HDLC4

HDL-Cholesterol Gen.4

Substrates

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
07528566 190	HDL-Cholesterol Gen.4 (350 tests)	System-ID 07 7589 4	COBAS INTEGRA 400 plus

Materials required (but not provided):

12172623 122	Calibrator f.a.s. Lipids (3 x 1 mL)	System-ID 07 6570 8	
05117003 190	PreciControl ClinChem Multi 1 (20 x 5 mL)	System-ID 07 7469 3	
05947626 190	PreciControl ClinChem Multi 1 (4 x 5 mL)	System-ID 07 7469 3	
05117216 190	PreciControl ClinChem Multi 2 (20 x 5 mL)	System-ID 07 7470 7	
05947774 190	PreciControl ClinChem Multi 2 (4 x 5 mL)	System-ID 07 7470 7	
20756350 322	Diluent NaCl 9 % (6 x 22 mL)	System ID 07 5635 0	

English

System information

Test HDLC4, test ID 0-389

Intended use

In vitro diagnostic test for the quantitative determination of the HDL-cholesterol concentration in human serum and plasma on COBAS INTEGRA systems.

Summary

High density lipoproteins (HDL) are responsible for the reverse transport of cholesterol from the peripheral cells to the liver. In the liver, cholesterol is transformed to bile acids which are then excreted into the intestine via the biliary tract.
Monitoring of HDL-cholesterol in serum or plasma is of clinical relevance as the HDL-cholesterol concentration is important in the assessment of atherosclerotic risk. Elevated HDL-cholesterol concentrations protect against coronary heart disease (CHD), whereas reduced HDL-cholesterol concentrations, particularly in conjunction with elevated triglycerides, increase cardiovascular risk.[1]

Two cholesterol related variables that are predictive of cardiovascular disease (CVD) have emerged. These are non-HDL-cholesterol[2,3,4] (= cholesterol - HDL-cholesterol) and the rate of cholesterol transfer from the macrophages to HDL, also described as cholesterol efflux capacity.[5] Whereas both cholesterol and HDL-cholesterol can be readily determined with high accuracy, currently, non-HDL-cholesterol appears to be best suited for patient management.

A variety of methods are available to determine HDL-cholesterol, including ultracentrifugation (reference method in combination with cholesterol measurement by the Abell-Kendall method), electrophoresis, HPLC, precipitation, and direct methods.[6] Of these, the direct methods are used routinely. Roche HDLC4 is also a direct method. The automated HDLC4 assay uses detergents, cholesterol esterase (CHER), cholesterol oxidase (CHOD) and peroxidase to form a colored pigment that is measured optically.[7,8]

The HDLC4 assay meets the 1998 National Institutes of Health (NIH) / National Cholesterol Education Program (NCEP) goals for precision and accuracy.[9,10]

Test principle[7,8]

Homogeneous enzymatic colorimetric test

Non-HDL lipoproteins such as LDL, VLDL and chylomicrons are combined with polyanions and a detergent forming a water-soluble complex. In this complex the enzymatic reaction of CHER and CHOD towards non-HDL lipoproteins is blocked.
Finally only HDL-particles can react with CHER and CHOD. The concentration of HDL-cholesterol is determined enzymatically by CHER and CHOD.
Cholesterol esters are broken down quantitatively into free cholesterol and fatty acids by CHER.

$$\text{HDL-cholesterol esters} + H_2O \xrightarrow{\text{CHER}} \text{HDL-cholesterol} + \text{RCOOH}$$

In the presence of oxygen, cholesterol is oxidized by cholesterol oxidase to Δ^4-cholestenone and hydrogen peroxide.

$$\text{HDL-cholesterol} + O_2 \xrightarrow{\text{CHOD}} \Delta^4\text{-cholestenone} + H_2O_2$$

In the presence of peroxidase, the hydrogen peroxide generated reacts with 4-amino-antipyrine and EMSE[a)] to form a dye. The color intensity of this dye is directly proportional to the cholesterol concentration and is measured photometrically.

