respons®910

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.
3. 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.

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 the calibration the 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 900 mg/dL cholesterol (in case of higher concentrations re-measure samples after manual dilution 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.

Manufacturer

IVD CE DiaSys Diagnostic Systems GmbH
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Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel

Identification	
This method is usable for analysis:	Yes
Name:	CHOL
Shortcut:	
Reagent barcode reference:	024
Host reference:	

Technic	
Type:	Endpoint
First reagent:[µL]	180
Blanc correction	Yes
Second reagent:[µL]	
Blanc correction	
Main wavelength:[nm]	508
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
1 st reading time [min:sec]	(-0.12)
Last reading time [min:sec]	06:00
Reaction way:	Increasing
Linear Kinetics Substrate deplation: absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate deplation: absorbance limit	
Endpoint Stability: largest remaining slope	-
Prozone Limit [%]	-

Sample	
Diluent	NaCl
Concentration technical limits-Lower	1
Concentration technical limits-Upper	900
SERUM	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	5
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	5
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	5
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume[µL]	5
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6

Results	
Decimals	0
Units	mg/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	All
Age	
SERUM	>= <=200
URINE	
PLASMA	>= <=200
CSF	
Genre	
Age	
SERUM	
URINE	
PLASMA	
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	

Calibrators details	
Calibrator list	**Concentration**
Cal. 1	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.120
Cal. 2	0.020
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8
Calculations	
Model	X degree
Degree	1

* Enter calibrator value