CHOLESTEROL

CHOD-PAP

Diagnostic reagent for determination of cholesterol concentration.

Liquid. Mono Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze.

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2091	5 x 100 mL	R2090	1364 Tests	S2091	1364 Tests	N2090	758 Tests
A2092	5 x 50 mL	R2091	455 Tests	BY2090	7955 Tests	N2091	424 Tests
T2090	5294 Tests	S2090	2182 Tests	BY2091	5682 Tests	K2090	4667 Tests
T2091	2353 Tests	L2090	5000 Tests	M2090	2273 Tests	K2091	3333 Tests
DM2090	990 Tests	L2091	2667 Tests	M2091	1364 Tests		

INTENDED USE

The test is applied for the quantitative determination of cholesterol in serum and plasma EDTA.

TEST PRINCIPLE

All cholesterol esters present in plasma are hydrolyzed quantitatively into free cholesterol and fatty acids by cholesterol esterase. In the presence of oxygen, free cholesterol is then oxidized by cholesterol oxidase to cholesten-4-ene- 3-one and H_2O_2. The H_2O_2 reacts with p-chlorophenol and 4-aminoantipyrine in the presence of peroxidase to form a quinoneimine dye. The intensity of color formed is proportional to the cholesterol concentration and can be measured photometrically between 480 and 520 nm.

TEST PARAMETERS

Method	: Colorimetric, Endpoint, Increasing Reaction, CHOD-PAP
Wavelength	: 510 nm, (480-520)
Temperature	: 37°C
Sample	: Serum, heparinized or EDTA-Plasma
Linearity	: 7 mg/dL - 700 mg/dL

REAGENT COMPOSITION

Good's buffer	pH 7.20,
sodium cholate	≤ 8.3 mM,
CHE	≥ 400 U/L,
CHOD	≥ 200 U/L,
POD	≥ 500 U/L,
4-AAP	≤ 0.8 mM,
4-chlorophenol	≤ 2.4 mM

REAGENT PREPARATION

Reagents are ready to use.

REAGENT STABILITY AND STORAGE

Reagents are stable up to expiration date on labels at 2-8°C.

Once opened vials (reagent 1) are stable minimum 60 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum and plasma EDTA are collected by standard procedures.

Sample is stable 3 days at 2-8°C, 3 days at 20-25°C and 1 month at -20°C.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

Cholesterol (mg/dl) =

$$\frac{\text{Absorbance Sample}}{\text{Absorbance Standard}} \times \text{Conc. of Std/Cal (mg/dL)}$$

Unit Conversion

mg/dL x 0.026 = mmol/L

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Desirable: 140 - 200 mg/dL

Borderline/high risk:	200 - 240 mg/dL
High risk:	> 240 mg/dL

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

All control sera with Cholesterol values determined by this method can be used. We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The assay requires the use of a Cholesterol Standard or a Cholesterol Calibrator.
We recommend:

A2090S	Cholesterol Standard (200 mg/dL)
A39050	Calibrator (ARCAL AUTO)

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 30 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 7 mg/dL.

High Linearity: The method is linear up to 700 mg/dL.

If the limit value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean conc.	SD	CV	n
101.50 mg/dL	1.84	1.80%	10
176.20 mg/dL	2.74	1.60%	10

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD	CV	n
100.99mg/dL	2.11	2.10%	20
176.51mg/dL	2.23	1.30%	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 1 mg/dL.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Interferences: No interference was observed by the presence of:

Hemoglobin	≤ 500 mg/dL
Bilirubin	≤ 15 mg/dL
Lipids	≤ 850 mg/dL

Methods comparison: A comparison between Archem and a commercially available product gave the following results:
Cholesterol Archem = x
Cholesterol competitor = y
n = 100
$y = 0.979x + 1.71$ mg/dl $r^2 = 0.995$

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.

S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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