

APOAT

Tina-quant Apolipoprotein A-1 ver.2



Order information

| REF | CONTENT | Analyzer(s) on which cobas c pack(s) can be used |
|--------------|---|--|
| 03032566 122 | Tina-quant Apolipoprotein A-1 ver.2 100 tests | System-ID 07 6568 6 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:

APOAT: ACN 168

For **cobas c** 502 analyzer:

APOAT: ACN 8168

Intended use

In vitro test for the quantitative determination of Apolipoprotein A-1 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. Apolipoprotein A-1 is the major protein constituent of high-density lipoproteins (HDL). HDL are synthesized by the intestines and the liver. They transport excess cellular cholesterol from extrahepatic tissue and peripheral cells to the liver. Additionally, apolipoprotein A-1 activates the enzyme lecithin-cholesterol-acyltransferase (LCAT), which catalyzes the esterification of cholesterol, thereby enhancing the lipid-carrying capacity of the lipoproteins.

Apolipoprotein A-1 levels increase in liver disease, pregnancy and as a result of estrogen administration (e.g. oral contraceptives). Apolipoprotein A-1 levels decrease in inherited hypo- α -lipoproteinemia (e.g. Tangier disease), cholestasis, sepsis and atherosclerosis. The liver also 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 main constituent of LDL.

The combined determination of apolipoprotein A-1/apolipoprotein B and the calculation of the apolipoprotein B : apolipoprotein A-1 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-1 (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 A-1 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: 3.8 %; detergent; preservative

R2 Anti-human apolipoprotein A-1 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 K₂-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 °C⁷
8 days at 2-8 °C⁷
2 months at (-15)-(-25) °C⁸ (only freeze once)

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

See "Order information" section

General laboratory equipment

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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.

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 / 6-19 | | |
| Wavelength (sub/main) | 700/340 nm | | |
| Reaction direction | Increase | | |
| Units | g/L (μmol/L, mg/dL) | | |
| Reagent pipetting | | Diluent (H ₂ O) | |
| R1 | 100 μL | – | |
| R2 | 25 μL | 30 μL | |
| Sample volumes | | | |
| | Sample | Sample dilution | |
| | | Sample | Diluent (NaCl) |
| Normal | 3 μL | 9 μL | 180 μL |
| Decreased | 3 μL | 9 μL | 180 μL |
| Increased | 3 μL | 9 μL | 180 μL |

cobas c 501/502 test definition

| | | | |
|------------------------------|---------------------|----------------------------|-----------------------|
| Assay type | 2-Point End | | |
| Reaction time / Assay points | 10 / 10-28 | | |
| Wavelength (sub/main) | 700/340 nm | | |
| Reaction direction | Increase | | |
| Units | g/L (μmol/L, mg/dL) | | |
| Reagent pipetting | | Diluent (H ₂ O) | |
| R1 | 100 μL | – | |
| R2 | 25 μL | 30 μL | |
| | | | |
| <i>Sample volumes</i> | <i>Sample</i> | <i>Sample dilution</i> | |
| | | <i>Sample</i> | <i>Diluent (NaCl)</i> |
| Normal | 3 μL | 9 μL | 180 μL |
| Decreased | 3 μL | 9 μL | 180 μL |
| Increased | 3 μL | 9 μL | 180 μL |

Calibration

| | | |
|-----------------------|--|-----------|
| Calibrators | S1: H ₂ O | |
| | S2-S6: C.f.a.s. Lipids | |
| | Multiply the lot-specific C.f.a.s. Lipids calibrator values by the factors below to determine the standard concentrations for the 6-point calibration curve: | |
| | S2: 0.208 | S5: 1.313 |
| | S3: 0.412 | S6: 2.006 |
| | S4: 1.000 | |
| Calibration mode | RCM | |
| Calibration frequency | Full calibration | |
| | <ul style="list-style-type: none"> • 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 SP1-01 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:

$$\begin{aligned} \text{g/L} \times 35.7 &= \mu\text{mol/L}^{13} \\ \text{g/L} \times 100 &= \text{mg/dL} \\ \text{mg/dL} \times 0.01 &= \text{g/L} \end{aligned}$$

Limitations - interference

Criterion: Recovery within $\pm 10\%$ of initial values at apolipoprotein A-1 levels of 1.00 g/L (35.7 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 or 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 A-1 concentration of 11 g/L (392 μmol/L, 1100 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 (7.14-143 μmol/L, 20-400 mg/dL)

Lower limits of measurement

Lower detection limit of the test

0.03 g/L (1.07 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).

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Expected values¹⁸

The following values were obtained using serum from healthy subjects:

Men 1.04-2.02 g/L (37.1-72.1 µmol/L, 104-202 mg/dL)

Women 1.08-2.25 g/L (38.6-80.3 µmol/L, 108-225 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 | 1.60 (57.1, 160) | 0.02 (0.7, 2) | 1.1 |
| Precipath L | 1.00 (35.7, 100) | 0.01 (0.4, 1) | 1.5 |
| Human serum 1 | 0.99 (35.3, 99.0) | 0.02 (0.7, 2) | 1.5 |
| Human serum 2 | 2.59 (92.5, 259) | 0.02 (0.7, 2) | 1.0 |
| Intermediate precision | Mean | SD | CV |
| | g/L (µmol/L, mg/dL) | g/L (µmol/L, mg/dL) | % |
| Precinorm L | 1.74 (62.1, 174) | 0.08 (2.9, 8) | 4.7 |
| Precipath L | 1.06 (37.8, 106) | 0.04 (1.4, 4) | 3.9 |
| Human serum 3 | 1.17 (41.8, 117) | 0.04 (1.4, 4) | 3.6 |
| Human serum 4 | 2.40 (85.7, 240) | 0.03 (1.1, 3) | 1.4 |

Method comparison

Apolipoprotein A-1 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) = 126

| Passing/Bablok ¹⁹ | Linear regression |
|----------------------------------|----------------------------------|
| $y = 1.014x + 0.073 \text{ g/L}$ | $y = 1.006x + 0.087 \text{ g/L}$ |
| $r = 0.949$ | $r = 0.996$ |

The sample concentrations were between 0.380 and 3.34 g/L (13.6 and 119 µmol/L, 38.0 and 334 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.

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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Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com



Distribution in USA by:

Roche Diagnostics, Indianapolis, IN

US Customer Technical Support 1-800-428-2336

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