

產品型號: BC-0014
V2.0



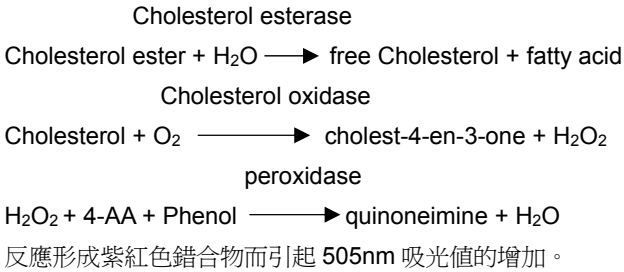
台塑膽固醇試劑（CHOL） - Enzymatic method

效能：
用於臨床實驗體外定量分析人體血清或血漿中總膽固醇的含量。

臨床意義：

高總膽固醇血症是冠心病的主要危險因素之一。病理狀態下高或低總膽固醇血症的有原發的和繼發的兩類。高總膽固醇原發的如家族性高膽固醇血症、混合性高脂蛋白血症；繼發的見於腎病綜合症、甲狀腺機能減退、糖尿病。低總膽固醇血症原發的如家族性的無 β 或低 β 脂蛋白血症；繼發的如營養不良、肝硬化等。

方法學原理：



試劑：

- 產品規格：
詳見外盒包裝標示。
- 成份與濃度：

	成份	濃度
R ₁ :	Phenol	10 mmol/L
	Sodium cholate	50 mmol/L
	4-AA	1.4 mmol/L
	Cholesterol esterase	200 U/L
	Cholesterol oxidase	180 U/L
	Peroxidase	3000 U/L

保存溫度：

2-8℃ 避光保存，請勿冰凍。

檢體：

新鮮無溶血的血清、肝素抗凝血漿。檢體採集後必須儘快離心處理。

操作步驟：

- 測定主波長：505 nm 測定副波長：660nm
溫度：37℃ 比色杯光徑：1.0 cm
- 本試劑盒為液態單試劑，可直接上機使用。

IVD 供體外診斷使用
For *In Vitro* Diagnostic

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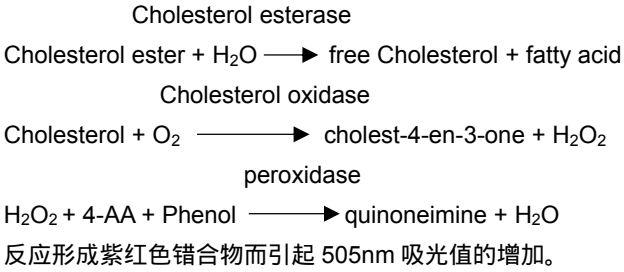
台塑胆固醇试剂（CHOL） - Enzymatic method

效能：
用于临床实验体外定量分析人体血清或血浆中总胆固醇的含量。

临床意义：

高总胆固醇血症是冠心病的主要危险因素之一。病理状态下高或低总胆固醇血症的有原发的和继发的两类。高总胆固醇原发的如家族性高胆固醇血症、混合性高脂蛋白血症；继发的见于肾病综合征、甲状腺机能减退、糖尿病。低总胆固醇血症原发的如家族性的无 β 或低 β 脂蛋白血症；继发的如营养不良、肝硬化等。

方法学原理：



试剂：

- 产品规格：
详见外盒包装标示。
- 成份与浓度：

	成份	浓度
R ₁ :	Phenol	10 mmol/L
	Sodium cholate	50 mmol/L
	4-AA	1.4 mmol/L
	Cholesterol esterase	200 U/L
	Cholesterol oxidase	180 U/L
	Peroxidase	3000 U/L

保存溫度：

2-8℃ 避光保存，請勿冰凍。

检体：

新鲜无溶血的血清、肝素抗凝血浆。检体采集后必须尽快离心处理。

操作步骤：

- 测定主波长：505 nm 测定副波长：660nm
温度：37℃ 比色杯光径：1.0 cm
- 本试剂盒为液态单试剂，可直接上机使用。

加入物	标准管	测定管	空白管
试剂 R ₁ (ml)	1.0	1.0	1.0
标准液 (ml)	0.01	----	----
检体 (ml)	----	0.01	----
ddH ₂ O (ml)	----	----	0.01

