APOBT

cobas®

Tina-quant Apolipoprotein B ver.2

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
03032574 122	Tina-quant Apolipoprotein B ver.2 100 tests	System-ID 07 6569 4	Roche/Hitachi **cobas c** 311, **cobas c** 501/502
12172623 122	Calibrator f.a.s. Lipids (3 x 1 mL)	Code 424	
12172623 160	Calibrator f.a.s. Lipids (3 x 1 mL, for USA)	Code 424	
10781827 122	Precinorm L (4 x 3 mL)	Code 304	
11285874 122	Precipath L (4 x 3 mL)	Code 305	
05117003 190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 391	
05947626 190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391	
05947626 160	PreciControl ClinChem Multi 1 (4 x 5 mL, for USA)	Code 391	
05117216 190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 392	
05947774 190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 392	
05947774 160	PreciControl ClinChem Multi 2 (4 x 5 mL, for USA)	Code 392	
04489357 190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3	

English

System information

For **cobas c** 311/501 analyzers:

APOBT: ACN 151

For **cobas c** 502 analyzer:

APOBT: ACN 8151

Intended use

In vitro test for the quantitative determination of apolipoprotein B in human serum and plasma on Roche/Hitachi **cobas c** systems.

Summary[1,2]

Apolipoproteins are the protein constituents of the lipoproteins. The lipoproteins are classified according to their ultracentrifugal flotation density. The liver synthesizes very low density lipoproteins (VLDL) which mainly contain triglycerides and cholesterol. In the presence of lipoprotein lipase, the triglycerides are hydrolyzed and LDL particles with a high proportion of cholesterol are formed. Apolipoprotein B is the major protein constituent of LDL. About one third of the LDL particles provide cholesterol to peripheral cells. The other two thirds are metabolized by the liver. LDL-uptake in all of these tissues occurs via LDL receptors. Apolipoprotein B levels increase in pregnancy, hypercholesterolemia, LDL receptor defects, bile obstruction, type II hyperlipidemia and nephrotic syndrome. Apolipoprotein B levels decrease during liver disease, α-β lipoproteinemia, sepsis and estrogen administration.

The combined determination of apolipoprotein A-I/apolipoprotein B and the calculation of the apolipoprotein B : apolipoprotein A-I ratio can reflect a lipid metabolism disorder and the risk of developing atherosclerosis or coronary heart disease particularly well, thus providing an excellent addition to the classical HDL/LDL-cholesterol determination. A high level of apolipoprotein A-I (HDL) and a low level of apolipoprotein B (LDL) correlate best with a low risk for these diseases.

Test principle[3,4,5,6]

Immunoturbidimetric assay.

Anti-apolipoprotein B antibodies react with the antigen in the sample to form antigen/antibody complexes which, following agglutination, can be measured turbidimetrically.

Reagents - working solutions

R1 TRIS buffer: 50 mmol/L, pH 8.0; PEG: 4.2 %; detergent; preservative

R2 Anti-human apolipoprotein B antibodies (sheep): dependent on titer; TRIS buffer: 100 mmol/L, pH 8.0; preservative

R1 is in position B and R2 is in position C.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

Reagent handling

Ready for use

Storage and stability

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Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	12 weeks

Diluent NaCl 9 %

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	12 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 and K_2-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.

Stability: 1 day at 15-25 °C[7]
8 days at 2-8 °C[7]
2 months at (-15)-(-25) °C[8] (only freeze once)

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

See "Order information" section

General laboratory equipment

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.

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Tina-quant Apolipoprotein B ver.2

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Application for serum and plasma

cobas c 311 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 6-31	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	g/L (µmol/L, mg/dL)	
Reagent pipetting		Diluent (H_2O)
R1	100 µL	–
R2	25 µL	30 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	6 µL	9 µL	180 µL
Decreased	6 µL	9 µL	180 µL
Increased	6 µL	9 µL	180 µL

cobas c 501/502 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 10-46	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	g/L (µmol/L, mg/dL)	
Reagent pipetting		Diluent (H_2O)
R1	100 µL	–
R2	25 µL	30 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	6 µL	9 µL	180 µL
Decreased	6 µL	9 µL	180 µL
Increased	6 µL	9 µL	180 µL

Calibration

Calibrators	S1: H_2O
	S2-S6: C.f.a.s. Lipids
	Multiply the lot-specific C.f.a.s. Lipids calibrator value by the factors below to determine the standard concentrations for the 6-point calibration curve:
	S2: 0.323 S5: 2.100
	S3: 0.600 S6: 3.500
	S4: 1.617
Calibration mode	RCM
Calibration frequency	Full calibration • after reagent lot change • 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 IFCC SP3-07 reference standard (WHO-IRP October 1992).[9,10,11,12]

Quality control

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.

