LDL-c direct FS*

Order Information

Cat. No.	Kit size
1 4131 99 11 921	Σ 480 (4 x 120)

Intended Use

Diagnostic reagent for quantitative in vitro determination of LDL-C (low density lipoprotein cholesterol) in serum or heparin plasma on automated DiaSys respons®910 VET.

For veterinary use only.

Method

Different methods exist to determine LDL-C. The reference method is the ultracentrifugation, which is tedious and technically demanding, therefore, not suitable for routine. A common approach to determine LDL-C in clinical laboratory is the Friedewald calculation, which estimates LDL-C from measurements of TC, triglycerides (TG), and HDL-C but the method only approximates LDL-C and is subject to well-established limitations. At the end of the last century, homogeneous LDL-C methods for fully automated determination were introduced. Those methods enable direct determination of LDL-cholesterol and show other advantages compared to previously used methods. LDL-c direct FS is a homogeneous method without centrifugation steps for direct measurement of LDL-cholesterol. Block polymer detergents protect HDL, VLDL and chylomicrons in a way that only LDL-cholesterol is selectively determined by an enzymatic cholesterol measurement.

LDL-cholesterol ester —(CHE & CHO)→ Δ^4-Cholestenon + free fatty acids + H_2O_2

H_2O_2 + 4-Aminoantipyrine + H-DAOS —(POD)→ Blue dye + H_2O

The intensity of the formed dye is directly proportional to the cholesterol concentration and is measured photometrically.

Reagents

Components and Concentrations

R1:	Buffer	pH 6.65	20 mmol/L
	Peroxidase (POD)		≥ 2000 U/L
	N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxyaniline sodium salt (H-DAOS)		≥ 0.7 mmol/L
R2:	Buffer	pH 8.15	20 mmol/L
	Cholesterol esterase (CHE)		≥ 2000 U/L
	Cholesterol oxidase (CHO)		≥ 2000 U/L
	Peroxidase (POD)		≥ 15000 U/L
	4-Aminoantipyrine (4-AA)		≥ 1.5 mmol/L

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 35.6 - 46.4°F and contamination is avoided. Do not freeze the reagents and protect them from light.

Warnings and Precautions

1. ⚠ Reagent 1: Warning. H317 May cause an allergic skin reaction. P280 Wear protective gloves/protective clothing/eye protection. P302+P352 If on skin: Wash with plenty of water/soap.
2. Reagent 2 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
4. Artificial lipid mixtures (e.g. Intralipid®) may interfere with the test. Serum samples from animals treated with such solutions should not be used.
5. Determination of samples from animals with a rare type of Hyperlipoproteinemia (Hyperlipoproteinemia Type III) may lead to false results.
6. In very rare cases, samples of animals with gammopathy might give falsified results.
7. Acetaminophen and metamizole medication leads to falsely low results in animal samples.
8. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the animal's medical history, clinical examinations and other findings.
9. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Serum or heparin plasma

Stability:
2 days at 39.2 – 46.4°F

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal Lipid is recommended for calibration. TruCal Lipid calibrator values have been made traceable to NIST-SRM®-1951 Level 2. Use DiaSys TruLab L Level 1 and Level 2 for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Lipid	1 3570 99 11 045	3 x 2 mL
TruLab L Level 1	5 9020 99 11 065	3 x 3 mL
TruLab L Level 2	5 9030 99 11 065	3 x 3 mL

Performance Characteristics

The performance characteristics were evaluated with human samples and might differ from results obtained with various animal specimen.

Measuring range up to 500 mg/dL. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	6 mg/dL
Onboard stability	4 weeks
Calibration stability	3 weeks

Interfering substance	**Interferences ≤ 9% up to**	**Analyte concentration [mg/dL]**
Ascorbic acid	500 mg/dL	81.1
	500 mg/dL	170
Bilirubin (conjugated)	60 mg/dL	75.3
	60 mg/dL	158
Bilirubin (unconjugated)	60 mg/dL	81.0
	60 mg/dL	177
Hemoglobin	1000 mg/dL	81.3
	1000 mg/dL	162
N-acetylcysteine (NAC)	1600 mg/L	78.6
	1600 mg/L	163
Lipemia (triglycerides)	1500 mg/dL	93.7
	1500 mg/dL	173

For further information on interfering substances refer to Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th. ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press, 2000.

** according to CLSI document EP17-A2, Vol. 32, No. 8

Conversion Factor
LDL-C [mg/dL] x 0.02586 = LDL-C [mmol/L]

Reference Range

Each laboratory should determine own reference ranges for its individual animal population.

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* Fluid Stable