



低密度脂蛋白膽固醇試劑（LDL-C）-直接法

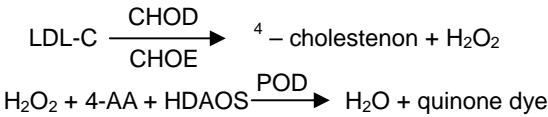
效能：

用於自動生化分析儀體外測定血清 LDL-C 含量。

臨床意義：

LDL-C (LDL-cholesterol)升高是高膽固醇最常見原因，與冠狀心臟疾病和動脈硬化成正相關。

方法學原理：



CHOD: cholesterol oxidase  
CHOE: cholesterol esterase  
POD: peroxidase

試劑：

- 產品規格:  
詳見外盒包裝標示。
- 成份與濃度：

	成份	濃度
R <sub>1</sub> :	HDAOS	3mmol/L
R <sub>2</sub> :	CHOD	≥0.5KU/L
	CHOE	≥0.5KU/L
	POD	≥10KU/L
	4-AA	0.5mmol/L

保存溫度：

2-8℃保存，請勿冰凍。

檢體：

空腹採血，新鮮無溶血的血清或用 EDTA 抗凝血漿。

操作步驟：

- 測定主波長：600 nm 測定副波長：700nm  
溫度：37 比色杯光徑：1.0 cm
- 本試劑盒為液態雙試劑，可直接上機使用。

加入物	樣品管	標準管	空白管
樣品 ml	0.0025	---	---
標準液 ml	---	0.0025	---
去離子水 ml	---	---	0.0025
R <sub>1</sub> ml	0.24	0.24	0.24
混勻，37 保溫 5 分鐘			
R <sub>2</sub> ml	0.08	0.08	0.08

各管立即搖勻後，於 37℃中放置 5 分鐘，以空白管調“零”點，分別在 546nm 及 660nm 處分別檢測各管的光吸收值，吸光值 A=A<sub>600</sub>-A<sub>700</sub>。

結果計算

$$\frac{\text{檢體中的 LDL-C (mmol/L)}}{\frac{A_{\text{檢體}}}{A_{\text{標準}}}} = \text{xLDL-C 標準濃度 (mmol/L)}$$

參考值：

65~160mg/dL

注意事項：

- 本試劑請用專用標準品(calibrator)，不另外提供質控血清(control)，建議質控血清為 Bio-Rad Lyphocheck control。
- 建議各實驗室建立獨立之品管系統，並定義專屬之參考值範圍。
- 本檢驗試劑限由醫師或醫檢師臨床使用。
- 本試劑線性可達 450mg/dL。若檢體中 LDL-C 濃度 >450mg/dL 時，可用生理食鹽水稀釋後重測，結果乘以稀釋倍數。
- 以上操作步驟適用於手工操作及一般半自動及全自動生化分析儀。
- 本品操作時需穿戴手套及必要之防護措施，若不慎沾上，應用水或肥皂水清洗。(詳細溶液物化性請洽詢經銷商索取物質安全資料表)
- 用畢應按醫療事業廢棄物處理。(詳細溶液物化性請洽詢經銷商索取物質安全資料表)
- 有效期限見試劑盒上標籤所示。
- 經專業人員建議，試劑與檢體用量可根據所用分析儀的要求按比例調整，其吸光值不變，不影響監測結果。
- 試劑特性及參數設定請參見第四頁。



低密度脂蛋白胆固醇试剂（LDL-C）-直接法

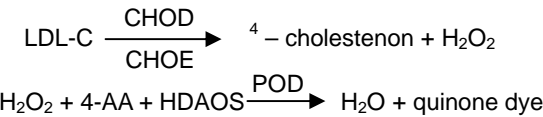
效能：

用于自动生化分析仪体外測定血清 LDL-C 含量。

临床意义：

LDL-C (LDL-cholesterol)升高是高胆固醇最常见原因，与冠状心脏疾病和动脉硬化成正相关。

方法学原理：



CHOD: cholesterol oxidase  
CHOE: cholesterol esterase  
POD: peroxidase

试剂：

- 产品规格:  
详见外盒包装标示。
- 成份与浓度：

	成份	浓度
R <sub>1</sub> :	HDAOS	3mmol/L
R <sub>2</sub> :	CHOD	0.5KU/L
	CHOE	0.5KU/L
	POD	10KU/L
	4-AA	0.5mmol/L

保存温度：

2-8℃保存，请勿冰冻。

检体：

空腹采血，新鲜无溶血的血清或用 EDTA 抗凝血浆。

操作步骤：

- 測定主波长：600 nm 測定副波长：700nm  
溫度：37 比色杯光徑：1.0 cm
- 本试剂盒为液态双试剂，可直接上机使用。

加入物	样品管	标准管	空白管
样品 ml	0.0025	---	---
标准液 ml	---	0.0025	---
去离子水 ml	---	---	0.0025
R <sub>1</sub> ml	0.24	0.24	0.24
混勻，37 保溫 5 分钟			
R <sub>2</sub> ml	0.08	0.08	0.08

各管立即搖勻后，于 37 中放置 5 分钟，以空白管调“零”点，分别在 546nm 及 660nm 处分别检测各管的光吸收值，吸光值 A=A<sub>600</sub>-A<sub>700</sub>。

结果计算

$$\frac{\text{检体中的 LDL-C (mmol/L)}}{\frac{A_{\text{检体}}}{A_{\text{标准}}}} = \text{xLDL-C 标准浓度 (mmol/L)}$$

参考值：

65~160mg/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 Lyphocheck 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 450mg/dL。若检体中 LDL-C 浓度 >450mg/dL 时，可用生理食盐水稀释后重测，结果乘以稀释倍数。
- 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。
- 本品操作时需穿戴手套及必要之防护措施，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。



塑生醫科技股份有限公司  
台北市敦化北路 201 號前棟五樓  
TEL：+886-2-2712-2211 #7822  
製造廠：台塑生醫宜蘭廠

Website: <http://www.fbc.com.tw/>  
FAX：+886-2-2717-8381  
廠址：宜蘭縣礁溪鄉龍潭村龍泉路 3 號



塑生医科技股份有限公司  
台北市敦化北路 201 号前栋五楼  
TEL：+886-2-2712-2211 #7822  
制造厂：台塑生医宜兰厂

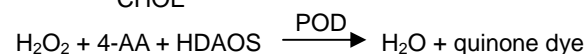
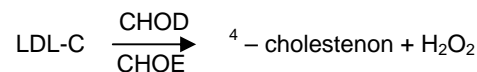
Website: <http://www.fbc.com.tw/>  
FAX：+886-2-2717-8381  
厂址：宜兰县礁溪乡龙潭村龙泉路 3 号

**MeDiPro LDL-CHOLESTEROL TEST - Direct method****INTENDED USE**

For the quantitative determination of LDL-cholesterol in serum.

**CLINICAL SIGNIFICANCE**

Of all the forms of cholesterol in the blood, the LDL cholesterol is considered the most important form in determining risk of heart disease. Elevated levels of LDL indicate risk for coronary artery disease and arteriosclerosis.

**PRINCIPLE**

CHOD: cholesterol oxidase  
CHOE: cholesterol esterase  
POD: peroxidase

**REAGENT**

3. Package: please see the reagent box label shown.

4. Components:

Component	Conc.
R <sub>1</sub> : HDAOS	3mmol/L
R <sub>2</sub> : CHOD	≥ 0.5KU/L
CHOE	≥ 0.5KU/L
POD	≥ 10KU/L
4-AA	0.5mmol/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**

Blood specimen should be drawn after the patient has fasted for at least 12 hours. Fresh serum and plasma are the choices.

**PROCEDURES**

1. Main wavelength : 600 nm  
Sub. wavelength : 700nm  
Reaction Temperature : 37°C  
Optical path length : 1.0 cm

2. This kit contains two reagents, ready to use.

	Specimen	Control	Blank
Specimen (ml)	0.0025	---	---
Control (ml)	---	0.0025	---
ddH <sub>2</sub> O (ml)	---	---	0.0025
R <sub>1</sub> (ml)	0.24	0.24	0.24
Mix, 37 incubate 5min			
R <sub>2</sub> (ml)	0.08	0.08	0.08

Mix, incubate at 37°C for 5min, and read the absorbance against reagent blank at 600nm and 700nm.  $A = A_{600} - A_{700}$ .