$$2\ H_2O_2 + \text{4-amino-antipyrine} + \text{EMSE} + H^+ + H_2O \xrightarrow{\text{Peroxidase}} \text{colored pigment} + 5\ H_2O$$

a) N-ethyl-N-(3-methylphenyl)-N'-succinylethylenediamine

Reagents - working solutions

R1 TAPSO[b)] buffer: 62.1 mmol/L, pH 7.77; polyanion: 1.25 g/L; EMSE: 1.08 mmol/L; ascorbate oxidase (cucurbita): ≥ 50 µkat/L; peroxidase (horseradish): ≥ 166.7 µkat/L; detergent; BSA: 2.0 g/L; preservative

SR Bis-Tris[c)] buffer: 20.1 mmol/L, pH 6.70; cholesterol esterase (microorganism): ≥ 7.5 µkat/L; cholesterol oxidase (recombinant E. coli): ≥ 7.17 µkat/L; cholesterol oxidase (microorganism): ≥ 76.7 µkat/L; peroxidase (horseradish): ≥ 333 µkat/L; 4-amino-antipyrine: 1.48 mmol/L; BSA: 3.0 g/L; detergents; preservative

b) 2-Hydroxy-N-tris(hydroxymethyl)methyl-3-aminopropanesulfonic acid

c) Bis(2-hydroxyethyl)iminotris(hydroxymethyl)methane

R1 is in position B and SR is in position C.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

Reagent handling

Ready for use

The intrinsic color of the reagent does not interfere with the test.

Storage and stability

HDLC4

Shelf life at 2-8 °C	See expiration date on **cobas c** pack label
On-board in use at 10-15 °C	12 weeks

Diluent NaCl 9 %

Shelf life at 2-8 °C	See expiration date on **cobas c** pack label
On-board in use at 10-15 °C	4 weeks

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.
Serum.
Plasma: Li-heparin, K_2- and K_3-EDTA plasma.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

Collect blood by using an evacuated tube or syringe. Specimens should preferably be analyzed on the day of collection.

Fasting and non-fasting samples can be used.[11,12]

Stability in serum:	72 hours at 15-25 °C[13]
	7 days at 2-8 °C[13]
	12 months at -20 °C[14]
	24 months at -70 °C[15]
Stability in Li-heparin, K_2- and K_3-EDTA plasma:	72 hours at 15-25 °C[13]
	7 days at 2-8 °C[13]
	3 months at (-15)-(-25) °C[13]
	18 months at -70 °C[13]
	18 months at -80 °C[16]

It is reported that EDTA stabilizes lipoproteins.[17]

Materials provided

See “Reagents – working solutions” section for reagents.

Materials required (but not provided)

NaCl Diluent 9 %, Cat. No. 20756350322, system-ID 07 5635 0 for automatic postdilution. NaCl Diluent 9 % is placed in its predefined rack position and is stable for 4 weeks on-board the COBAS INTEGRA 400 plus analyzer.

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer-specific assay instructions.

Application for serum and plasma

COBAS INTEGRA 400 plus test definition

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	R1-S-SR
Reaction direction	Increase
Wavelength A/B	583/800 nm
Calc. first/last	33/69
Unit	mmol/L

Pipetting parameters

		Diluent (H_2O)
R1	120 µL	
Sample	2.5 µL	7 µL
SR	40 µL	
Total volume	169.5 µL	

Calibration

Calibrator	C.f.a.s. Lipids
	Use deionized water as zero calibrator.
Calibration mode	Linear regression
Calibration replicate	Duplicate recommended
Calibration interval	Each lot and as required following quality control procedures

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Traceability: This method has been standardized against the designated CDC reference method (ultracentrifugation method).[9] The standardization meets the requirements of the “HDL Cholesterol Method Evaluation Protocol for Manufacturers” of the US National Reference System for Cholesterol, CRMLN (Cholesterol Reference Method Laboratory Network), November 1994.[13]

Quality control

Reference range	PreciControl ClinChem Multi 2
Pathological range	PreciControl ClinChem Multi 1
Control interval	24 hours recommended
Control sequence	User defined
Control after calibration	Recommended

For quality control, use control materials as listed in the "Order information" section.

