HDL DIRECT SYSTEM PACK

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400

(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
UNI21	HDL Direct System Pack	4x30 + 4x10 ml

BEACON

INTENDED USE

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

CLINICAL SIGNIFICANCE

High-density lipoproteins (HDL) compose one of the major classes of plasma lipoproteins. They are synthesized in lilver as complexes of apolipoprotein and phospholipid and are capable of picking up cholesterol and carring it from arteries to the liver, where the cholesterol is converted to bile acids and excreted into the intestine.

An inverse relationship between HDL-cholesterol (HDL-C) levels in serum and the incidence/prevalence of coronary heart disease (CHD) has been demonstrated in a number of epidemiological studies. The importance of HDL-C as a risk factor for CHD is now recognized.

Accurate mesurement of HDL-C is of vital importance when assessing patient's risk for CHD.

PRINCIPLE

The assay is based on a modified polyvinyl sulfonic acid (PVS) and polyethyleneglycol-methyl ether (PEGME) coupled classic precipitation method with the improvements in using optimized quantities of PVS/PEGME and selected detergents. LDL, VLDL and chylomicron (CM) react with PVS and PEGME and the reaction results in inaccessibililty of LDL, VLDL and CM by cholesterol oxidase (CHOD) and cholesterol esterase (CHER).

The enzymes selectively react with HDL to produce H_2O_2 which is detected through a Trinder reaction.

$$\text{HDL + LDL + VLDL + CM} \xrightarrow[\text{PEGME}]{\text{PVS}} \text{HDL + (LDL+ VLDL + CM) PVS/PEGME}$$

$$\text{HDL} \xrightarrow{\text{CHOD, CHER}} \text{Fatty Acid + } H_2O_2$$

$$2H_2O_2 + \text{4-AA + TODB} \xrightarrow{\text{Peroxidase}} \text{Quinone + 5H}_2\text{O}$$

REAGENT COMPOSITION

Reagent 1 : R1 Reagent

Buffer	> 5 mmol/l
$MgCl_2$	> 2 mmol/l
TOOS	< 2 mmol/l

Reagent 2 : R2 Reagent

CHE	> 2 U/L
COD	< 5 KU/L
POD	< 10 KU/L
Reagent 3:**Ultima HDL Calibrator**	Concentration see on label

REAGENT PREPARATION

Reagents R1 and R2 are liquid, ready to use.

Calibrator reconstitute with 1 ml of deionised water at 20-25°C and mix gently (avoid foaming). Allow to stand for at least 30 minutes until complete reconstitution before use. Store reconstituted calibrator at 2-8°C

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.

The reconstituted calibrator is stable for 7 days at 2-8°C.

On board stability: Min 30 days if refrigerated (2-10°C) 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: 24 hours at 20–25°C
7 days at 4–8°C
12 weeks at -20°C

Discard contaminated specimens.

CALIBRATION

Calibration with HDL Direct calibrator is recommended.

QUALITY CONTROL

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

NORMAL VALUE

Adult Male 35 - 80 mg/dl
Adult Female 42 - 88 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.
Data obtained in your laboratory may differ from these values.

Limit of quantification: 2.32 mg/dl
Linearity: 180 mg/dl
Measuring range: 2.32 – 180 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	112	3.18	2.84
Sample 2	28	0.85	3.09

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	31	0.74	2.36

COMPARISON

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

y = 1.072x + 0.705 mg/dl
r = 0.995

INTERFERENCES

Following substances do not interfere:
haemoglobin up to 10 g/l, bilirubin up to 40 mg/dl, triglycerides up to 2000 mg/dl. Interference by N-acetylcysteine (NAC), acetoainophen and metamizole causes falsely low results. To carry out the test, blood withdrawal should be performed prior toadministration of drugs.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handles by entitled and professionally educated person. Reagent of the kit are not classified like dangerous.

Serum used in th manufacture of the calibrator has been tested by FDA-approved methods and found non reactive for hepatitis B surface antigen (HbsAg), antibody to Hepatitis C (HCV), HIV-1 p24 antigen and antibody to HIV1/2. The test procedures do not guarantee that all infectious agents will be detected. Because no test method can offer complete assurance that Hepatitis B virus Hepatitis C virus and HIV ½ or other infectious agents are absent, the material should be handled as potentially infectious.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter for Unicorn 480, Bonavera Chem 480 &

Bonavera chem 400 (Fully Auto Biochemistry Analyzer)

TEST NAME	HDL DIRECT
FULL NAME	HDL DIRECT
PRI WAVE	578 nm
SEC WAVE	700 nm
ASSAY/POINT	1 POINT END
START	-
END	33
DECIMAL	0
UNIT	mg/dl
LINEARITY RANGE LOW	2.32
LINEARITY RANGE HIGH	180
SAMPLE VOLUME	2 µ l
REAGENT 1 (R1) VOLUME	150 µl
REAGENT 1 (R2) VOLUME	50 µl
SUBSATRATE DEPLETED	-
LINEARITY	180 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

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3. Gordon, T. et al., High density lipoprotein as a protective factor against coronary heart disease, Am. J, Med.,62;707 (1977).
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5. National Institutes of Health publication No. 93-3095, September (1993).
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7. Kannel, w.B., Castelli, W.P., Gordon, T., Cholesterol in the prediction of atherosclerotic disease; new perspectives based on the Framingham study, Ann. Intern. Med., 90:85, (1979)
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9. Pisani T, Gebski CP, Leary Et, et al. Accurate DirectDetermination of Low-Density Lipoprotein Cholesterol Assay. Arch Pat Lab Med 1995; 119:1127.
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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