各管立即摇匀后，于 37 中放置 10 分钟，在 505nm 处，以空白管调“零”点，分别检测各管的吸光值。

结果计算

$$\begin{aligned} & \text{总胆固醇 (mg/dL)} \\ & = \frac{A_{\text{检体}}}{A_{\text{标准}}} \times \text{总胆固醇标准浓度 (mg/dL)} \end{aligned}$$

参考值：

150~250 mg/dL

注意事项：

- 本试剂请用专用标准品(calibrator)，不另外提供质控血清(control)，建议质控血清为 Bio-Rad Lyphochek control。
- 建议各实验室建立独立之品管系统，并定义专属之参考值范围。
- 本检验试剂限由医师或医检师临床使用。
- 本试剂线性可达 400 mg/dL，当检体中胆固醇浓度超过 400 mg/dL 时，可用生理食盐水稀释检体，结果乘以稀释倍数。
- 为保证结果的准确性，必须在检体加入后 30 分钟内检测吸光值。抗坏血酸(Vitamin C)会干扰此试剂的测定。
- 以上操作步骤适用于手工操作及一般半自动及全自动生化分析仪。
- 本品操作时请穿戴手套及必要之防护措施，操作中若不慎沾上，应用水或肥皂水清洗。(详细溶液物化性请洽询经销商索取物质安全数据表)
- 用毕应按医疗事业废弃物处理。(详细溶液物化性请洽询经销商索取物质安全数据表)
- 有效期限见试剂盒上标签所示。
- 经专业人员建议，试剂与检体用量可根据所用分析仪的要求按比例调整，其吸光值不变，不影响监测结果。
- 试剂特性及参数设定请参见第四页。

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MeDiPro CHOLESTEROL TEST (CHOL) - Enzymatic method

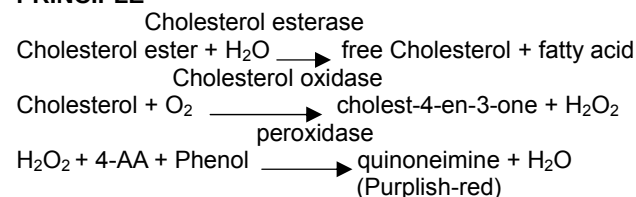
INTENDED USE

For the use of quantitative determination of cholesterol in serum or plasma.

CLINICAL SIGNIFICANCE

Total cholesterol in the blood is elevated in idiopathic hypercholesterolemia, primary and secondary hyperlipidemias, diabetes mellitus, nephrotic syndrome, hypothyroidism and biliary obstruction. Pregnancy may also accompanied by a moderate increase of cholesterol level. Decrease of cholesterol is seen in patients with severe hepatitis and occasionally in severe anemia or infection.

PRINCIPLE



REAGENT

- Package: please see the reagent box label shown.
- Components:

Component	Conc.
Phenol	10 mmol/L
Sodium cholate	50 mmol/L
4-AA	1.4 mmol/L
Cholesterol esterase	200 U/L
Cholesterol oxidase	180 U/L
peroxidase	3000 U/L

STORE TEMPERATURE

The standard is stable up to the end of the indicated expiration date. If stored at 2 – 8 °C., reagent should be protected from light and contamination should be avoided.

Do not freeze the reagent!

SPECIMEN COLLECTION AND PREPARATION

Serum or heparinized plasma is recommended. The use of oxalate, citrate, fluoride and EDTA might result in slightly lower cholesterol values.

PROCEDURES

- Main wavelength : 505 nm
Sub. wavelength : 660nm
Reaction Temperature : 37°C
Optical path length : 1.0 cm
- This kit contains single reagent, ready to use.

