

Triglycerides

Order information

REF	CONTENT	Analyzer(s) on which cobas c pack(s) can be used
20767107 322	Triglycerides (250 tests)	System-ID 07 6710 7 cobas c 311, cobas c 501/502
10759350 190	Calibrator f.a.s. (12 x 3 mL)	Code 401
10759350 360	Calibrator f.a.s. (12 x 3 mL, for USA)	Code 401
10171743 122	Precinorm U (20 x 5 mL)	Code 300
10171735 122	Precinorm U (4 x 5 mL)	Code 300
12149435 122	Precinorm U plus (10 x 3 mL)	Code 300
12149435 160	Precinorm U plus (10 x 3 mL, for USA)	Code 300
10781827 122	Precinorm L (4 x 3 mL)	Code 304
10171778 122	Precipath U (20 x 5 mL)	Code 301
10171760 122	Precipath U (4 x 5 mL)	Code 301
12149443 122	Precipath U plus (10 x 3 mL)	Code 301
12149443 160	Precipath U plus (10 x 3 mL, for USA)	Code 301
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:

TRIGL: ACN 781

For **cobas c 502** analyzer:

TRIGL: ACN 8781

Intended use

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

Summary^{1,2,3,4,5,6}

Triglycerides are esters of the trihydric alcohol glycerol with 3 long-chain fatty acids. They are partly synthesized in the liver and partly ingested in food.

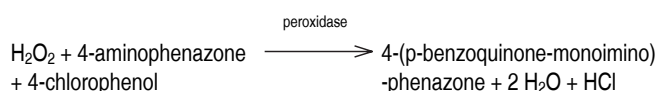
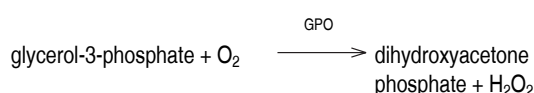
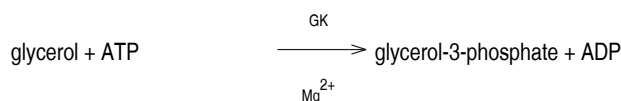
The determination of triglycerides is utilized in the diagnosis and treatment of patients having diabetes mellitus, nephrosis, liver obstruction, lipid metabolism disorders and numerous other endocrine diseases.

The enzymatic triglycerides assay as described by Eggstein and Kreutz still required saponification with potassium hydroxide. Numerous attempts were subsequently made to replace alkaline saponification by enzymatic hydrolysis with lipase. Bucolo and David tested a lipase/protease mixture; Wahlefeld used an esterase from the liver in combination with a particularly effective lipase from *Rhizopus arrhizus* for hydrolysis.

This method is based on the work by Wahlefeld using a lipoprotein lipase from microorganisms for the rapid and complete hydrolysis of triglycerides to glycerol followed by oxidation to dihydroxyacetone phosphate and hydrogen peroxide. The hydrogen peroxide produced then reacts with 4-aminophenazone and 4-chlorophenol under the catalytic action of peroxidase to form a red dyestuff (Trinder endpoint reaction). The color intensity of the red dyestuff formed is directly proportional to the triglyceride concentration and can be measured photometrically.

Test principle⁶

Enzymatic colorimetric test.



Reagents - working solutions

R1 PIPES buffer: 50 mmol/L, pH 6.8; Mg^{2+} : 40 mmol/L; sodium cholate: 0.20 mmol/L; ATP: ≥ 1.4 mmol/L; 4-aminophenazone: ≥ 0.13 mmol/L; 4-chlorophenol: 4.7 mmol/L; lipoprotein lipase (*Pseudomonas spec.*): ≥ 83 $\mu\text{kat/L}$; glycerokinase (*Bacillus stearothermophilus*): ≥ 3 $\mu\text{kat/L}$; glycerol phosphate oxidase (*E. coli*): ≥ 41 $\mu\text{kat/L}$; peroxidase (horseradish): ≥ 1.6 $\mu\text{kat/L}$; preservative, stabilizers

R1 is in position B.

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

TRIGL

Triglycerides

Shelf life at 2-8 °C: See expiration date on **cobas c** pack label.

On board in use and refrigerated on the analyzer: 8 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.

		Sample	Diluent (NaCl)
Normal	2 µL	–	–
Decreased	4 µL	15 µL	135 µL
Increased	2 µL	–	–

cobas c 501 test definition

Assay type	1-Point
Reaction time / Assay points	10 / 70
Wavelength (sub/main)	700 / 505 nm
Reaction direction	Increase
Units	mmol/L (mg/dL, g/L)
Reagent pipetting	Diluent (H ₂ O)
R1	120 µL 28 µL

Sample volumes	Sample	Sample dilution	
		Sample	Diluent (NaCl)
Normal	2 µL	–	–
Decreased	4 µL	15 µL	135 µL
Increased	2 µL	–	–

cobas c 502 test definition

Assay type	1-Point
Reaction time / Assay points	10 / 70
Wavelength (sub/main)	700 / 505 nm
Reaction direction	Increase
Units	mmol/L (mg/dL, g/L)
Reagent pipetting	Diluent (H ₂ O)
R1	120 µL 28 µL

Sample volumes	Sample	Sample dilution	
		Sample	Diluent (NaCl)
Normal	2 µL	–	–
Decreased	4 µL	15 µL	135 µL
Increased	4 µL	–	–

Calibration

Calibrators	S1: H ₂ O S2: C.f.a.s.
Calibration mode	Linear
Calibration frequency	2-point 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 ID/MS method.

