Cholesterol FS*

Diagnostic reagent for quantitative in vitro determination of cholesterol in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 1300 99 10 923
4 containers for 200 tests each

Method

"CHOD-PAP": enzymatic photometric test

Principle

Determination of cholesterol after enzymatic hydrolysis and oxidation. The colorimetric indicator is quinoneimine which is generated from 4-aminoantipyrine and phenol by hydrogen peroxide under the catalytic action of peroxidase (Trinder's reaction) [1,2].

Cholesterol ester + H_2O $\xrightarrow{CHE}$ Cholesterol + Fatty acid

Cholesterol + O_2 $\xrightarrow{CHO}$ Cholesterol-3-one + H_2O_2

2 H_2O_2 + 4-Aminoantipyrine + Phenol $\xrightarrow{POD}$ Quinoneimine + 4 H_2O

Reagent

Components and Concentrations

Good's buffer	pH 6.7	50 mmol/L
Phenol		5 mmol/L
4-Aminoantipyrine		0.3 mmol/L
Cholesterol esterase	(CHE)	≥ 200 U/L
Cholesterol oxidase	(CHO)	≥ 50 U/L
Peroxidase	(POD)	≥ 3 kU/L

Storage Instructions and Reagent Stability

The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagent!

Warnings and Precautions

1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. In very rare cases, samples of patients with gammopathy might give falsified results [8].
3. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
4. 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 patient's medical history, clinical examinations and other findings.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

Specimen

Serum, heparin plasma or EDTA plasma

Stability [3]:

7 days	at	20 – 25°C
7 days	at	4 – 8°C
3 months	at	–20°C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. The assigned values of the calibrator have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). For internal quality control DiaSys TruLab N and P or TruLab L controls should be assayed. Each laboratory should establish corrective actions in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
TruLab L Level 1	5 9020 99 10 065	3 x 3 mL
TruLab L Level 2	5 9030 99 10 065	3 x 3 mL

Performance Characteristics

Measuring range up to 750 mg/dL cholesterol (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	1 mg/dL cholesterol
On-board stability	8 weeks
Calibration stability	4 weeks

Interfering substance	Interferences < 10%	Cholesterin [mg/dL]
Ascorbate	up to 6 mg/dL	222
Hemoglobin	up to 230 mg/dL	152
	up to 230 mg/dL	223
Bilirubin, conjugated	up to 15 mg/dL	147
	up to 25 mg/dL	236
Bilirubin, unconjugated	up to 21 mg/dL	149
	up to 23 mg/dL	237
Lipemia (triglycerides)	up to 2200 mg/dL	136
	up to 2200 mg/dL	234
For further information on interfering substances refer to Young DS [4].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	139	209	268
Coefficient of variation [%]	2.13	1.66	2.70
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	144	224	261
Coefficient of variation [%]	2.29	2.86	2.12

Method comparison (n=106)	
Test x	DiaSys Cholesterol FS (Hitachi 917)
Test y	DiaSys Cholesterol FS (respons®910)
Slope	0.995
Intercept	–0.797 mg/dL
Coefficient of correlation	0.996

** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor

Cholesterol [mg/dL] x 0.02586 = Cholesterol [mmol/L]

Reference Range [5]

Desirable	< 200 mg/dL (5.2 mmol/L)
Borderline high risk	200 - 240 mg/dL (5.2 – 6.2 mmol/L)
High risk	≥ 240 mg/dL (> 6.2 mmol/L)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Clinical Interpretation

The European Task Force on Coronary Prevention recommends to lower TC concentration to less than 190 mg/dL (5.0 mmol/L) and LDL-cholesterol to less than 115 mg/dL (3.0 mmol/L) [6].

Literature

1. Artiss JD, Zak B. Measurement of cholesterol concentration. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press, 1997: p. 99-114.
2. Deeg R, Ziegenhorn J. Kinetic enzymatic method for automated determination of total cholesterol in serum. Clin Chem 1983; 29: 1798-802.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 22-3.
4. 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.
5. Schaefer EJ, McNamara J. Overview of the diagnosis and treatment of lipid disorders. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC press, 1997: p. 25-48.
6. Recommendation of the Second Joint Task Force of European and other Societies on Coronary Prevention. Prevention of coronary heart disease in clinical practice. Eur Heart J 1998; 19: 1434-503.
7. Rifai N, Bachorik PS, Albers JJ. Lipids, lipoproteins and apolipoproteins. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 809-61.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

respons®920

Cholesterol FS*

Diagnostic reagent for quantitative in vitro determination of cholesterol in serum or plasma on DiaSys respons®920

Order Information

Cat. No. 1 1300 99 10 923
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Cholesterol oxidase	(CHO)	≥50 U/L
Peroxidase	(POD)	≥3 kU/L

Storage Instructions and Reagent Stability

The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagent!

Warnings and Precautions

1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
3. In very rare cases, samples of patients with gammopathy might give falsified results [8].
4. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
5. 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 patient's medical history, clinical examinations and other findings.
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Performance Characteristics

Measuring range up to 750 mg/dL cholesterol (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 cholesterol
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences < 10% by
Ascorbate up to 6 mg/dL
Hemoglobin up to 600 mg/dL
Bilirubin up to 10 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
For further information on interfering substances refer to Young DS [4].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	133	206	247
Coefficient of variation [%]	1.40	1.16	1.31
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	132	202	250
Coefficient of variation [%]	1.46	1.13	2.31

Method comparison (n=110)	
Test x	DiaSys Cholesterol FS (Hitachi 917)
Test y	DiaSys Cholesterol FS (respons®920)
Slope	0.985
Intercept	0.636 mg/dL
Coefficient of correlation	0.993

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Conversion factor

Cholesterol [mg/dL] x 0.02586 = Cholesterol [mmol/L]

Reference Range [5]

Desirable	≤200 mg/dL (≤5.2 mmol/L)
Borderline high risk	200 – 240 mg/dL (5.2 – 6.2 mmol/L)
High risk	>240 mg/dL (>6.2 mmol/L)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Clinical Interpretation

The European Task Force on Coronary Prevention recommends to lower TC concentration to less than 190 mg/dL (5.0 mmol/L) and LDL-cholesterol to less than 115 mg/dL (3.0 mmol/L) [6].

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IVD CE

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* fluid stable