	Control	Specimen	Blank
R ₁ (ml)	1.0	1.0	1.0
Control (ml)	0.01	----	----
Specimen (ml)	----	0.01	----
ddH ₂ O (ml)	----	----	0.01

Mix, incubate at 37°C for 10 min, and read the absorbance against reagent blank. $A = A_{505} - A_{660}$

CALCULATION

With standard or calibrator

$$\text{Cholesterol (mg/dL)} = \frac{A_{\text{sample}}}{A_{\text{std./cali.}}} \times \text{conc. Std./cali. (mg/dL)}$$

REFERENCE RANGE

150~250 mg/dL

WARNINGS AND PRECAUTIONS

- This kit offers an optional calibrator, which is sold individually. Bio-Rad Lyphochek control is recommended to use as serum control.
- Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.
- This kit is for professionals and *in vitro* diagnostic use only.
- To ensure the accuracy of result, the absorbance should be measured within 30 minutes after sample addition. Specimen should avoid ascorbic acid which might interfere with the test result.
- The test is developed to determine cholesterol concentrations up to 400mg/dL. When values exceed this range, samples should be diluted with normal saline and calculate the results by multiplying the dilution factor.
- The above-mentioned procedures are suitable either for the general semi-automatic, full-automatic biochemical analysis instrument or manual operation.
- Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
- Waste management please refers to the local legal requirements.
- Please refer to the manufacturer's safety data sheet and the product labeling for information on potentially hazardous components. (MSDS could be obtained from local dealer.)
- According to the technical suggestion, the volume of reagent and specimen could be adjusted in a ratio for full-automatic biochemical analysis instrument use. It won't affect the absorbance and the result.



MeDiPro CHOLESTEROL TEST (CHOL) - Enzymatic method

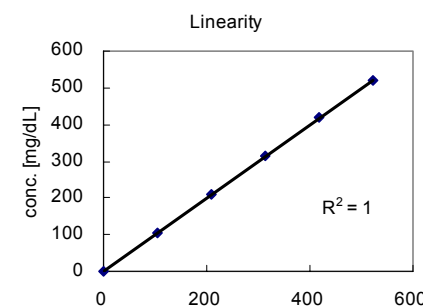
11. Validity please see the reagent box label shown.

REAGENT CHARACTERS

- Precision (Within run)

N=15	Mean[mg/dL]	SD [mg/dL]	CV[%]
Sample1	243	2.50	1.03
Sample2	128	0.96	0.75
Sample3	131	1.08	0.83

- Linearity



This kit has a good linearity up to 500mg/dL.

- Interference

Interference	Influence effect
Hemoglobin	No interference was observed by hemoglobin up to 200mg/dL
Ascorbic acid	Not suitable when sample contain reducing agent
Bilirubin (free form)	No interference was observed by bilirubin up to 12mg/dL
Bilirubin (conjugate form)	No interference was observed by bilirubin up to 16mg/dL
Intrafat	No interference was observed by intrafat up to 1.0%

- Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE

- Allain, cc, Poon, LS, Chan, LS, et.al. Enzymatic determination of total serum cholesterol. Clin. Chem. 1974, 20:470.
- Bishop ML, Duben-Engelkirk JL, Fody EP. Clinical Chemistry: principles, procedures, correlations. Fourth edition, 2000.

PARAMETER SETUP

Hitachi 7170/917 Applications

TEST	[CHOL]
ASSAY CODE	[1 POINT]: [34]-[0]
SAMPLE VOLUME	[2]
R1 VOLUME	[200]
R2 VOLUME	[0]
WAVELENGTH (nm)	[660][505]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[CHOL]
ASSAY CODE	[1 POINT]: [50]-[0]
SAMPLE VOLUME	[2]
R1 VOLUME	[200]
R2 VOLUME	[0]
WAVELENGTH(nm)	[660][505]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0014M	MeDiPro CHOLESTEROL TEST	R1 6×20ml
BC-0014A	MeDiPro CHOLESTEROL TEST	R1 4×60ml
BC-0014B	MeDiPro CHOLESTEROL TEST	R1 4×100ml
BC-0014C	MeDiPro CHOLESTEROL TEST	R1 4×300ml
BC-0014D	MeDiPro CHOLESTEROL TEST	R1 4×500ml



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