TRIGL

cobas®

Triglycerides

Order information

REF		CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
20767107322	20767107500	Triglycerides (250 tests)	System-ID 07 6710 7	**cobas c** 311, **cobas c** 501/502, COBAS INTEGRA 400 plus

Materials required (but not provided):

		cobas c 311, **cobas c** 501/502	COBAS INTEGRA 400 plus
10759350190	Calibrator f.a.s. (12 x 3 mL)	Code 401	System-ID 07 3718 6
12149435122	Precinorm U plus (10 x 3 mL)	Code 300	System-ID 07 7999 7
12149443122	Precipath U plus (10 x 3 mL)	Code 301	System-ID 07 8000 6
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 391	System-ID 07 7469 3
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391	System-ID 07 7469 3
05117216190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 392	System-ID 07 7470 7
05947774190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 392	System-ID 07 7470 7
04489357190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3	n.a.

English

Intended use

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

Summary

Triglyceride measurements, performed with this assay in human serum and plasma are used as an aid in identifying patients at risk of developing atherosclerosis and for the diagnosis of dyslipidemias.

Triglycerides are esters of the trihydric alcohol glycerol with 3 long-chain fatty acids.[1] They are partly synthesized in the liver and partly ingested in food. Triglycerides are water-insoluble molecules and are carried in the circulation in water-soluble complexes called lipoproteins. The plasma triglyceride level reflects the concentration of the triglyceride-carrying lipoproteins VLDL (very-low-density lipoproteins) and chylomicrons.[2] Chylomicrons are primarily involved in the absorption and delivery of dietary fat while VLDLs deliver endogenous lipids to other tissues.

Triglycerides are considered a risk factor for atherosclerotic cardiovascular disease.[3] Cardiovascular risk is increased when fasting triglycerides are > 1.7 mmol/L (> 150 mg/dL). Individuals with triglycerides > 2.3 mmol/L (> 200 mg/dL) are considered at high risk. The determination of triglycerides is utilized in the diagnosis of patients having diabetes mellitus, nephrosis, liver obstruction, lipid metabolism disorders and numerous other endocrine diseases.[4]

Elevated levels of plasma triglycerides are also associated with an increased risk of acute pancreatitis and aortic valve stenosis.[5]

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.[6] 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.[7, 8]

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.[9,10]

Test principle[10]

Enzymatic colorimetric test.

$$\text{triglycerides} + 3\ H_2O \xrightarrow{\text{LPL}} \text{glycerol} + 3\ \text{RCOOH}$$

$$\text{glycerol} + \text{ATP} \xrightarrow[Mg^{2+}]{\text{GK}} \text{glycerol-3-phosphate} + \text{ADP}$$

$$\text{glycerol-3-phosphate} + O_2 \xrightarrow{\text{GPO}} \text{dihydroxyacetone phosphate} + H_2O_2$$

$$H_2O_2 + \text{4-aminophenazone} + \text{4-chlorophenol} \xrightarrow{\text{peroxidase}} \text{4-(p-benzoquinone-monoimino)-phenazone} + 2\ H_2O + HCl$$

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

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.

For COBAS INTEGRA systems: EDTA tubes that are less than 1/2 full may cause a negative bias for triglycerides results.

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.

See the limitations and interferences section for details about possible sample interferences.

Stability in serum:
2 days at 20-25 °C[11]
10 days at 2-8 °C[12]
3 months at -20 °C (± 5 °C)[13]

	several years at -70 °C (± 5 °C)[13]

Freeze only once.

Stability in plasma:	2 days at 20-25 °C[11]
	15 days at 2-8 °C[14]
	3 months at -20 °C (± 5 °C)[13]
	several years at -70 °C (± 5 °C)[13]

Freeze only 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.

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

Calculation

The 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

Expected values according to NCEP[15]

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

Clinical interpretation according to the recommendations of the European Atherosclerosis Society: [16]

	mmol/L	mg/dL	Lipid metabolism disorder
Cholesterol Triglycerides	< 5.18 < 2.26	< 200 < 200	No
Cholesterol	5.18-7.77	200-300	Yes if HDL-cholesterol < 0.9 mmol/L (< 35 mg/dL)
Cholesterol Triglycerides	> 7.77 > 2.26	> 300 > 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.[13]

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

cobas c systems

System information

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

TRIGL: ACN 781

For **cobas c** 502 analyzer:

TRIGL: ACN 8781

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 µkat/L; glycerol kinase (Bacillus stearothermophilus): ≥ 3 µkat/L; glycerol phosphate oxidase (E. coli): ≥ 41 µkat/L; peroxidase (horseradish): ≥ 1.6 µkat/L; preservative, stabilizers

R1 is in position B.

Storage and stability

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

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_2O)
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 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_2O)
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_2O)
R1	120 µL	28 µL

TRIGL

Triglycerides

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_2O
	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.

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.

Limitations - interference

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

Icterus:[17] No significant interference up to an I index of 10 for conjugated bilirubin and 10 for unconjugated bilirubin (approximate conjugated bilirubin concentration: 171 µmol/L or 10 mg/dL; approximate unconjugated bilirubin concentration: 171 µmol/L or 10 mg/dL).