In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory’s individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Quality control materials are intended for use only as monitors of accuracy and precision.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

COBAS INTEGRA analyzers automatically calculate the analyte concentration of each sample. For more details, please refer to Data Analysis in the Online Help (COBAS INTEGRA 400 plus analyzers).

Conversion factors:	mmol/L x 38.66 = mg/dL
	mg/dL x 0.0259 = mmol/L

Limitations - interference[18]

Criterion: Recovery within ± 10 % of initial value at a HDL-cholesterol concentration of 1 mmol/L (38.7 mg/dL).

Icterus:[19] No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:[19] No significant interference up to an H index of 1200 (approximate hemoglobin concentration: 745 µmol/L or 1200 mg/dL).

Lipemia (Intralipid):[19] No significant interference up to an L index of 2000. No significant interference from native triglycerides up to 13.7 mmol/L or 1200 mg/dL. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Other: Elevated concentrations of free fatty acids and denatured proteins may cause falsely elevated HDL-cholesterol results.

Ascorbic acid up to 2.84 mmol/L (50 mg/dL) does not interfere.

Abnormal liver function affects lipid metabolism; consequently, HDL and LDL results are of limited diagnostic value. In some patients with abnormal liver function, the HDL-cholesterol result may significantly differ from the DCM (designated comparison method) result due to the presence of lipoproteins with abnormal lipid distribution.[20]

Drugs: No interference was found at therapeutic concentrations using common drug panels.[21,22]

Statins (Simvastatin) and fibrates (Bezafibrate) tested at therapeutic concentration ranges did not interfere.

N-acetylcysteine: No significant interference up to a N-acetylcysteine concentration of 2.76 mmol/L (450 mg/L).

Acetaminophen intoxications are frequently treated with N-acetylcysteine. N-acetylcysteine at the therapeutic concentration when used as an antidote and the acetaminophen metabolite N-acetyl-p-benzoquinone imine (NAPQI) independently may cause falsely low HDL-cholesterol results.

Metamizole: Venipuncture should be performed prior to the administration of metamizole. Venipuncture immediately after or during the administration of metamizole may lead to falsely low results.

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[23]

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

ACTION REQUIRED
Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on COBAS INTEGRA analyzers. Refer to the CLEAN Method Sheet for further instructions and for the latest version of the Extra wash cycle list.
Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges

Measuring range

0.08-3.88 mmol/L (3.09-150 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:2 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2.

Lower limits of measurement

Limit of Blank, Limit of Detection and Limit of Quantitation

Limit of Blank	= 0.08 mmol/L (3.09 mg/dL)
Limit of Detection	= 0.08 mmol/L (3.09 mg/dL)
Limit of Quantitation	= 0.08 mmol/L (3.09 mg/dL)

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples.

The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with a precision of ≤ 30 % CV. It has been determined using low concentration HDL-cholesterol samples.

Expected values

	No risk	Moderate risk	High risk
Females[24,25,26]	> 1.68 mmol/L	1.15-1.68 mmol/L	< 1.15 mmol/L
	(> 65 mg/dL)	(45-65 mg/dL)	(< 45 mg/dL)
Males[24,25,26]	> 1.45 mmol/L	0.90-1.45 mmol/L	< 0.90 mmol/L
	(> 55 mg/dL)	(35-55 mg/dL)	(< 35 mg/dL)

National Cholesterol Education Program (NCEP) guidelines:[27]

< 40 mg/dL: Low HDL-cholesterol (major risk factor for CHD)

≥ 60 mg/dL: High HDL-cholesterol ("negative" risk factor for CHD)

HDL-cholesterol is affected by a number of factors, e.g. smoking, exercise, hormones, sex and age.

