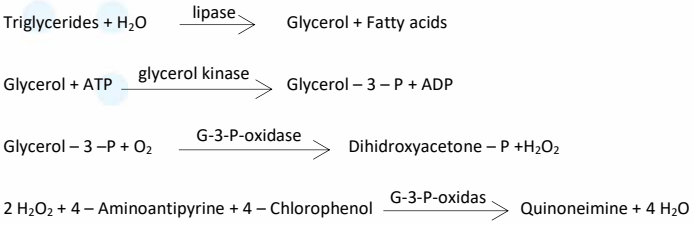
TRIGLYCERIDES

GPO-PAP

Intended use:
Enzymatic in vitro test for the quantitative determination of cholesterol in human serum and plasma.

Test principle:
Triglycerides in the sample originates, by means of the coupled reactions described below, acoloured complex that can be measured by spectrophotometry.



Reagent concentration:
R1:

Pipes	45 mmol/L
magnesium chloride	5 mmol/L
4-chlorophenol	6 mmol/L
lipase	> 100 U/mL
glycerol kinase	>1.5 U/mL
glycerol-3-phosphate oxidase	> 4 U/mL
peroxidase	> 0.8 U/mL,
4-aminoantipyrine	0.75 mmol/L
ATP	0.9 mmol/L
pH	7.0

Preparation and stability:
Reagent and standard are ready for use.
The unopened kit components: Up to expiry date at +2°C to +8°C
Onboard stability: R1: 28 days

Indications of deterioration:
Reagent: Presence of particulate material, turbidity, absorbance of the blank over 0.150 at 500 nm (1 cm cuvette).

Specimen:
Collect serum using standard sampling tubes.
Heparinized or EDTA plasma. Do not use citrate, oxalate or fluoride-plasma.
Stability: 5 - 7 days at +2°C to +8°C
3 months at -20°C Fasting and nonfasting samples can be used.

Limitations - interference:
Criterion: Recovery within ±10% of initial value.
Icterus: No significant interference up to an index I of 8 (approximate bilirubin concentration: 8 mg/dl).
Hemolysis: No significant interference up to an index H of 450 (approximate hemoglobin concentration: 450 mg/dl).

Expected values:

Desirable	< 200 mg/dl (diet) (2.3 mmol/l)
High-risk limit	200 - 400 mg/dl (2.3 – 4.5 mmol/l)
High risk	> 400 mg/dl (4.5 mmol/l)

Testing procedure:
Applications for automated systems are available on request
Materials provided
• Working solutions as described above
Additional materials required
• Calibrators and controls as indicated below
• 0.9% NaCl – solution

Manual procedure	
Wavelength:	505 nm (500nm - 550nm)
Temperature:	+37°C
Cuvette:	1 cm light path
Zero adjustment:	Reagent blank

	Sample / Calibrator
Sample / Calibrator	10 µl
R1	1000 µl
Mix and incubate 5 minutes. Read the absorbance against blank within 30 minutes.	
Calculation: $\frac{\text{A sample}}{\text{A Calibrator}}$ x Calibrator conc. = Triglycerides in mg/dl	

Measuring /reportable range:

10-600 mg/dl
Determine samples having higher activities via the rerun function. On instruments without rerun function, manually dilute the samples with 0.9% NaCl-solution or distilled/deionized water (e.g. 1 + 2). Multiply the result by the appropriate dilution factor (e.g. factor 3).

Analytical sensitivity (lower detection limit):
Detection limit: 10 mg/dL
The lower detection limit represents the lowest measurable cholesterol concentration that can be distinguished from zero.

Imprecision:
Reproducibility was determined using controls within run (n = 20).
The following results were obtained:
Repeatibility (within run):

Mean Concentration	CV	n
44 mg/dL = 0.50 mmol/L	2.8 %	20
207 mg/dL = 2.34 mmol/L	1.6 %	20

Reproducibility (run to run):

Mean Concentration	CV	n
44 mg/dL = 0.50 mmol/L	2.9 %	25
207 mg/dL = 2.34 mmol/L	2.7 %	25

Trueness: Results obtained with this procedure did not show systematic differences when compared with a reference procedure. Details of the comparison experiments are available on request.

