

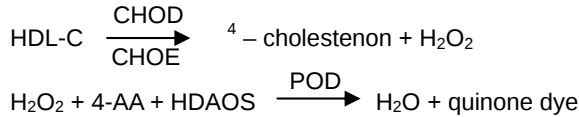


高密度脂蛋白膽固醇（HDL-C）試劑-直接法

效能：
用於臨床實驗體外定量分析人體血清中 HDL-C 的含量。

臨床意義：
低 HDL-C(HDL-cholesterol)是缺血性心臟病的單獨危險因子，其濃度的增減被做為動脈硬化的重要指標。

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 ₁ :	MOPS buffer	100mmol/L
	HDAOS	2mmol/L
	Magnesium sulfate	10mmol/L
R ₂ :	PIPES	100mmol/L
	4-AA	0.5mmol/L
	CHOE	≥0.5KU/L
	CHOD	≥1KU/L
	POD	≥10KU/L

保存溫度：
2-8 避光保存，請勿冰凍。未開啓試劑自生產日起 2-8 下可穩定一年。

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	0.004	---	---
標準液 ml	---	0.004	---
去離子水 ml	---		0.004
R ₁ ml	0.3	0.3	0.3
混勻，37 保溫 5 分鐘			
R ₂ ml	0.1	0.1	0.1

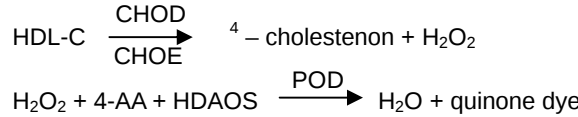


高密度脂蛋白胆固醇（HDL-C）试剂-直接法

效能：
用于临床实验体外定量分析人体血清中 HDL-C 的含量。

临床意义：
低 HDL-C(HDL-cholesterol)是缺血性心脏病的单独危险因子，其浓度的增减被做为动脉硬化的重要指标。

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 ₁ :	MOPS buffer	100mmol/L
	HDAOS	2mmol/L
	Magnesium sulfate	10mmol/L
R ₂ :	PIPES	100mmol/L
	4-AA	0.5mmol/L
	CHOE	0.5KU/L
	CHOD	1KU/L
	POD	10KU/L

保存温度：
2-8 避光保存，请勿冰冻。未开启试剂自生产日起 2-8 下可稳定一年。

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	0.004	---	---
标准液 ml	---	0.004	---
去离子水 ml	---		0.004
R ₁ ml	0.3	0.3	0.3
混勻，37 保溫 5 分鐘			
R ₂ ml	0.1	0.1	0.1

各管立即摇匀后，于 37 中放置 5 分钟，以空白管调“零”点，分别在 600nm 及 700nm 处分别检测各管的光吸收值，吸光值 A = A₆₀₀-A₇₀₀。

结果计算

$$\text{检体中的 HDL-C (mg/dL)} = \frac{A_{\text{检体}}}{A_{\text{标准}}} \times \text{HDL-C 标准浓度 (mg/dL)}$$

参考值：
32~76 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 150mg/dL。若检体中 HDL-C 浓度大于 150mg/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。



MeDiPro HDL-CHOLESTEROL TEST - Direct method

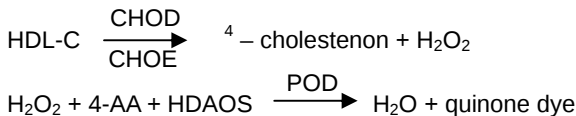
INTENDED USE

For the quantitative determination of HDL-cholesterol in serum.

CLINICAL SIGNIFICANCE

HDL-cholesterol(HDL-C) is a very strong negative correlation between the risk of coronary artery disease. Low levels predict high risk and vice versa. Results from Framingham study showed higher incidence rates of coronary artery disease when HDL-cholesterol was below 45 mg/dl. However, HDL-C levels do not necessarily correlate with total cholesterol and LDL-cholesterol. A person may have normal total cholesterol content yet at high risk due to too low levels of HDL-cholesterol.

PRINCIPLE



CHOD: cholesterol oxidase
CHOE: cholesterol esterase
POD: peroxidase

REAGENT

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

	Component	Conc.
R ₁ :	MOPS buffer	100mmol/L
	HDAOS	2mmol/L
	Magnesium sulfate	10mmol/L
R ₂ :	PIPES	100mmol/L
	4-AA	0.5mmol/L
	CHOE	≥0.5KU/L
	CHOD	≥1KU/L
	POD	≥10KU/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)	0.004	---	---
Control (ml)	---	0.004	---
ddH ₂ O (ml)	---	---	0.004
R ₁ (ml)	0.3	0.3	0.3
Mix, 37 incubate 5min			
R ₂ (ml)	0.1	0.1	0.1

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

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

REFERENCE RANGE

32~76 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. Bilirubin might be interfere the result.
- The test is developed to determine HDL-C concentrations up to 150mg/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



MeDiPro HDL-CHOLESTEROL TEST - Direct method

requirements.

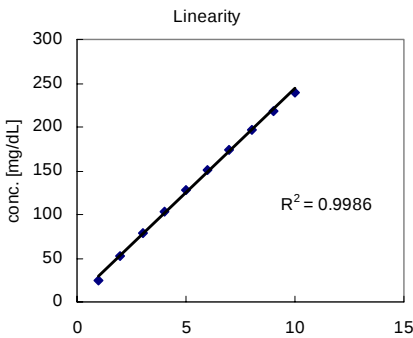
9. Please refer to the manufacturer's safety data sheet and the product labeling for information on potentially hazardous components. (MSDS could be obtained from local dealer.)
10. According to the technical suggestion, the volume of reagent and specimen could be adjusted in a ratio for full-automatic 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	63.8	0.41	0.64
Sample2	36.4	0.27	0.73
Sample3	35.1	0.24	0.69

2. Linearity



This kit has a good linearity up to 250mg/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 16mg/dL
Intrafat	No interference was observed by intrafat up to 3%

4. Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE

1. Lopes-Virella, M.F., Stone, P., Ellis, S., Colwell, J.A., Cholesterol Determination in High-Density Lipoproteins Separated by Three Different Methods, Clinical Chem. 23/5, 882-884, 1977.

2. Demacker, P.N.M., Hifmans, A.G.M., Vos-Janssen, H.E., van't Laar, A., Jansen, A.P., A Study of the Use of Polyethylene Glycol in Estimating Cholesterol in High-Density Lipoprotein, Clinical Chem. 26/13,1775-1779, 1980.

PARAMETER SETUP

Hitachi 7170/917 Applications

TEST	[HDL]
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	[HDL]
ASSAY CODE	[2 Point]: [24]-[50]
SAMPLE VOLUME	[2.5]
R1 VOLUME	[240]
R2 VOLUME	[80]
WAVELENGTH(nm)	[700][600]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0020M	MeDiPro HDL-CHOLESTEROL TEST	R1 6×15ml R2 3×10ml
BC-0020A	MeDiPro HDL-CHOLESTEROL TEST	R1 4×45ml R2 2×30ml
BC-0020B	MeDiPro HDL-CHOLESTEROL TEST	R1 3×90ml R2 3×30ml
BC-0020C	MeDiPro HDL-CHOLESTEROL TEST R1	R1 2×300ml
BC-0020D	MeDiPro HDL-CHOLESTEROL TEST R1	R1 2×500ml
BC-0020G	MeDiPro HDL-CHOLESTEROL TEST R2	R2 2×100ml



FORMOSA BIOMEDICAL TECHNOLOGY CORP.

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TEL: +886-2-2712-2211 #7822
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