serum.
2. If the sample contains anticoagulant, only whole blood anticoagulated by heparin or EDTA can be used.
3. The whole blood should be tested as soon as possible after collection.
4. Serum samples can be stored at 2°C～8°C for 7 days, and it can be stored at -20°C for one month. Serum samples should not be repeatedly frozen and thawed.

Test Method

1. Prepare the required items: dry biochemical analyzer and other required items.
2. Please read the instructions of the dry biochemical analyzer in detail and be familiar with the operation of the analyzer.
3. Check whether the code chip is consistent with the information on the test card label.
4. Place the test card to the correct position of the analyzer and add 45μl sample.
5. The analyzer starts the test, and the result is displayed on the analyzer screen after the test is completed.

Reference intervals

Urea:	Male: 3.1 - 9.5mmol/L(18.6 - 57mg/dL);
	Female: 2.6 - 8.8mmol/L(15.6 – 52.8mg/dL)
Creatinine:	Male: 57 - 111μmol/L(0.644 – 1.254mg/dL);
	Female: 41 - 81μmol/L(0.463 – 0.915mg/dL)
Uric acid:	Male: 208 - 428μmol/L(3.494 – 7.190mg/dL);
	Female: 155 - 357μmol/L(2.604 – 5.998mg/dL).

It is recommended that each laboratory establish its own reference range according to the actual situation.

Test Result

The dry biochemical analyzer automatically test the test card with blood specimen, and the uric acid and creatinine are showed in μmol /L and urea in mmol/L.

Limitation of Test Method

1. Diagnosis and treatment should not rely solely on the test result. Clinical history and other laboratory tests should be considered.
2. Other factors may also cause inaccuracy of test results, such as technical factors, misoperation, etc.
3. The test card showed no significant interference at the following concentrations of interfering substances: plasma free hemoglobin ≤10mg/dL, bilirubin ≤60mg/dL, triglyceride ≤100mg/dL, ascorbic acid ≤5mg/dL, and ammonia ion ≤400μmol/L.

Performance Specification

1. Accuracy
   a) Relative bias of urea: ≤±10%;
   b) Relative bias of creatinine: ≤±10%;
   c) Relative bias of uric acid: ≤±10%;
2. Repeatability
   a) CV (Coefficient of Variation) of urea: ≤7.5%.
   b) CV (Coefficient of Variation) of creatinine: ≤7.5%.
   c) CV (Coefficient of Variation) of uric acid: ≤7.5%.
3. Inter-batch difference
   a) CV (Coefficient of Variation) of urea: ≤10%.
   b) CV (Coefficient of Variation) of creatinine: ≤10%.
   c) CV (Coefficient of Variation) of uric acid: ≤10%.
4. Linearity

Test item	Linearity Range	Correlation requirements
Urea	2.5～40mmol/L (15～240mg/dL)	r≥0.9900
Creatinine	30～1000μmol/L (0.339～11.300mg/dL)	r≥0.9900
Uric acid	120～1200μmol/L (2.016～20.160mg/dL)	r≥0.9900

NOTES

1. **This product is for In Vitro Diagnostic use only.**
2. **Use the test card prior to the expiration date.**
3. **During the operation, the blood sample should be dripped into the test card at one time. If the amount of blood dripped on the test card is insufficient, a new test card and fresh blood sample should be used for testing.**
4. **This product is for single-use only. Always handle blood specimens with care as they may be infectious. Consult local environment authorities for proper disposal. Always wear protective gloves when handling blood specimens and test cards with specimen.**

Symbol and Explanation

Symbol	Explanation
IVD	In vitro diagnostic medical device
	Consult instructions for use
	Caution
LOT	Batch code
	Date of manufacture
	Manufacturer
	Temperature limit
	Use-by date
	Do not reuse
CE	CE mark
EC REP	Authorized representative in the European community

Bibliography

1. Shang Hong, Wang Yusan, Shen Ziyu, etc. National Clinical Laboratory Procedures [M]. 4th edition. Beijing: People's Medical Publishing House, 2014: 309-311.
2. WS/T404.5-2015 Reference intervals for common clinical biochemistry tests— Part5: Serum urea and creatinine

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