Blood lipid and blood glucose test card (dry chemical method) Instructions for use

Product Name

Common name: blood lipid and blood glucose test card (dry chemical method)

Package Specification

Model: DiaCard-1 (TC + HDL-C + TG + GLU), Specification: 10 pcs/box, 20 pcs/box, 50 pcs/box

Model: DiaCard-2 (TC + HDL-C + TG), Specification: 10 pcs/box, 20 pcs/box, 50 pcs/box

Model: DiaCard-3 (TC + GLU), Specification: 10 pcs/box, 20 pcs/box, 50 pcs/box

Intended Use

It is used for in vitro quantitative detection of TC (total cholesterol), HDL-C (high density lipoprotein cholesterol), TG (triglycerides) and GLU (glucose) in human whole blood or serum samples. It is not used for glucose self-testing.

As one of the indexes of lipid metabolism, total cholesterol, high-density lipoprotein cholesterol and triglyceride are mainly used for the analysis of cardiovascular diseases. The test results can help patients find problems and seek medical treatment in time. Glucose can quickly detect the changes of glucose in the blood of diabetic patients, which has important guiding significance for life rules, activities, sports, diet and rational drug use, and helps patients find problems and seek medical treatment in time.

At present, the clinical and laboratory methods for detecting TC mainly include oxidase method, enzyme-coupled colorimetric method, COD-PAP method; the methods for detecting HDL-C mainly include HDL-CHO method, enzymatic method, and direct method; the methods for detecting TG mainly include enzymatic colorimetric method, end-point method, oxidase method; the methods for detecting GLU mainly include glucose oxidase method, dry chemical method.

Test Principle

After the blood sample is added to the test card, the blood cells are filtered out and the serum diffuses to the reaction layer. The substance to be measured in the serum reacts with enzymes and chemicals in the reaction layer and produces color changes. 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 principle of each index is as follows:

Total cholesterol:

$$\text{Cholesterol ester} + H_2O \xrightarrow{\text{Cholesterol esterase}} \text{Cholesterol} + \text{free fatty acid}$$

$$\text{Cholesterol} + O_2 + H_2O \xrightarrow{\text{Cholesterol oxidase}} \Delta 4\text{-cholestenone} + H_2O_2$$

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

Triglycerides:

$$\text{Triglyceride} + 3H_2O \xrightarrow{\text{Lipoprotein lipase}} \text{Glycerin} + \text{3 free fatty acids}$$

$$\text{Glycerin} + ATP \xrightarrow{\text{Glycerol kinase, } Mg^{2+}} \text{3-Glycerol phosphate} + ADP$$

$$\text{3-Glycerol phosphate} + O_2 \xrightarrow{\text{Glycerophosphate oxidase}} \text{Dihydroxyacetone phosphate} + H_2O_2$$

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

High-density lipoprotein cholesterol:

After precipitating LDL-C and VLDL-C with phosphotungstic acid in the presence of magnesium ions, HDL-C is measured using the same principle as the measurement of TC.

Glucose:

$$\text{D- Glucose} + O_2 + H_2O \xrightarrow{\text{Glucose oxidase}} \text{D-Gluconic acid} + H_2O_2$$

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

Composition

1. The blood lipid and blood glucose test card contains the following active ingredients:

Name	Content	Name	Content
Cholesterol esterase	1.6U	Peroxidase	13U
Cholesterol oxidase	1.0U	Phosphotungstic acid	0.3mg
4-aminoantipyrine	150μg	Lipoprotein lipase	4.2U
N, N-disubstituted aniline	136μg	Glycerol kinase	2.4U
Glycerophosphate oxidase	1.7U	Adenosine triphosphate	50μg
Glucose oxidase	3.2U		

2. code chip

The code chip contains specific batch number of test card for checking the test card batch number.

Storage Conditions and Expiry Date

1. The test card should be sealed and stored at 2°C～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,Compass2000-3dry biochemical analyzer and Compass2800-1, Compass2800-2 portable dry biochemical analyzerproduced 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. Whole blood samples can be stored for 30 minutes at room temperature 25°C.
4. Serum samples can be stored at 2°C~8°C for 7 days, and it can be stored at -20°C for 31 days.

