

CHOLESTEROL SYSTEM PACK

(CHOD / POD METHOD)

B Auto 200, Unicorn 230, Unicorn 120 , Bonavera Chem 200 ,
Beaconnic chem 200,Beaconnic B200,Beaconnic analyzer 120 &
Bonavera chem 100(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA212	Cholesterol System Pack	5x40 ml

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Cholesterol in human serum and plasma.

CLINICAL SIGNIFICANCE

Measurement of serum cholesterol levels can serve as an indicator of liver function, biliary function, intestinal absorption, propensity towards 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.

PRINCIPLE

This reagent is based on the formulation of allain et al and the modification of roeschlau with further improvements to render the reagent stable in solution.

- Cholesterol ester + H₂O $\xrightarrow{\text{CHE}}$ Cholesterol + Fatty acids
- Cholesterol + O₂ $\xrightarrow{\text{CHO}}$ Cholestenone + H₂O₂
- H₂O₂ + 4AAP + Phenol $\xrightarrow{\text{POD}}$ Quinoneimine dye + H₂O

where

CHE = Cholesterol Esterase
CHO = Cholesterol Oxidase
4AAP = 4-aminoantipyrine
POD = Peroxidase

- Cholesterol esters are enzymatically hydrolysed by cholesterol esterase to cholesterol and free fatty acids.
- Free cholesterol, including that originally present, then oxidized by Cholesterol oxidase to cholest-4-en-3-one and hydrogen peroxide.
- The hydrogen peroxide combines with 4-aminoantipyrine to form a chromophore (quinoneimine dye) which may be quantitated at 505 nm.

REAGENT COMPOSITION

Reagent 1: Cholesterol Enzyme Reagent

Goods Buffer > 80 mmol/L
Phenol >10 mmol/L
4-aminoantipyrine >0.3 mmol/L
Cholesterol esterase >250 U/L
Cholesterol oxidase >250 U/L
Peroxidase >2250 U/L



REAGENT PREPARATION

Reagent is liquid, ready to use.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2 - +8°C.

On board stability: Min 30 days if refrigerated (+8 - +14°C) and not contaminated.

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

SPECIMEN COLLECTION AND HANDLING

Use serum, plasma (heparin, EDTA).

It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability

in serum/plasma: at +2 - +8°C 7 days

Discard contaminated specimens.

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagent performance.

UNIT CONVERSION

mg/dl x 0.026 = mmol/L

EXPECTED VALUES

Serum 130 - 250 mg/dl

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon system.

Data obtained in your laboratory may differ from these values.

Limit of quantification: 4.2 mg/dl

Linearity: 1000 mg/dl

Measuring range: 4.2 - 1000 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	158.70	2.00	1.26
Sample 2	290.85	4.18	1.44

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	96.80	1.08	1.12

COMPARISON

A comparison between Cholesterol System Pack (y) and commercially available test (x) using 20 samples gave following results:

$$y = 1.003x - 0.086 \text{ mg/dl}$$

$$r = 0.999$$

INTERFERENCES

Following substances do not interfere:

haemoglobin upto 5 g/l, bilirubin up to 20 mg/dl, triglycerides up to 2000 mg/dl.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handles by entitled and professionally educated person.

Reagents of the kit are not classified like dangerous but contain less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment. MSDS will be provided on request.

WASTE MANAGEMENT

Please refer to local legal requirement.

Parameter For B Auto 200, Unicorn 230, Unicorn 120 Bonavera Chem 200, Beaconic chem 200, Beaconic B200, Beaconic analyzer 120 & Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Test Name	CHOLESTEROL
Full Name	CHOLESTEROL
PRI Wave	505 nm
SEC Wave	630 nm
Assay/Point	1 POINT END
Start	-
End	17
Decimal	2
Unit	mg/dl
Linearity Range Low	4.2
Linearity Range High	1000
Sample Volume	2 µl
Reagent 1 (R1) Volume	200 µl
Reagent 1 (R2) Volume	-
Substrate Depleted/Abs.limit	-
Linearity	1000 mg/dl
Out Of Linearity Range	-
Calibration Type	2 Point linear
Points	2
Blank Type	Reagent
Concentration Blank	0.00
Concentration Std	Refer calibrator value sheet

NOTE

The program is made as per the in house testing, it can be modified as per requirements.

Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

REFERENCES

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3. Flegg HM. Ann Clin Biochem. 1973 : 11 : 79.
4. Richmond, W. Clin. Chem 1973: 19 : 1350-1356.
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6. Roeschlau P, Bernt, E. and Gruber, W. A. Clin. Chem. Ciin. Biochem. 1974; 12:1226
7. Henry, R. J. Clinical Chemistry: Principles and Techniques Harper & Row, Hagerstown, 1974.
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10. National Committee for Clinical Laboratory Standards.

Symbols Used On Labels

	Catalogue Number		Manufacturer
	See Instruction for Use		Lot Number
	Content		Storage Temperature
	Expiry Date		In Vitro Diagnostics

BEA/24/CHO/SB/IFU Ver-03
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