LDL DIRECT SYSTEM PACK

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200
(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA225	LDL Direct System Pack	2x30 + 2x10 ml

BEACON

INTENDED USE

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

CLINICAL SIGNIFICANCE

Low Density Lipoproteins (LDL) are synthesized in the liver by the action of various lipolytic enzymes on triglyceride-rich Very Low Density Lipoproteins (VLDLs). Specific LDL receptors exist to facilitate the elimination of LDL from plasma by liver parenchymal cells. It has been shown that most of the cholesterol stored in atherosclerotic plaques originates from LDL. For this reason the LDL Cholesterol concentration is considered to be the most important clinical predictor of all single parameters, with respect to coronary atherosclerosis.

Accurate measurement of LDL Cholesterol is of vital importance in therapies which focus on lipid reduction to prevent atherosclerosis or reduce its progress and to avoid plaque rupture. Can be applied on automated analyzers.

PRINCIPLE

The reagent is based on the following reactions:

1. Elimination of non LDL-Cholesterol

$$\text{Cholesterol esters} + H_2O \xrightarrow{\text{Cholesterol esterase}} \text{Cholesterol} + \text{fatty acids}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol oxidase}} \text{Cholestenone} + H_2O_2$$

$$H_2O_2 \xrightarrow{\text{Catalase}} O_2 + H_2O$$

2. Specific measurement of LDL-Cholecterol after release of LDL-Cholesterol by detergents in Reagent 2.

$$\text{Cholesterol ester} + H_2O \xrightarrow{\text{Cholesterol esterase}} \text{Cholesterol} + \text{fatty acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol oxidase}} \text{Cholestenone} + H_2O_2$$

$$H_2O_2 + \text{4-AA} + \text{TOOS} \xrightarrow{\text{Peroxidase}} \text{Quinone} + H_2O$$

The Intensity of the quinone pigment produced is proportional to the cholesterol concentration when measured at 578 nm

REAGENT COMPOSITION

Reagent 1 : R1 Reagent

Tris buffer	>80 mmol/L
4-AAP	>0.5 mmol/L
Detetgent	Q.S
Cholesterol Esterase	>3000 U/L
Cholesterol Oxidase	>900 U/L

Reagent 2 : R2 Reagent

Peroxidase	>1000 U/L
Reagent 3 : Ultima LDL Calibrator	Refer vial label for concentration

REAGENT PREPARATION

Reagents R1 and R2 are 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.

Reagents are light-sensitive. Do not let bottles remain open. Keep containers tightly closed.

On board stability: Min. 30 days if refrigerated (2-10°) and not contaminated.

SPECIMEN COLLECTION AND HANDLING

Use serum or hepairin plasma.

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

Stability in serum/plasma: 12 hours at 20–25°C
10 days at 4–8°C
12 weeks at -20°C

Discard contaminated specimens.

CALIBRATION

Calibration with LDL Direct calibrator is recommended.

QUALITY CONTROL

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

UNIT CONVERSION

mg/dl = 0.026 mmol/L

NORMAL VALUE

< 130 mg/dl	Desirable
130 - 159 mg/dL	Border line high risk for CHD
> 160 mg/dL	High risk for CHD

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: 2.60 mg/dl
Linearity: 1000 mg/dl
Measuring range: 2.60 – 1000 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	131	2.56	1.96
Sample 2	47	0.91	1.94

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	66	0.90	1.36

COMPARISON

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

y = 0.960x + 0.462 mg/dl
r = 0.994

INTERFERENCES

Following substances do not interfere:
haemoglobin up to 10 g/l, bilirubin up to 40 mg/dl, triglycerides up to 2000 mg/dl.

WARNING AND PRECAUTIONS

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

Reagent of the kit are not classified like dangerous.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter For B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 (Fully Auto Biochemistry Analyzer)

TEST NAME	LDL DIRECT
FULL NAME	LDL DIRECT
PRI WAVE	578 nm
SEC WAVE	700 nm
ASSAY/POINT	1 POINT END
START	-
END	27
DECIMAL	2
UNIT	mg/dl
LINEARITY RANGE LOW	2.60
LINEARITY RANGE HIGH	1000
SAMPLE VOLUME	2 µ l
REAGENT 1 (R1) VOLUME	150 µl
REAGENT 1 (R2) VOLUME	50 µl
SUBSATRATE DEPLETED	-
LINEARITY	1000 mg/dl
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTARTION STD	Refer calibrator label.
SAMPLE VOLUME	2 µ l

NOTE

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

REFERENCES

1. "Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult tretment Panel III)", JAMA, 285:2486 (2001).
2. Crouse JR et al., Studies of low density lipoprotein molecular weight in human beings with coronary artery disease, J. Lipid Res., 26; 566 (1985).
3. Castelli WP et al., Cholesterol and other lipids n coronary heart disease, Circulation, 55; 767 (1977).
4. Barr DP, Russ EM, Eder HA, Protein-lipid relationships in humanplasma, Am. J. Med., 11;480 (1951).
5. Badimon JJ, Badimon L., Fuester V., Regression of Atherosclerotic Lesions by High- Density Lipoprotein Plasma Fraction in the Cholesterol-Fed Rabbit, Journal of Clinical Investigation, 85 : 1234-41(1990). 6. Gordon T. et al., High density lipoprotein as a Protective factor against coronary heart disease, Am. J. Med., 62; 707 (1977).
6. Kannek WB, Castelli WP, Gordon T., Cholesterol in the prediction of atherosclerotic disease; New perspective based on the Framingham study, Am. Intern. Med., 90; 85(1979).
7. William P., Robinson D., Baily A., High density lipoprotein and coronary risk factor, Lancet, 1;72 (1979).
8. Castelli, W. P., et al, Cholesterol and other lipids in coronary heart disease.
9. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of the High Blood Cholesterol in Adult (Adult Treatment Panel III).
10. Pisani T, Gebski CP, Leary Et, et al. Accurate Direct Determination of Low-Density Lipoprotein Cholesterol Assay. Arch Pathol Lab Med 1995; 119:1127)

IVD

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