LDL DIRECT

Cat. No.	Pack Name	Packaging (Content)
XSYS0044	LDL C 80	R1: 2 x 30 ml, R2: 2 x 10 ml, R3 CAL 1x1 ml

EN

CE IVD

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 LDLCholesterol concentration is considered to be the most important clinical predictor, of all single parameters, with respect to coronary atherosclerosis. [2–8]
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 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. 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), whereas HDL reacts with the enzymes. Addition of R2 containing a specific detergent releases LDL from the PVS/PEGME complex. The released LDL reacts with the enzymes to produce H_2O_2 which is quantified by the Trinder reaction.

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

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

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

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

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

REAGENT COMPOSITION
R1

MES buffer (pH 6.5)	50 mmol/l
Polyvinylsulfonic acid	50 mg/l
Polyethyleneglycolmethylester	30 ml/l
4-aminoantipyrine	0.9 g/l
Cholesterol esterase	5 kU/l
Cholesterol oxidase	20 kU/l
Peroxidase	5 kU/l
Detergent	

R2

MES buffer (pH 6.5)	50 mmol/l
Detergent	
TODB N,N-Bis(4-sulfobutyl)-3-methylaniline	3 mmol/l

R3 CAL

HDL/LDL Calibrator	concentration: see bottle label

REAGENT PREPARATION
Reagents R1 and R2 are liquid, ready for 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:	12 hours	at 20–25 °C
	10 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 1951b 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]
Less than 100 mg/dl – optimal
100–129 mg/dl – near/above optimal
130–159 mg/dl – borderline high
160–189 mg/dl – high
≥190 mg/dl – very high
It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

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PERFORMANCE DATA
Limit of quantification: 2.60 mg/dl
Linearity: 263 mg/dl
Measuring range: 2.60–263 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	50.346	0.885	1.72
Sample 2	82.308	1.808	2.21

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	47.00	0.885	1.91
Sample 2	92.69	1.500	1.61

COMPARISON
A comparison between XL-Systems LDL Cholesterol (y) and a commercially available test (x) using 40 samples gave following results:
y = 0.964x -1.615 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), acetoaminophen and metamizole causes falsely low results. To carry out the test, blood withdrawal should be performed **prior to administration of drugs.**

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.

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

N/02/19/H/INT *Date of revision: 2. 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	LDL	LDL	LDL	LDL	LDL	LDL
Test Code	50	50	50	50	50	50
Report Name	LDL Direct	LDL Direct	LDL Direct	LDL Direct	LDL Direct	LDL 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	34	34	48	61	29	34
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	0.9	0.9	0.9	0.9
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	2.60	2.60	2.60	2.60	2.60	2.60
Technical Maximum	263	263	263	263	263	263
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	LDL R1	LDL R1	LDL R1	LDL R1	LDL R1	LDL R1
Reagent R2	LDL R2	LDL R2	LDL R2	LDL R2	LDL R2	LDL R2
Reagent R3	NA	NA	NA	NA	NA	NA
Test Volumes						
Test	LDL	LDL	LDL	LDL	LDL	LDL
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	LDL	LDL	LDL	LDL	LDL	LDL
Sample Type	SERUM	SERUM	SERUM	SERUM	SERUM	SERUM
Reference Range	Default	Default	Default	Default	Default	Default
Category Male						
Normal-Lower Limit	0	0	0	0	0	0
Normal-Upper Limit	130	130	130	130	130	130
Panic-Lower Limit	NA	NA	NA	NA	NA	NA
Panic-Upper Limit	NA	NA	NA	NA	NA	NA
Category Female						
Normal-Lower Limit	0	0	0	0	0	0
Normal-Upper Limit	130	130	130	130	130	130
Panic-Lower Limit	NA	NA	NA	NA	NA	NA
Panic-Upper Limit	NA	NA	NA	NA	NA	NA
Revision Number						
Revision	**<A-100-LDL-2 26.09.2013>**	**<A-200-LDL-2 26.09.2013>**	**<A-300/600-LDL-2 26.09.2013>**	**<A-640-LDL-2 26.09.2013>**	**<A-1000-LDL-2 26.09.2013>**	**<A-180-LDL-1 12.12.2013>**

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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/02/19/H/INT

Date of revision: 2. 7. 2019