Total Cholesterol Assay Kit (CHO)

Method: CHOD-PAP

Cat .No	Size	Instrument
GB100Z	R1: 5×100 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS101Z	R1: 6×70 ml	For Hitachi 917 & OlympusAU640/400/600
GH101Z	R1: 6×50 ml	For Hitachi 902
GT101Z	R1: 7×50 ml	TOSHIBA
GX101Z	R1: 2×100 ml	For SYNCHRON CX4-5-7-9 /LX20/DXC600-800

INTENDED USE
For the *in vitro* quantitative determination of cholesterol in serum.

CLINICAL SIGNIFICANCE
Measurement of serum cholesterol levels can serve as an indicator of liver function, biliary function, intestinal absorption, propensity toward coronary artery disease, thyroid function and adrenal disease. Cholesterol levels are important in the diagnosis and classification of hyperlipoproteinemias. Stress, age, gender, hormonal balance and pregnancy affect normal cholesterol levels.

ASSAY PRINCIPLE[1,2,3]

$$\text{Cholesterol Esters} \xrightarrow{\text{Cholesterol Esterase}} \text{Cholesterol+Fatty Acids}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholestero Oxidase}} \text{Cholesten-3-one} + H_2O_2$$

$$2H_2O_2 + \text{4-Aminoantipyrine+Phenol} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine（red dye）} + 4H_2O$$

Quinoneimine dye colored red is formed from 4-aminoantipyrine, phenol, and hydrogen peroxide. The absorption of the solution of this dye is proportional to the concentration of cholesterol in the sample.

SAMPLE COLLECTION AND PREPARATION
Serum samples or heparin, EDTA plasma samples.
Samples are stable for 3 days at 2-8°C, or for some weeks at -20°C.

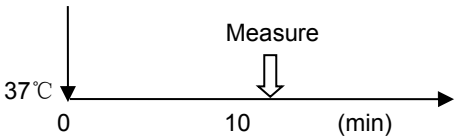
REAGENT COMPOSITION

Contents	Concentration
Good's buffer	50 mmol/L, pH 6.7
Phenol	5 mmol/L
4AA	0.3 mmol/L
Cholesterol esterase	≥ 200 U/L
Cholesterol oxidase	≥ 50 U/L
Peroxidase	≥ 3 KU/L

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
The reagent after opening is stable for 28 days month on-board the analyzer .

ASSAY PROCEDURE
Assay Mode: end point
Wave Length (main/sub): 520 nm/660 nm

Sample:2 µl
R1: 200 µl



1. Mix 3 µl sample with 300 µl R1 and incubate at 37℃ for 10 minutes.
2. Measure the absorbance of the sample (A_{sample}) and calibrator ($A_{calibrator}$) against reagent blank.

CALCULATION
Calculation using calibration

$$\text{Concentration} = \frac{\Delta A_{sample}/\text{min}}{\Delta A_{calibrator}/\text{min}} \times \text{calibrator value}$$

CALIBRATION
Recommend that this assay should be calibrated using Gcell calibration serum, calibration trace to NIST 909b. Randox calibration also can be used, Randox calibration choosing method: (Cholesterol Oxidase)

QUALITY CONTROL
Use Gcell multi quality control serum serum or Randox control serum, values obtained should fall within a specified range. If these values fall outside the defined limits , the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE
Serum: ≤ 5.20 mmol/L (200 mg/dl)
Clinical risk patients cholesterol range (mg / dl):

	Low risk	Middle risk	High risk
<20 years old	<170	>170	>185
20-30 years old	<200	>200	>220
30-40 years old	<220	>220	>240
>40 years old	<240	>240	>280

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY
The method is linear up to 19.4 mmol/L. Sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION
The CV of the test should be less than 5%.

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Intra assay precision		
N=20	Level1	Level 2
Mean (mmol/L)	4.08	7.44
SD	0.05	0.06
CV	1.34%	0.83%
Inter assay precision		
N=5	Level1	Level 2
Mean (mmol/L)	4.17	7.40
SD	0.08	0.10
CV	1.96%	1.38%

SENSITIVITY

The minimum detectable level that can be distinguished from zero has been determined as 0.03 mmol/L.

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Hemoglobin: 300 mg/dl
Intralipid: 1000 mg/dl
Bilirubin: 10 mg/dl

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y=1.069X-0.4637, and a correlation coefficient of 0.9942. 32 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Richmond, N., Clin. Chem. 1973; 19: 1350-1356.
2. Roeschlau, P., Bernt, E. and Gruber, W.J., Clin. Chem.Clin. Biochem. 1974; 12: 403.
3. Trinder, P., Ann. Clin. Biochem. 1969; 6: 24.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
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