**CALCULATION**

With standard or calibrator

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

**REFERENCE RANGE**

65~160mg/dL

**WARNINGS AND PRECAUTIONS**

1. This kit offers an optional calibrator, which is sold individually. Bio-Rad Lyphochek control is recommended to use as serum control.
2. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.
3. This kit is for professionals and *in vitro* diagnostic use only.
4. To ensure the accuracy of result, the absorbance should be measured within 30 minutes after sample addition. Bilirubin might be interfere the result.
5. The test is developed to determine LDL-C concentrations up to 450mg/dL. When values exceed this range, samples should be diluted with normal saline and calculate the results by multiplying the dilution factor.
6. The above-mentioned procedures are suitable either for the general semi-automatic, full-automatic biochemical analysis instrument or manual operation.
7. 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.

**MeDiPro LDL-CHOLESTEROL TEST - Direct method**

8. Waste management please refers to the local legal requirements.

9. 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.)

10. 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.

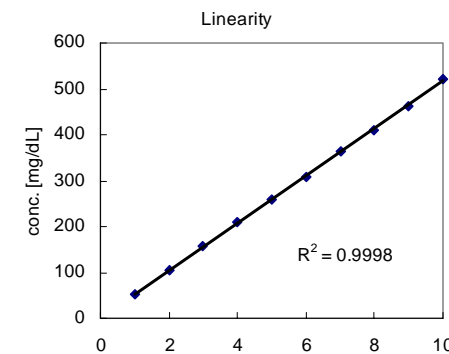
11. Validity please see the reagent box label shown.

**REAGENT CHARACTERS**

1. Precision (Within run)

N=15	Mean[mg/dL]	SD [mg/dL]	CV[%]
Sample1	188.0	1.04	0.56
Sample2	90.9	1.09	1.19
Sample3	89.7	1.34	1.49

2. Linearity



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

3. Interference

Interference	Influence effect
Hemoglobin	No interference was observed by hemoglobin up to 500mg/dL
Ascorbic acid	No interference was observed by ascorbic acid up to 100mg/dL
Bilirubin (free form)	No interference was observed by bilirubin up to 40mg/dL
Bilirubin (conjugate form)	No interference was observed by bilirubin up to 40mg/dL
Intrafat	No interference was observed by intrafat up to 3%

4. Stability

Expire day	1 year
Open vial stability	30 day

**REFERENCE**

Bachorik PS. Measurement of low-density lipoprotein cholesterol. In: Rifai N, Warnick GR, eds. Handbook of lipoprotein testing. Washington, DC: AACC press, 1997; 145.

**PARAMETER SETUP**

Hitachi 7170/917 Applications

TEST	[LDL]
ASSAY CODE	[2 POINT]: [16]-[34]
SAMPLE VOLUME	[2]
R1 VOLUME	[180]
R2 VOLUME	[60]
WAVELENGTH(nm)	[700][600]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[LDL]
ASSAY CODE	[2 POINT]: [24]-[50]
SAMPLE VOLUME	[3]
R1 VOLUME	[240]
R2 VOLUME	[80]
WAVELENGTH(nm)	[700][600]
CALIB. METHOD	[Linear]

**ORDERING INFORMATION**

Cat. No.	Product	Package
BC-0023M	MeDiPro LDL-CHOLESTEROL TEST	R1 6x15ml R2 3x10ml
BC-0023A	MeDiPro LDL-CHOLESTEROL TEST	R1 4x45ml R2 2x30ml
BC-0023B	MeDiPro LDL-CHOLESTEROL TEST	R1 3x90ml R2 3x30ml
BC-0023C	MeDiPro LDL-CHOLESTEROL TEST R1	R1 2x300ml
BC-0023D	MeDiPro LDL-CHOLESTEROL TEST R1	R1 2x500ml
BC-0023G	MeDiPro LDL-CHOLESTEROL TEST R2	R2 2x100ml

**FORMOSA BIOMEDICAL TECHNOLOGY CORP.**

F-5F, No. 201, Tunghua N. Rd, Taipei, 105, Taiwan Website: <http://www.fbc.com.tw/>  
TEL: +886-2-2712-2211 #7822 FAX: +886-2-2717-8381  
Factory: No. 3, Longchuan Rd, Longtang Village, Jiaosi, Yilan County, 262, Taiwan

**FORMOSA BIOMEDICAL TECHNOLOGY CORP.**

F-5F, No. 201, Tunghua N. Rd, Taipei, 105, Taiwan Website: <http://www.fbc.com.tw/>  
TEL: +886-2-2712-2211 #7822 FAX: +886-2-2717-8381  
Factory: No. 3, Longchuan Rd, Longtang Village, Jiaosi, Yilan County, 262, Taiwan