Hemolysis:[17] No significant interference up to an H index of 700 (approximate hemoglobin concentration: 434 µmol/L or 700 mg/dL).

Lipemia:[17] The L index correlates with sample turbidity but not with triglycerides level. Extremely lipemic samples (triglycerides greater than 3000 mg/dL) can produce normal results[18].

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

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

Drugs: No interference was found at therapeutic concentrations using common drug panels.[19,20]

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.

Dicynone (Etamsylate) at therapeutic concentrations may lead to false-low results.[21]

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.[22]

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 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 required in certain cases.

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).

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 on the **cobas c** 501 analyzer:

	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

The data obtained on **cobas c** 501 analyzer(s) are representative for **cobas c** 311 analyzer(s).

Method comparison

Triglycerides values for human serum and plasma samples obtained on a **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/Bablok[23]	Linear regression
y = 1.015x - 0.005 mmol/L	y = 1.001x + 0.018 mmol/L
τ = 0.976	r = 0.999

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

The data obtained on **cobas c** 501 analyzer(s) are representative for **cobas c** 311 analyzer(s).

COBAS INTEGRA systems

System information

TRIGL: Test ID 0-010

Reagents - working solutions

R	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 µkat/L; glycerol kinase (Bacillus stearothermophilus): ≥ 3 µkat/L; glycerol phosphate oxidase (E. coli): ≥ 41 µkat/L; peroxidase (horseradish): ≥ 1.6 µkat/L; preservative; stabilizers

R is in position B.

Storage and stability

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

Application for serum and plasma

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	R-S
Reaction direction	Increase
Wavelength A/B	512/659 nm
Calc. first/last	17/42
Unit	mmol/L

Pipetting parameters

		Diluent (H_2O)
R	120 µL	
Sample	2 µL	28 µL
Total volume	150 µL	

Calibration

Calibrator	Calibrator f.a.s. 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 ID-MS method.

Quality control

Reference range	Precinorm U plus or PreciControl ClinChem Multi 1
Pathological range	Precipath U plus or PreciControl ClinChem Multi 2
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.

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

Limitations - interference

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

Criterion: Recovery within ± 10 % of initial value.

Icterus:[17] No significant interference up to an I index of 5 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 86 µmol/L or 5 mg/dL).

Hemolysis:[17] No significant interference up to an H index of 600 (approximate hemoglobin concentration: 373 µmol/L or 600 mg/dL).

Lipemia:[17] Extremely lipemic samples (triglycerides greater than 3000 mg/dL) can produce false low results[18].

Drugs: No interference was found at therapeutic concentrations using common drug panels.[19,20] Exceptions: Ca-Dobesilate, L-α-Methyldopa, Levodopa, and Phenylbutazone cause artificially low triglycerides values at the tested drug level.

Dicynone (Etamsylate) at therapeutic concentrations may lead to false-low results.[21]

No significant interference by physiological ascorbic acid concentrations. Ascorbic acid levels higher than 114 µmol/L (2 mg/dL) decrease the apparent triglycerides concentration significantly.

Acetaminophen intoxications are frequently treated with N-Acetylcysteine. N-Acetylcysteine at a plasma concentration above 333 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.[22]

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

0.1-10 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 1:10 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 10.

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 a zero sample (zero sample + 3 SD, repeatability, n = 30).

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 and intermediate precision (2 aliquots per run, 2 runs per day, 20 days). The following results were obtained on the COBAS INTEGRA 700 analyzer:

	Level 1	Level 2
Mean	0.97 mmol/L	1.63 mmol/L
	(85.9 mg/dL)	(144 mg/dL)
CV repeatability	1.6 %	1.6 %
CV intermediate precision	1.9 %	1.9 %

The data obtained on COBAS INTEGRA 700 analyzer(s) are representative for COBAS INTEGRA 400 analyzer(s).

Method comparison

Triglycerides values for human serum and plasma samples obtained on a COBAS INTEGRA 700 analyzer using the COBAS INTEGRA Triglycerides (TRIGL) reagent (y) were compared with those determined using commercially available reagents for triglycerides on a COBAS INTEGRA 700 analyzer (COBAS INTEGRA TRIG reagent) (x) and an alternative manufacturer's clinical chemistry system (x). Samples were measured in duplicate. Sample size (n) represents all replicates.

The sample concentrations were between 0.53 and 7.0 mmol/L (46.9 and 620 mg/dL).

		COBAS INTEGRA 700 analyzer
Sample size	(n)	222
Correlation coefficient	(r)	0.998
	(r_s)	0.994
Linear regression		y = 1.038x - 0.065 mmol/L
Passing/Bablok[23]		y = 1.013x - 0.030 mmol/L

		Alternative system
Sample size	(n)	200
Correlation coefficient	(r)	0.998
	(r_s)	0.996
Linear regression		y = 1.002x + 0.039 mmol/L
Passing/Bablok[23]		y = 1.012x + 0.007 mmol/L

The data obtained on COBAS INTEGRA 700 analyzer(s) are representative for COBAS INTEGRA 400 analyzer(s).

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 navifyportal.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume for reconstitution
GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

TRIGL

Triglycerides

CE 0123

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