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

National Cholesterol Education Program (NCEP) guidelines are based on serum values. When classifying patients, serum or serum equivalent values should be used. Therefore the NCEP recommends using a factor of 1.03 to convert EDTA plasma values to serum values. A later study found EDTA plasma concentrations to be 4.7 % lower than those in serum.[28] To comply with the 1998 NCEP goal of a bias < 5 % it is recommended that each laboratory validates this conversion factor and enters it into the test parameters for HDL-cholesterol.[29]

Treatment goals for non-HDL-cholesterol have been proposed:[2]

	NCEP ATP III	ADA/AHA Guidelines for patients with increased cardiometabolic risk
Optional goal for very-high/highest risk patients (known CVD, diabetes with elevated risk)	< 3.37 mmol/L (< 130 mg/dL)	< 2.59 mmol/L (< 100 mg/dL)
Optional goal for those with established cardiovascular disease and multiple major risk factors	< 2.59 mmol/L (< 100 mg/dL)	
Optional goal for high-risk patients, CHD-risk-equivalent (Framingham 10-year risk score > 20 %/10 years, diabetes without other major risk factors)	< 3.37 mmol/L (< 130 mg/dL)	< 3.37 mmol/L (< 130 mg/dL)
Optional goal for moderately-high/intermediate risk patients (≥ 2 major CVD risk factors, Framingham 10-year risk score from 10-20 %)	< 4.14 mmol/L (< 160 mg/dL)	< 3.37 mmol/L (< 130 mg/dL)
Optional goal for high-risk patients, CHD-risk-equivalent (Framingham 10-year risk score > 20 %/10 years, diabetes without other major risk factors)	< 3.37 mmol/L (< 130 mg/dL)	

Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Repeatability and intermediate precision were determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP5 requirements (4 aliquots per run, 1 run per day, 21 days). The following results were obtained:

Repeatability	*Mean* *mmol/L (mg/dL)*	*SD* mmol/L (mg/dL)	*CV* %
PCCC Multi 1	0.71 (27.5)	0.01 (0.27)	1.0
PCCC Multi 2	1.73 (66.9)	0.02 (0.85)	1.2
Human serum 1	0.23 (8.89)	0.004 (0.16)	1.9
Human serum 2	1.00 (38.7)	0.01 (0.43)	1.1
Human serum 3	1.47 (56.8)	0.02 (0.66)	1.2
Human serum 4	1.91 (73.8)	0.02 (0.77)	1.0
Human serum 5	3.44 (133)	0.05 (1.79)	1.3

Intermediate precision	*Mean* mmol/L (mg/dL)	*SD* mmol/L (mg/dL)	*CV* %

PCCC Multi 1	0.70 (27.1)	0.01 (0.43)	1.5
PCCC Multi 2	1.70 (65.7)	0.03 (1.004)	1.6
Human serum 1	0.23 (8.89)	0.01 (0.19)	2.3
Human serum 2	1.00 (38.7)	0.01 (0.54)	1.4
Human serum 3	1.47 (56.8)	0.02 (0.77)	1.4
Human serum 4	1.91 (73.8)	0.03 (0.97)	1.3
Human serum 5	3.44 (133)	0.05 (2.01)	1.5

PCCC = PreciControl ClinChem

Method comparison

HDL-cholesterol values for human serum and plasma samples obtained on a COBAS INTEGRA 400 plus analyzer (y) were compared with those determined using the corresponding reagent on a Roche/Hitachi **cobas c** 501 analyzer (x).

Sample size (n) = 60

Passing/Bablok[30]	Linear regression
y = 1.012x - 0.005 mmol/L	y = 1.010x - 0.005 mmol/L
τ = 0.973	r = 0.999

The sample concentrations were between 0.08 and 3.74 mmol/L (3.09 and 144.58 mg/dL).

References

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume after reconstitution or mixing

HDLC4

HDL-Cholesterol Gen.4

cobas®
Substrates

GTIN	Global Trade Item Number

CE 0123

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