Method comparison:
A comparison of the BIOANALYTIC TRIGLYCERIDES (y) with a commercial obtainable assay (x) gave with 38 samples the following result (mg/dl):
y = 0.999 x – 0.034; r = 0.997

Quality Control:
Control Serum:

BIOCON N	5 x 5 ml	#B10814
BIOCON P	5 x 5 ml	#B10817

The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Calibration:
S1: 0.9% NaCl
S2: BIOCAL H 5 x 3 ml #B11895

Calibration frequency:
A two-point-calibration is recommended in case of:
1-change of lot
2- quality control requirements

TRIGLYCERIDES

GPO-PAP

Literature:

1. Colombo J-P (ed) Klinisch - chemische Urindiagnostik. Rotkreuz: Labolive-Verlagsgesellschaft 1994:180
2. DiGiorgio J; Henry RJ, et al eds. Clinical Chemistry: Principles and Technics. 2nd ed. New York NY: Harper and Row; 1974:532.
3. Elking SM, Kabat HF. Am Soc Hosp Pharm. 1969;25:485.
4. Glick MR. Ryder KW. Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation, Clin Chem 1986;32:470-474
5. Greiling H, Gressner AM, eds. Lehrbuch der Klinischen Chemie und Pathobiochemie, 3re ed. Stuttgart/New York: Schattauer Verlag; 1995.
6. Guder WG, Narayanan S, Wisser H, Zawta B, List of Analytes ; Pre analytical Variables. Brochure in Samples: From the Patient to the Laboratory. Darmstadt :GIT Verlag 1996
7. Haug HG. Diagnostik. 1972;18:137.
8. Kageyama N. A direct colorimetric determination of uric acid in serum and urine with uricase-catalase system. Clin Chim Acta 1971;31:421-426.
9. Kaiser E, et.al. Wiener Klin Wschr. 1972;84:217.
10. Keller H, ed. Klinisch-chemische Labordiagnostik für die Praxis, 2nd ed. Stuttgart/New York: Georg Thieme Verlag,1991.
11. Kim EK,wadel LD, sunderland MLE et al Observations on Diagnostic Kits for the Determination of Uric Acid. Clin Biochem. 1971;4:279-286.
12. Krieg M et al Vergleichende quantitative Analytik klinisch-chemischer Kenngrößen im 24 Stunden –Urin und Morgenurin. J Clin Chem Clin Biochem 1986;24:863-869.
13. Kueffer H. Therap Umschau.1971;28:669.
14. Praetorius E Poulsen H. Enzymatic Determination of Uric Acid with Detailed Directions. Scandinav J Clin Lab Investigation 1953;3:273-280.Mac Kay EM Mac Kay LL J Clin Invest 1927;4:295
15. Rice EW Gorgan BS. Clin chem. 1962;8:181.
16. Sing HP, et al Clin Chem. 1972;18:137.
17. Thefeld W, Hoffmeister H, Busch EW et al. Normalwerte der Serumharnsäure
in Abhängigkeit von Alter und Geschlecht mit einem neue enzymatischen Harnsäurefarbtest. Dtsch Med Wschr 1973;98:380-384.
18. Tietz NW. Clinical Guide to Laboratory Tests 3rd ed. Philadelphia, Pa. WB Saunders Company. 1995:624-629.
19. Town MH, Gehm S, Hammer B, Ziegenhorn J. J Clin Chem Clin Biochem 1985; 23:591.
20. Young DS, et al Clin Chem 1972;18:1042

Order information (Cat No.) :

CC470	BTRIG250	B25281	B32280	B42280
OL470	BTRIG125	B27280	B33280	B80280
AB470	B21280	B27281	B33281	B80281
KL470	B21281	B28281	B34280	B80282
SH470	B22280	B30280	B35280	
CR480	B24280	B30281	B36280	
BTRIG500	B25280	B31280	B37280	

Manufacturer

Diaclinica Diagnostik Kimya.San.Tic.Ltd.Şti
Adress : İkitelli O.S.B Mutsan San.Sit. M4 Blok No:17-19 Başakşehir/İSTANBUL
Tel:+90(212) 549 33 88- Fax:+90 (212) 549 55 50
Web :www.diaclinica.com

SYMBOLS

IVD	for in vitro diagnostic use only
LOT	lot of manufacturing
REF	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions