LDL – Direct Reagent
CliniQuant – FSR

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 LDL Direct Reagent	R2 LDL Direct Reagent	R3 LDL Direct Calibrator	R4 LDL Direct Lipid Control
LDLFSR-01	1x24 / 1 x 8ml	1 x 24ml	1 x 8ml	1 x 1ml	1 x 1ml
LDLFSR-02	2x30 / 2x 10ml	2 x 30ml	2 x 10ml	1 x 1ml	1 x 1ml

INTENDED USE

This reagent is intended for quantitative determination of low-density lipoprotein cholesterol (LDL-C) concentration in human serum or plasma.

CLINICAL SIGNIFICANCE

Numerous clinical studies have shown that the different lipoprotein classes have very distinct and varied effects on coronary heart disease risk. The studies all point to LDL cholesterol as the key factor in the pathogenesis of atherosclerosis and coronary artery disease (CAD), while HDL cholesterol has been observed to have a protective effect. Even within the normal range of total cholesterol concentrations, an increase in LDL cholesterol can occur with an associated increased risk for CAD.

PRINCIPLE OF THE METHOD

The method is in a two reagent form and depends on the properties of a unique detergent. This detergent (Reagent 1) solubilizes only the non LDL lipoprotein particles. The cholesterol released is consumed by cholesterol esterase and cholesterol oxidase in a non color forming reaction. A second detergent (Reagent 2) solubilizes the remaining LDL particles and a chromogenic coupler allows for color formation. The enzyme reaction with LDL-C in the presence of the coupler produces color that is proportional to the amount of LDL cholesterol present in the sample.

KIT COMPONENTS

Composition

R1 - LDL Direct Reagent : Good 's Buffer 25 mmol/l, HDAOS 0.64 mmol/l, COD 5000 U/l, Ascorbate Oxidase 5000 U/l, Catalase 10000 U/l

R2 - LDL Direct Reagent : Goods buffer 25 mmol/l, 4-AAP 3.4 mmol/l, POD 25000 U/l

R3 - LDL Direct Calibrator : Concentration is lot specific, see vial label.

R4 - LDL Direct Lipid Control : Concentration range is lot specific, see pack insert/instructions for use.

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, saline.

REAGENT PREPARATION, STORAGE & STABILITY

Reagent 1 and Reagent 2 are ready to use. Protect the reagent from direct sunlight.

Calibrator and Lipid Control should be reconstituted by adding distilled or deionized water mentioned on the vial label. Close the vial and let stand for 5 minutes. Dissolve the contents of the vial by swirling gently avoiding formation of foam. Do not shake.

Stability: unopened reagents, calibrator and lipid control are stable up to expiration date on labels at 2-8 °C. Do not freeze the reagents

Once opened reagents are stable up to 4 weeks at 2-8 °C.

Once reconstituted, calibrator and lipid control is stable for 2 weeks at 2-8 °C. Reconstituted calibrator and lipid control may be aliquoted and stored at -20 °C.

REAGENT DETERIORATION

Inability to recover control values. Presence of extreme turbidity or growth.

Do not use reagents after the expiration date printed on the reagent label. Avoid thawing and freezing of aliquoted calibrator and lipid control.

WARNINGS AND PRECAUTIONS

1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully by entitled and professionally educated person,, avoiding contact with skin and ingestion. Do not pipette by mouth.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Use unhemolysed serum or EDTA plasma. Avoid use of citrate or heparin as anticoagulant. Serum / plasma is stable for 7 days at 2-8 °C or one month at -20°C when frozen once.

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Programme Parameter for MERILYZER CliniQuant

Reading Mode	End Point
Calibrator Conc.	(mg/dl) See vial label
Filter - 1 (nm)	546
Filter - 2 (nm)	670
Temperature	37 °C
Volume (µl)	400
Delay Time (Sec)	5
Unit	mg/dl
Reaction Direction	Increase
Reference Low	60
Reference High	130
Linearity	450

TEST PROCEDURE

Dispense	Blank	Calibrator	Sample
Reagent 1	450 µl	450 µl	450 µl
Calibrator	-	5 µl	-
Sample	-	-	5 µl
Mix, incubate for 5 min at 37°C.			
Reagent 2	150 µl	150 µl	150 µl
Mix, incubate for 5 min at 37°C. Read absorbance of calibrator (Ac) & sample (Ax) against reagent blank at 546/670 nm.			

RESULT CALCULATION

Serum/plasma:

LDL Cholesterol mg/dl = Ax/Ac x Concentration of Calibrator

SI conversion factor: 1 mg/dl x 0.02586 = 1 mmol/l

EXPECTED VALUES

Optimal: < 100 mg/dl	OR	2.59 mmol/l
Borderline High: 130 – 160 mg/dl	OR	3.36 - 4.14 mmol/l
High: 161 - 190 mg/dl	OR	4.16 – 4.91 mmol/l
Very High: ≥ 190 mg/dl	OR	≥ 4.91 mmol/l

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed lipid control provided in the kit, to confirm the validity of the test and assure the accuracy of patient result.

Using the Calibrator included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

The linearity is up to 450 mg/dl or 11.6 mmol/l.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 3.0 mg/dl.

The limit of quantification is 6.6 mg/dl.

3. Interferences

No interference has been observed for the following

Hemoglobin up to 500 mg/dl; Bilirubin up to 20 mg/dl

Triglyceride up to 1200 mg/dl; Ascorbic acid up to 50 mg/dl

4. Precision

Intra-assay/ Within run precision

n = 20	Mean (mg/dl)	SD (mg/dl)	CV (%)
sample 1	62.13	0.62	1.00
sample 2	103.25	0.91	0.88

Inter-assay/ Run to run precision

n = 20	Mean (mg/dl)	SD (mg/dl)	CV (%)
sample 1	63.58	0.53	0.84
sample 2	105.82	0.91	0.86

5. Methods Comparison

Comparison was done between CliniQuant FSR- LDL Direct Reagent (y) and reference LDL Direct Reagent (x).

N = 31 $y = 0.975x + 1.09$ $r^2 = 0.9806$

LIMITATIONS

Samples with values above 450 mg/dl should be diluted with D.I. water 1:1, re-run and multiply results by 2.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 1024 – 1030.

2. Data on file: Meril Diagnostics.

IFU/LDLFSR01/00

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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged

EC REP Authorized European Representative in the European Community