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

Calculation

Roche/Hitachi **cobas c** systems automatically calculate the analyte concentration of each sample.

Conversion factors:	g/L x 1.95[a)] = µmol/L[13]
	g/L x 100 = mg/dL
	mg/dL x 0.01 = g/L

a) measured as B_{100}

Limitations - interference

Criterion: Recovery within ± 10 % of initial values at apolipoprotein B levels of 1.00 g/L (1.95 µmol/L, 100 mg/dL).

Icterus:[14] No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 60 mg/dL or 1026 µmol/L).

Hemolysis:[14] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L (1000 mg/dL)).

Lipemia (Intralipid):[14] No significant interference up to an L index of 1000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Rheumatoid factors ≤ 1200 IU/mL do not interfere.

High dose hook-effect: No false result occurs up to an apolipoprotein B concentration of 9.0 g/L (17.6 µmol/L, 900 mg/dL).

Drugs: No interference was found at therapeutic concentrations using common drug panels.[15,16]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[17]

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 Roche/Hitachi **cobas c** systems. The latest version of the carry-over evasion list can be found with the NaOHD-SMS-SmpCln1+2-SCCS Method Sheets. For further instructions refer to the operator's manual. **cobas c** 502 analyzer: All special wash programming necessary for avoiding carry-over is available via the **cobas** link, manual input is not required.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges

Measuring range

0.2-4.0 g/L (0.39-7.8 µmol/L, 20-400 mg/dL)

Lower limits of measurement

Lower detection limit of the test

0.03 g/L (0.06 µmol/L, 3 mg/dL).

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Expected values[18]

The following values were obtained using serum from healthy subjects:

Men:	0.66-1.33 g/L (1.28-2.59 µmol/L, 66-133 mg/dL)
Women:	0.60-1.17 g/L (1.17-2.28 µmol/L, 60-117 mg/dL)

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

Specific performance data

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

Precision

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 21) and intermediate precision (3 aliquots per run, 1 run per day, 21 days). The following results were obtained:

Repeatability	*Mean*	*SD*	*CV*
	g/L (µmol/L, mg/dL)	*g/L (µmol/L, mg/dL)*	*%*
Precinorm L	0.82 (1.60, 82.0)	0.01 (0.02, 1.0)	1.8
Precipath L	1.75 (3.41, 175)	0.02 (0.04, 2)	1.4
Human serum 1	0.83 (1.62, 83.0)	0.01 (0.02, 1.0)	1.1
Human serum 2	1.23 (2.40, 123)	0.01 (0.02, 1)	1.1
Intermediate precision	*Mean*	*SD*	*CV*
	g/L (µmol/L, mg/dL)	*g/L (µmol/L, mg/dL)*	*%*
Precinorm L	0.83 (1.62, 83.0)	0.03 (0.03, 3.0)	3.1
Precipath L	1.86 (3.63, 186)	0.04 (0.08, 4)	2.3
Human serum 3	0.87 (1.70, 87.0)	0.03 (0.03, 3.0)	2.9
Human serum 4	2.34 (4.56, 234)	0.06 (0.12, 6)	2.7

Method comparison

Apolipoprotein B values for human serum and plasma samples obtained on a Roche/Hitachi **cobas c** 501 analyzer (y) were compared with those determined using the corresponding reagent on a Roche/Hitachi 917 analyzer (x).

Sample size (n) = 123

Passing/Bablok[19]	Linear regression
y = 1.000x + 0.050 g/L	y = 0.995x + 0.054 g/L
τ = 0.960	r = 0.997

The sample concentrations were between 0.220 and 3.78 g/L (0.429 and 7.39 µmol/L, 22.0 and 378 mg/dL).

References

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18 Data on file at Roche Diagnostics.

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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.

Symbols

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

CONTENT	Contents of kit
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

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