



HDL-c direct FS*

Order Information

Cat. No. 1 3561 99 11 921
 Kit size  480 (4 x 120)

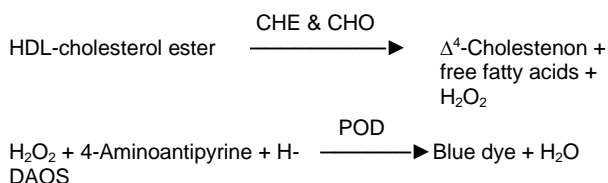
Intended Use

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

For veterinary use only.

Method

Previous HDL-cholesterol determinations were performed by time-consuming precipitation methods or ultracentrifugation (reference method in combination with cholesterol measurement by Abell- Kendall). However, the direct determination of HDL-cholesterol is used in routine. HDL-c direct FS is a homogeneous method for HDL-cholesterol measurement without centrifugation steps. Block polymer detergents protect LDL, VLDL and chylomicrons in a way that only HDL-cholesterol is selectively determined by an enzymatic cholesterol measurement.



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

Reagents

Components and Concentrations

R1:	Buffer	pH 6.85	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)		≥ 400 U/L
	Cholesterol oxidase (CHO)		≥ 700 U/L
	Peroxidase (POD)		≥ 15000 U/L
	4-Aminoantipyrine		≥ 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. Protect the reagents from light.

Warnings and Precautions

- ⚠ 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.
- Reagent 2 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- The reagents contain animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
- Acetaminophen and metanzazole medication leads to falsely low results in animal samples.
- In very rare cases, samples of animals with gammopathy might give falsified results.
- 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.
- 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 (Lithium)

Stability:
2 days at 39.2 – 46.4°F

Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal Lipid is recommended for calibration. Calibrator values have been made traceable to a commercially available assay, which is standardized against the designated CDC reference method (ultracentrifugation method). 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 200 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**	3 mg/dL	
Onboard stability	6 weeks	
Calibration stability	3 weeks	
Interfering substance	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	60 mg/dL	35.0
	60 mg/dL	81.0
Bilirubin (conjugated)	40 mg/dL	38.8
	40 mg/dL	79.4
Bilirubin (unconjugated)	60 mg/dL	42.7
	60 mg/dL	80.7
Hemoglobin	800 mg/dL	31.2
	1000 mg/dL	70.1
Lipemia (triglycerides)	1000 mg/dL	38.8
N-acetylcysteine (NAC)	1700 mg/L	36.7
	1700 mg/L	74.3
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

HDL-C [mg/dL] x 0.02586 = HDL-C [mmol/L]



Reference Range

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



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* Fluid Stable