HDL DIRECT

Erba Mannheim
XL SysPack

Cat. No.	Pack Name	Packaging (Content)
XSYS0043	HDL C 160	R1: 4 x 30 ml, R2: 4 x 10 ml, R3 CAL 1x1 ml

EN

CE IVD

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 liver as complexes of apolipoprotein and phospholipid and are capable of picking up cholesterol and carrying 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.[1-8]
Accurate measurement 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 polyethylene-glycol-methyl ether (PEGME) coupled classic precipitation method with the improvements in using optimized quantities of PVS/PEGME and selected detergents.[9] LDL, VLDL and chylomicron (CM) react with PVS and PEGME and the reaction results in inaccessibility 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.

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

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

$$2H_2O_2 + \text{4-AA+TODB} \xrightarrow{\text{Peroxidase}} \text{Quinone + 5 } H_2O$$

REAGENT COMPOSITION

R1	
MES buffer (pH 6.5)	6.5 mmol/l
TODB N, N-Bis(4-sulfobutyl)-3-methylaniline	3 mmol/l
Polyvinyl sulfonic acid	50 mg/l
Polyethylene-glycol-methyl ester	30 ml/l
$MgCl_2$	2 mmol/l
R2	
MES buffer (pH 6.5)	50 mmol/l
Cholesterol esterase	5 kU/l
Cholesterol oxidase	20 kU/l
Peroxidase	5 kU/l
4-aminoantipyrine	0.9 g/l
Detergent	0.5 %
R3 CAL	
HDL/LDL Calibrator	concentration: see bottle 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.
On board stability: min. 30 days if refrigerated (2–10°C) and not contaminated.
Once opened both reagents R1 & R2 are stable for 60 days at 2–8°C, when protected from contamination.
Reagents are light-sensitive. Do not let bottles remain open. Keep containers tightly closed.
The reconstituted calibrator is stable for 6 days at 2–8°C.

SPECIMEN COLLECTION AND HANDLING
Use serum or heparin 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/LDL calibrator is recommended.
Calibration frequency: it is recommended to do a calibration
• after reagent lot change
• as required by internal quality control procedures
Traceability:
This calibrator has been standardized using the NIST SRM 1951c reference material.

QUALITY CONTROL
For quality control ERBA NORM, Cat. No. BLT00080 and ERBA PATH, Cat. No. BLT00081 are recommended.

CALCULATION
The XL Results are calculated automatically by the instrument.

UNIT CONVERSION
mg/dl x 0.026 = mmol/l

EXPECTED VALUES [11]
Adults male: 35.3 – 79.5 mg/dl
Adults female: 42.0 – 88.0 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 ERBA XL systems. Data obtained in your laboratory may differ from these values.

Limit of quantification: 1.90 mg/dl
Linearity: 193 mg/dl
Measuring range: 1.90 – 193 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	29.154	0.423	1.48
Sample 2	70.538	1.462	2.05

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	26.65	0.615	2.32
Sample 2	65.77	1.000	1.54

COMPARISON
A comparison between XL-Systems HDL Cholesterol (y) and a commercially available test (x) using 40 samples gave following results:
y = 1.056x + 0.154 mg/dl
r = 0.998

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), acetoaminophen and metamizole causes falsely low results. To carry out the test, blood withdrawal should be performed prior to administration of drugs
N-acetyl-p-benzoquinone imine (metabolite of paracetamol) could generate erroneously low results in samples for patients that have taken toxic doses of paracetamol.

WARNING AND PRECAUTIONS
For *in vitro* diagnostic use. To be handled by entitled and professionally educated person. Reagents of the kit are not classified as dangerous.
Serum used in the 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 1/2 or other infectious agents are absent, the material should be handled as potentially infectious.

WASTE MANAGEMENT
Please refer to local legal requirements.

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erbamannheim.com, www.erbamannheim.com

12000004
N/01/19/H/INT
Date of revision: 8. 7. 2019

ASSAY PARAMETERS

Instrument	XL-100 EM-100	XL-200 EM-200	XL-300/600 EM-360	XL-640	XL-1000	XL-180
Test Details						
Test	HDLC	HDLC	HDLC	HDLC	HDLC	HDLC
Test Code	26	26	26	26	26	26
Report Name	HDL Direct	HDL Direct	HDL Direct	HDL Direct	HDL Direct	HDL Direct
Unit	mg/dl	mg/dl	mg/dl	mg/dl	mg/dl	mg/dl
Decimal Places	1	1	1	1	1	1
Wavelength-Primary	600	600	600	600	600	600
Wavelength-Secondary	700	700	700	700	700	700
Assay type	2-Point	2-Point	2-Point	2-Point	2-Point	2-Point
Curve type	Linear	Linear	Linear	Linear	Linear	Linear
M1 Start	16	16	12	24	14	16
M1 End	16	16	12	24	14	16
M2 Start	32	34	48	61	29	32
M2 End	34	36	51	63	31	34
Sample replicates	1	1	1	1	1	1
Standard replicates	3	3	3	3	3	3
Control replicates	1	1	1	1	1	1
Control interval	0	0	0	0	0	0
Reaction Direction	Increasing	Increasing	Increasing	Increasing	Increasing	Increasing
React. Abs. Limit	0.8	0.8	0.8	0.8	0.8	0.8
Prozone Limit %	0	0	0	0	0	0
Prozone Check	Lower	Lower	Lower	Lower	Lower	Lower
Linearity Limit %	0	0	0	0	0	0
Delta Abs/Min	0	0	0	0	0	0
Technical Minimum	1.90	1.90	1.90	1.90	1.90	1.90
Technical Maximum	193	193	193	193	193	193
Y=aX+b						
a=	1	1	1	1	1	1
b=	0	0	0	0	0	0
Reagent Abs Min	0	0	0	0	0	0
Reagent Abs Max	0.3	0.3	0.3	0.3	0.3	0.3
Auto Rerun	No	No	No	No	No	No
Total Reagents	2	2	2	2	2	2
Reagent R1	HDLC R1	HDLC R1	HDLC R1	HDLC R1	HDLC R1	HDLC R1
Reagent R2	HDLC R2	HDLC R2	HDLC R2	HDLC R2	HDLC R2	HDLC R2
Reagent R3	NA	NA	NA	NA	NA	NA
Test Volumes						
Test	HDLC	HDLC	HDLC	HDLC	HDLC	HDLC
Sample Type	SERUM	SERUM	SERUM	SERUM	SERUM	SERUM
Sample Volumes						
Normal	2	2	3	2	2	2
Dilution Ratio	1	1	1	1	1	1
Increase	4	4	4	4	4	4
Dilution Ratio	1	1	1	1	1	1
Decrease	2	2	2	2	2	2
Dilution Ratio	5	5	1	5	5	5
Standard volume	2	2	3	2	2	2
Reagent Volumes and Stirrer speed						
RGT-1 Volume	180	180	210	180	180	180
R1 Stirrer Speed	High	High	NA	High	High	High
RGT-2 Volume	60	60	70	60	0	60
R2 Stirrer Speed	High	High	NA	High	NA	High
RGT-3 Volume	0	0	0	0	60	0
R3 Stirrer Speed	NA	NA	NA	NA	High	NA
Reference Ranges						
Test	HDLC	HDLC	HDLC	HDLC	HDLC	HDLC
Sample Type	SERUM	SERUM	SERUM	SERUM	SERUM	SERUM
Reference Range	Default	Default	Default	Default	Default	Default
Category Male						
Normal-Lower Limit	35.3	35.3	35.3	35.3	35.3	35.3
Normal-Upper Limit	79.5	79.5	79.5	79.5	79.5	79.5
Panic-Lower Limit	NA	NA	NA	NA	NA	NA
Panic-Upper Limit	NA	NA	NA	NA	NA	NA
Category Female						
Normal-Lower Limit	42	42	42	42	42	42
Normal-Upper Limit	88	88	88	88	88	88
Panic-Lower Limit	NA	NA	NA	NA	NA	NA
Panic-Upper Limit	NA	NA	NA	NA	NA	NA
Revision Number						
Revision	**<A-100-HDLC-1 20.08.2013>**	**<A-200-HDLC-1 20.08.2013>**	**<A-300/600--HDLC-1 20.08.2013>**	**<A-640-HDLC-1 20.08.2013>**	**<A-1000-HDLC-1 20.08.2013>**	**<A-180-HDLC-1 12.12.2013>**

Erba Mannheim
XL SysPack

REFERENCES

1. Dominiczak M, McNamara J. The system of Cardiovascular prevention. 103–125; Nauk M, Wiebe D, Warnick G. Measurement of High-Density-Lipoprotein Cholesterol. 221–244. In: Handbook of Lipoprotein Testing (eds. Rifai, Warnick and Dominiczak), 2nd edition.
2. Barr, D.P., Russ E. M., Eder, H.A., Protein-lipid relationships in human plasma, Am. J. Med., 11;480 (1951).
3. Gordon, T. et al., High density lipoprotein as a protective factor against coronary heart disease, Am. J, Med., 62;707 (1977).
4. Castelli, W.P. et al., HDL Cholesterol and other lipids in coronary heart disease, Circulation, 55;767 (1977).
5. National Institutes of Health publication No. 93-3095, September, (1993).
6. Williams, P., et al,, High density lipoprotein and coronary risk factor, Lancet, 1;72, (1979).
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).
8. Castelli, W. P., et al, Cholesterol and other lipids in coronary heart disease.
9. Pisani T, Gebski CP, Leary Et, et al. Accurate Direct Determination of Low-Density Lipoprotein Cholesterol Assay. Arch Pathol Lab Med 1995; 119:1127
11. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Burtis, C.A., Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders Comp., 2012.

USED SYMBOLS

REF Catalogue Number

Manufacturer

See Instruction for Use

LOT Lot Number

IVD In vitro Diagnostics

Storage Temperature

Expiry Date

CONT Content

QUALITY SYSTEM CERTIFIED ISO 13485

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erbamannheim.com, www.erbamannheim.com

N/01/19/H/INT *Date of revision: 8. 7. 2019*