BIOLABO
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TRIGLYCERIDES GPO Method

Reagent for quantitative determination of triglycerides in human serum and plasma

I REF K1519	**R1**	4 x 17 mL
I REF K2519	**R1**	4 x 30 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD

Made In France

I: corresponds to significant modifications

I INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantitative determination of triglycerides in human serum and plasma.

I GENERALITIES (1)

The measurement of the concentration in blood triglycerides is important for the diagnosis and the follow-up of hyperlipidemia. Its increase can be of genetic origin or secondary to other metabolic disorders such as: diabetes mellitus, hyper and hypothyroidisms, hepatic diseases, acute and chronic pancreatitis, nephrosis. A rise in triglycerides also represents an atherogenic risk factor. It is responsible for the opalescence, or even the cloudiness of the serum. Corticoids and estrogen/progestin treatments can also aggravate hypertriglyceridemia.

PRINCIPLE (4) (5)

Fossati and Prencipe method associated with Trinder reaction. Reaction scheme is as follows:

$$\text{Triglycerides} \xrightarrow{\text{Lipase}} \text{Glycerol} + \text{free fatty acids}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow{\text{GK}} \text{Glycerol 3 Phosphate} + \text{ADP}$$

$$\text{Glycerol 3 Phosphate} + O_2 \xrightarrow{\text{GPO}} \text{DihydroxyacetonePhosphate} + H_2O_2$$

$$H_2O_2 + \text{4-Chlorophenol} + \text{PAP} \xrightarrow{\text{POD}} \text{Quinoneimine (pink)} + H_2O$$

The absorbance of the colored complex (quinoneimine), proportional to the amount of triglycerides in the specimen, is measured at 500 nm.

REAGENTS

R1 TG2	Reagent	
PIPES	100	mmol/L
Magnesium chloride	9.8	mmol/L
Chloro-4-phenol	3.5	mmol/L
Lipase	≥ 1000	IU/L
Peroxidase (POD)	≥ 1700	IU/L
Glycerol 3 phosphate oxidase (GPO)	≥ 2000	IU/L
Glycerol Kinase (GK)	≥ 1000	IU/L
4 - Amino – antipyrine (PAP)	0.5	mmol/L
Adenosine triphosphate Na (ATP)	1.3	mmol/L
Clearing Agent	1.5	mmol/L

According to 1272/2008/EC Regulation, this reagent is not classified as dangerous.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, used and stored as described, reagents are stable:

Unopened:

- Until expiry date stated on the label.

Once opened:

- Reagent is stable at least 3 months.
- Discard any reagent if cloudy, in case of loss of sensitivity or if reagent blank is upper than 0.400 at 505nm.

This reagent must be refrigerated during transport.

SPECIMEN COLLECTION AND HANDLING (2)

Serum or plasma (Heparin or EDTA) fasting ≥ 12 hours.

Separate from cells within 2 hours.

Do not use oxalate, fluoride or citrate.

Triglycerides are stable in specimen for:

- 5-7 days at 2-8°C.
- 3 months at –20°C.
- Many years at –70°C.

Avoid repeated freezing and thawing.

LIMITS (3)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

EXPECTED VALUES (6)

Triglycerides	mg/dL	[mmol/L]
Reference range	35 -160	[0.40-1.82]

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On Kenza 240TX, at 37°C, 505 nm:

Linearity Range: between 10 and 1000 mg/dL

Detection limit: approx. 6 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	55	136	262
S.D. mg/dL	0.9	1.6	3.0
C.V. %	1.6	1.2	1.1

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	57	139	259
S.D. mg/dL	1.6	2.1	4.6
C.V. %	2.9	1.5	1.8

Comparison studies with commercially available liquid reagent:
Realized on human specimens (n=103) between 21.9 and 526.3 mg/L

y = 1.0139 x – 2.4376 r = 0.9977

Analytical sensitivity: approx. 0.0018 abs for 1 mg/dL

Interferences:

Total bilirubin	Negative interference from 238 µmol/L
Direct bilirubin	Negative interference from 90 µmol/L
Ascorbic acid	Negative interference from 304 mg/dL
Glucose	No interference up to 1064 mg/dL
Hemoglobin	Positive interference from 333 µmol/L
Free glycerol (1) (2)	Overestimation of approx. 10 mg/dL (0,11 mmol/L) due to endogen glycerol

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration Stability: 2 months

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

Performances and stability data on Kenza 450TX/ISE and Kenza One are available on request.

CALIBRATION (7)

- REF 95015 Multicalibrator traceable to Internal Masterlot

The calibration frequency depends on proper instrument functions and on the preservation of reagent.

QUALITY CONTROL

- REF 95010 EXATROL-N Level 1
- REF 95011 EXATROL-P Level 2

or

- REF 95516 Lipids Control serum Level 1
- REF 95526 Lipids Control serum Level 2
- External quality control program

It is recommended to control in the following cases:

- At least once a run
- At least once within 24 hours
- When changing vial of reagent
- After maintenance operations on the instrument

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly final result.
Refer to the instruction of use of Kenza analyzer.

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 809-857.*
(2) *Clinical Guide to Laboratory Test, 4thEd., N.W. TIETZ (2006) p. 1074-1077.*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-573 to 3-589*
(4) *Fossati P., Prencipe L., Clin. Chem. (1982), 28, p.2077-2080.*
(5) *Trinder P. Ann. Clin. Biochem. (1969), 6, p.27-29.*
(6) *TIETZ N.W. Text book of clinical chemistry, 2nd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1994)p. 1030-1058 et p. 1073-1080.*
(7) *SRM: Standard Reference Material ®*

					
Manufacturer	**Expiry date**	**In vitro diagnostic**	**Storage temperature**	**Dematerialized water**	**Biological risk**
					→
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with