Quality control

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

In addition, other suitable control material can be used.

Stability in serum:	2 days at 20-25 °C ⁷
	10 days at 4 °C ⁸
	3 months at -20 °C ⁹
	several years at -70 °C ⁹
Stability in plasma:	2 days at 20-25 °C ⁷
	15 days at 4 °C ¹⁰
	3 months at -20 °C ⁹
	several years at -70 °C ⁹

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.

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	1-Point
Reaction time / Assay points	10 / 57
Wavelength (sub/main)	700 / 505 nm
Reaction direction	Increase
Units	mmol/L (mg/dL, g/L)
Reagent pipetting	Diluent (H ₂ O)
R1	120 µL 28 µL
Sample volumes	Sample Sample dilution

Triglycerides

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:

mmol/L x 88.5 = mg/dL mmol/L x 0.885 = g/L
mg/dL x 0.0113 = mmol/L mg/dL x 0.01 = g/L

Limitations - interference

Criterion: Recovery within $\pm 10\%$ of initial values at triglyceride levels of 2.3 mmol/L (203 mg/dL).

Icterus:¹¹ No significant interference up to an I index of 10 for conjugated bilirubin and 35 for unconjugated bilirubin (approximate conjugated bilirubin concentration: 171 μ mol/L or 10 mg/dL; approximate unconjugated bilirubin concentration: 599 μ mol/L or 35 mg/dL).

Hemolysis:¹¹ No significant interference up to an H index of 700 (approximate hemoglobin concentration: 434 μ mol/L or 700 mg/dL).

Lipemia:¹¹ The L index correlates with sample turbidity but not with triglycerides level. Extremely lipemic samples (triglycerides greater than 3000 mg/dL) can produce normal results¹².

Prozone Check: The flag > Kin is an indicator for extremely high triglyceride concentrations in the sample. False normal results are due to oxygen depletion during assay reaction.

Endogenous unesterified glycerol in the sample will falsely elevate serum triglycerides.

Dicynone (Etamsylate) at therapeutic concentrations may lead to false-low results.¹³

Drugs: No interference was found at therapeutic concentrations using common drug panels.^{14,15}

Exception: Ascorbic acid and calcium dobesilate cause artificially low triglyceride results. Intralipid is directly measured as analyte in this assay and leads to high triglyceride results.

Acetaminophen intoxications are frequently treated with N-Acetylcysteine. N-Acetylcysteine at a plasma concentration above 166 mg/L and the Acetaminophen metabolite N-acetyl-p-benzoquinone imine (NAPQI) independently may cause falsely low results.

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. A significant interference may occur at plasma Metamizole concentrations above 0.05 mg/mL.

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.¹⁶

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-SmpCin1+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

0.1-10.0 mmol/L (8.85-885 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:5 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 5.

Lower limits of measurement

Lower detection limit of the test

0.1 mmol/L (8.85 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 according to NCEP¹⁷

Normal range: < 1.70 mmol/L (< 150 mg/dL).

Clinical interpretation according to the recommendations of the European Atherosclerosis Society: ¹⁸

	mmol/L	mg/dL	Lipid metabolism disorder
Cholesterol	< 5.18	< 200	No
Triglycerides	< 2.26	< 200	No
Cholesterol	5.18-7.77	200-300	Yes if HDL-cholesterol < 0.9 mmol/L (< 35 mg/dL)
Cholesterol	> 7.77	> 300	Yes
Triglycerides	> 2.26	> 200	Yes

Note: If the free glycerol is to be taken into account, the 0.11 mmol/L (10 mg/dL) must be subtracted from the triglycerides value obtained.⁹

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 mmol/L (mg/dL)	SD mmol/L (mg/dL)	CV %
Precinorm U	1.41 (125)	0.01 (1)	0.9
Precipath U	2.40 (212)	0.02 (2)	0.8
Human serum 1	1.67 (148)	0.02 (2)	1.1
Human serum 2	2.72 (241)	0.02 (2)	0.7

	Intermediate precision		
	Mean mmol/L (mg/dL)	SD mmol/L (mg/dL)	CV %
Precinorm U	1.39 (123)	0.03 (3)	2.0
Precipath U	2.33 (206)	0.04 (4)	1.6
Human serum 3	1.18 (104)	0.02 (2)	1.9
Human serum 4	2.95 (261)	0.05 (4)	1.8

Method comparison

Triglycerides 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) = 71

Passing/Bablok¹⁹

y = 1.015x - 0.005 mmol/L

r = 0.976

Linear regression

y = 1.001x + 0.018 mmol/L

r = 0.999

The sample concentrations were between 0.560 and 9.13 mmol/L (49.6 and 808 mg/dL).

References

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- Bablok W, Passing H, Bender R, et al. A general regression procedure for method transformation. Application of linear regression procedures for method comparison studies in clinical chemistry, Part III. J Clin Chem Clin Biochem 1988 Nov;26(11):783-790.

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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