CHOLESTEROL SYSTEM PACK

(CHOD/POD METHOD)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic Chem 400 (Fully Auto Biochemistry Analyzer)

BEACON

Code	Product Name	Pack Size
UNI12	Cholesterol System Pack	4 x50 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.

1. Cholesterol ester + H_2O $\xrightarrow{CHE}$ Cholesterol + Fatty acids

2. Cholesterol + O_2 $\xrightarrow{CHO}$ Cholestenone + H_2O_2

3. H_2O_2 + 4AAP + Phenol $\xrightarrow{POD}$ Quinoneimine dye + H_2O

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

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

REAGENT COMPOSITION

Reagent 1 : Cholesterol Enyme Reagent

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

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 (hepairin, 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 referance 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	286	2.11	0.74
Sample 2	250	2.44	0.98

Intra-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	151	1.95	1.29

COMPARISON

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

y = 1.002x - 3.333 mg/dl
r = 0.997

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.

WASTE MANAGEMENT

Please refer to local legal requirement.

Parameter For B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic Chem 400
(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	33
DECIMAL	2
UNIT	mg/dl
LINEARITY RANGE LOW	4.2
LINEARITY RANGE HIGH	1000
SAMPLE VOLUME	2 µ l
REAGENT 1 (R1) VOLUME	200 µl
REAGENT 1 (R2) VOLUME	-
SUBSTRATE DEPLETED	-
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.

REFERENCES

1. Searcy, R. L. “Diagnostic Biochemistry” McGraw-Hill, New York, NY. 1996.
2. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Burtis, C.A. Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders Comp., 2012.
3. Flegg HM. Ann Clin Biochem. 1973: 11 : 79.
4. Richmond, W. Clin. Chem 1973: 19 : 1350-1356.
5. Allain, C.C. Poon, L.S, Chan, C.S.G, Richmond, W. and Fu, P. C. Clin Chem. 1974; 20 : 470-475.
6. Roeschlau P, Bernt, E. and Gruber, W. A. Clin. Chem. Clin. Biochem. 1974; 12 : 226.
7. Henry, R. J. Clinical Chemistry: Principles and Techniques Harper & Row, Hagerstown, 1974.
8. Young, D. S. et al. Clin. Chem 1975; 21.
9. NCEP Expert Panel. Arch. Intern. Med. 1988; 148 : 36-69.
10. National Committee for Clinical Laboratory Standards. User evaluation of Precision Performance of Clinical Laboratory Devices. NCCLS; 1984, NCCLS Publication EP5-T.

SYMBOLS USED ON LABELS

REF Catalogue Number | Manufacturer | See Instruction for Use

LOT Lot Number | CONT Content | Storage Temperature

Expiry Date | IVD In Vitro Diagnostics