Test Method

1. Prepare the necessary items for operation: blood sample, dry biochemical analyzer, test card of corresponding type and other items required for operation.
2. Read this instructions for use of the dry biochemical analyzer carefully and be familiar with the operation of the analyzer.
3. Check if the code chip is consistent with the information on the test card label.
4. Insert the blood lipid and blood glucose test card into the correct position of the analyzer. The test card DiaCard-1 requires 45μl blood specimen, DiaCard-2 requires 45μl

blood specimen, and DiaCard-3 requires 20μl blood specimen.

5. The analyzer starts the test, and the result is displayed on the analyzer screen after reacting at 37°C for 3 minutes.
6. This product uses the national standard material GBW(E)090998 to calibrate total cholesterol, high-density lipoprotein cholesterol and triglycerides; the national standard material GBW(E)091004 to calibrate glucose.
7. This product uses Randox quality control serum (item number: HE1532 and HN1530) for quality control.

Reference Intervals

This product tests and analyzes the serum samples of healthy adults. The upper limit of the reference interval for TC is the 95th percentile; the lower limit of the reference interval for HDL-C is the 5th percentile; the upper limit of the reference interval for TG is the 95th percentile; the reference interval for glucose is adopted x±1.96s, and the reference range of each item is as follows:

Test Items	Sample cases	Reference range
TC	155	＜5.2mmol/L(200 mg/dL)
HDL-C	155	＞1.0mmol/L(40 mg/dL)
TG	155	＜1.7mmol/L(150 mg/dL)
GLU	155	3.9～6.1mmol/L(70～110 mg/dL)

Each laboratory shall determine the applicability of the reference interval through tests, and establish its own reference interval range based on the patient population being tested when necessary.

Test Result

Interference factors:

Bilirubin (>20mg/dL), vitamin C (>10mg/dL), uric acid (>10mg/dL) will make the test results low.

Dopamine (>1.8mg/dL) will make the test results low.

Limitation of Test Method

Diagnosis and treatment should not rely solely on the test result. Clinical history and other laboratory tests should be considered.

Performance Specification

1. Blank limit

All items shall not be higher than 0.3mmol/L.

2. Linearity

Test item	Linearity Range mmol/L(mg/dL)	Correlation requirements
TC	2.59～12.93mmol/L(100～500 mg/dL)	r≥0.975
TG	0.51～7.34mmol/L(45～650 mg/dL)	r≥0.975
HDL-C	0.39～2.59mmol/L(15～100 mg/dL)	r≥0.975
GLU	2.0～18.0mmol/L(36～324 mg/dL)	r≥0.975

3. Repeatability

(1) The CV (Coefficient of Variation) of total cholesterol is ≤7.5%;

(2) The CV (Coefficient of Variation) of triglycerides is ≤6%;

(3) The CV (Coefficient of Variation) of HDL-C is ≤7.5%;

(4) The CV (Coefficient of Variation) of glucose is ≤5%.

4. Inter-batch difference

(1) The inter-batch difference of total cholesterol is ≤15%;

(2) The inter-batch difference of triglyceride is ≤15%;

(3) The inter-batch difference of HDL-C is ≤15%;

(4) The inter-batch difference of glucose is ≤10%.

5. Accuracy

(1) The relative deviation of total cholesterol is ≤±10%;

(2) The relative deviation of triglycerides is ≤±15%;

(3) The relative deviation of HDL-C is ≤±15%;

(4) Relative deviation of glucose is ≤±10%.

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, fill the test card in one continuous process. Do not refill repeatedly. If the test card cannot be filled with enough blood specimen in one continuous process, use another new test card to perform the test again.**
4. **This product is for single-use only. Always handle blood specimens with care as they may be infectious. Consult your local environment authorities for proper disposal. Always wear protective gloves when handling blood specimens and test cards with specimen.**

Symbol and Explanation

Symbol	Explanation	Symbol	Explanation
IVD	In vitro diagnostic medical device		Date of manufacture
	Consult instructions for use		Manufacturer
	Caution	LOT	Batch code
	Temperature limit		Do not reuse
	Use-by date	CE	CEmark
EC REP	Authorizedrepresentativeinthe European community	Konsung	Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.

Bibliography

1. Joint committee for guideline revision of Chinese Adult Dyslipidemia Prevention, Chinese guidelines for the management of dyslipidemia in adults (2016 Revised Edition). Chinese Circulation Journal, 2016, 31: 937-953.
2. Friedewald et al. Clin Chem. 1972, 8(6):499-502.

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